TEXAS TECH PHYSICIANS OF LUBBOCK  
LUBBOCK, TEXAS  

Point-of-Care Manual  

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Point-of-Care General Testing Policy

Date Prepared: 02/04/02

Author: Tina Anderson, MT (ASCP)

Date Effective: 03/01/02

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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Revised:

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Risk Assessment: High

Complexity Level: Waived, PPM
I. **Title:** Point-of-Care General Testing Policy

II. **Statement of Purpose:**
To establish guidelines for Point-of-Care Testing (POC). To ensure that manufacturer's guidelines, quality control, competency testing policy and procedures are followed according to accrediting agencies to ensure quality patient care.

III. **Statement of Policy:**
The Point-of-Care General Policy outlines the requirements to be routinely followed for all testing personnel.

IV. **Point-of-Care Oversight:**
The Point-of-Care Program Oversight is under the direction of the Chief Medical Officer for Texas Tech Physicians of Lubbock, Chair to Clinic Operations Board (COB). (The Technical Supervisor for Pathology provides day-to-day oversight and Point-of-Care Program Operational functions in conjunction with TTMC Director of Nursing). The Point-of-Care Coordinator in association with the Nurse Managers supports the Point-of-Care Quality Performance Program. Monthly reports are compiled and forwarded to each Clinic's Chairman, Administrator and Nurse Manager. Quarterly reports are generated and reported to the Director of Performance Improvement who presents findings to the COB on a quarterly basis.

V. **Color-Blindness Testing:**
Personnel who are involved in testing of patient or quality control samples will be evaluated for color-blindness. Some ancillary test results are visually read and color differentiation should not be interpreted by those who are color-blind or visually impaired, until complete testing has been done to determine degree of impairment.

VI. **Training:**
The Texas Tech Physicians of Lubbock Point-of-Care Program is designed to work in association with the Clinical Providers, Nursing Personnel and ancillary staff to provide a standard of care across the TTMC Outpatient System. The Point-of-Care program has been developed to ensure Policies and Procedures are developed and approved prior to implementing. Training protocols and competency requirements are completed prior to the testing personnel performing tests. Quality Control records and proficiency results are evaluated to determine compliance. Quality control and annual training is based on historical tracking and trending, a practical and sustainable way to promote optimal compliance.
The Director of Medical Staff is responsible for credentialing of Licensed Practitioners in order to provide a list for POC testing. Other testing personnel will be trained for Point-of-Care testing by the Technical Supervisor of Pathology or the Point-of-Care Coordinator or a trained designee. Upon completion of training, the individual must possess the following:

1. Skills required for proper specimen collection  
2. Patient preparation skills  
3. Labeling and proper handling of reagents to include date received, date in use and date of expiration  
4. Skills required for implementing procedures  
5. Skills required for performing each test method and for proper use  
6. A working knowledge of reagent stability and storage  
7. Skills required to implement the quality control Policies and Procedures  
8. An awareness of the factors that influence test results  
9. Skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results

The Nurse Manager of each section will maintain the training records. Testing Personnel will not perform testing until competency can be determined. Competency will be determined annually. Competency may be determined, but not limited by the following:

1. The individual can follow the procedure for specimen handling and processing, test analysis reporting and maintaining records of patient results.  
2. The individual can adhere to procedural guidelines for quality control, calibration and maintenance.  
3. The individual can follow the established corrective action policies and procedures whenever test systems are not within the established acceptable levels of performance.  
4. The individual is capable of identifying problems that may adversely affect test performance or reporting of test results and they must correct the problems or immediately notify the Nurse Manager or Director of Nursing.  
5. The individual can document all corrective actions taken when test systems deviate from established performance specifications.  
6. Completion of written competency test with a passing grade of 80%.

VII. Supplies:  
All supplies will be procured through the purchasing contract established by TTMC Purchasing Department.

VIII. Quality Control:  
The Technical Supervisor or Director of Nursing or Point-of-Care Coordinator or a trained designee will review all quality control records. The Nurse Manager or designee will evaluate any discrepancies with quality control performance. All reagents must be labeled with date received, date opened and date expired. Any discrepancies with quality control will be corrected before implementation for patient use.

Review of all Point-of-Care practices will be on a routine basis by the Nurse Manager or Director of Nursing, Point-of-Care Coordinator or trained designee. All documentation of quality controls will be maintained in the clinic.
A. Fecal Occult Blood  
1. Quality control will be accomplished by utilizing the “Performance Control Area” on the test card area before each patient testing.  
2. Quality controls are performed once on each lot and documented on Quality Control sheet in each clinic.

B. Whole Blood Glucose  
1. Quality control must be performed and documented according to the established procedure at least once every 24 hours of patient testing. Protect reagent from heat, humidity and freezing temperatures.  
2. The quality control will be documented on Quality Control sheet in each clinic.

C. Urinalysis  
1. Nursing staff will perform and document the results of two levels of quality controls with every new lot number if testing is performed manually, every 24 hours of patient testing if automated.  
2. The quality control will be documented on Quality Control sheet in each clinic.

D. Urine Pregnancy, Qualitative  
1. Nursing staff will perform and document the results of quality control. External positive and negative patient controls may be used.  
2. The quality control will be documented on Quality Control sheet in each clinic.

E. Hemoglobin A1C  
1. Quality control must be performed and documented according to the established procedure at least once every 24 hours of patient testing. Protect reagent from heat, humidity and freezing temperatures.  
2. The quality control will be documented on Quality Control sheet in each clinic.

F. Whole Blood Cholesterol  
1. Quality control must be performed and documented according to the established procedure at least once every 24 hours of patient testing. Protect reagent from heat, humidity and freezing temperatures.  
2. The quality control will be documented on Quality Control sheet in each clinic.

G. Rapid Strep Group A/Rapid Flu/ Rapid RSV  
1. Quality control must be performed and documented per lot number.  
2. The quality control will be documented on Quality Control sheet in each clinic.

H. Urine Microscopic  
1. Performed by Clinical Providers only. Proficiency testing is not required.  
2. The quality control will be documented on Quality Control sheet in each clinic.

I. Wet Prep  
   Performed by Clinical Providers only. Proficiency testing required by Physician only.
J. KOH

*Performed by Clinical Providers only.* Proficiency testing required by Physician only.

K. MONOSPOT

1. Quality control must be performed and documented per lot number.
2. The quality control will be documented on Quality Control sheet in each clinic.

L. MICROALBUMIN

1. Quality control must be performed and documented per lot number if read manually. If performed by automation, Quality Control must be performed each 24 hours of patient testing.
2. The quality control will be documented on Quality Control sheet in each clinic.

M. COAGUCHEK PT-INR

The CoaguChek XS System has quality control functions integrated into the meter and test strips, so you never have to run quality control tests with liquid quality controls. The meter automatically runs its own quality control test as part of every blood test. The internal quality control check is documented on the Quality Control sheet in each clinic.

N. i-STAT

The i-STAT System has quality control functions integrated into the meter and cartridges, so you never have to run quality control tests with liquid quality controls. The meter automatically runs its own quality control test as part of every blood test. Each new lot number of cartridges are checked for level of performance and documented on the Quality Control Sheet in the POC QC Manual for each clinic.

IX. Safety:

All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

X. Performance Improvement:

A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.

B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.
Color Blindness Testing Policy

Date Prepared: 02/04/03

Author: Tina Anderson, MT (ASCP)

Date Effective: 02/04/03

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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Revised:

Risk Assessment: N/A

Complexity Level: N/A
I. Title: Color-Blindness Testing Policy

II. Statement of Purpose:
To establish a procedure for the testing of individuals who may have a color impairment.

III. Principle of Procedure:
Personnel who are involved in testing of patient samples will be evaluated for color-blindness. Some ancillary test results are visually read and color differentiation should not be interpreted by those who are color-blind or visually impaired, until complete testing has been done to determine degree of impairment.

IV. Procedure:
A. The Director of Nursing or Point of Care Coordinator or designee will conduct testing during the new employee Orientation.
B. The Concise Edition of Ishihara’s Test for Color-Blindness will be utilized for initial evaluation of employees.
C. The Department of Pathology Technical Supervisor will further evaluate the employee who requires additional information prior to participation in ancillary testing and determine if the employee is able to perform bedside testing procedures. Documentation will be forwarded to the appropriate Nurse Manager and Director of Nursing.
D. The plates are designed to be positioned correctly in a room that is lit adequately by daylight. The introduction of direct sunlight or the use of electric light may produce some discrepancy in the results because of an alteration in the appearance of shades of color. When it is convenient only to use electric light, it should be adjusted as far as possible to resemble the effect of natural daylight. The plates are held 75 cm. (arm's length) from the subject and tilted so that the plane of the paper is at right angles to the line of vision. The numerals, which are seen on plates, are stated, and each answer should be given without more than three seconds delay. Plate number 11 is traceable.

It is not necessary in all cases to use the whole series of plates. Plates 12, 13 and 14 may be omitted if the test is designed merely to separate the color defectives from those with normal color appreciation.

E. An assessment of the readings of plates 1 to 11 determines the normality or defectiveness of color vision. If 10 or more plates are read normal, the color vision is regarded as normal, if only 7 or less than 7 plates read normal, the color vision is regarded as deficient. In reference to plate 9, only those who read the numeral 2 and read it easier than those on plate 8 are recorded as abnormal.

It is rare to find a person whose recording of normal answer is 9 or 8 plates. An assessment of such a case requires the use of other color vision tests.
# ISHIHARA'S TEST FOR COLOR-BLINDNESS

<table>
<thead>
<tr>
<th>PLATE #</th>
<th>RESPONSE/ANSWER</th>
<th>CORRECT RESPONSE</th>
</tr>
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<tbody>
<tr>
<td>PLATE 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PLATE 2</td>
<td></td>
<td></td>
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<tr>
<td>PLATE 3</td>
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<td></td>
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<tr>
<td>PLATE 4</td>
<td></td>
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<tr>
<td>PLATE 5</td>
<td></td>
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<tr>
<td>PLATE 6</td>
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<tr>
<td>PLATE 7</td>
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<td>PLATE 8</td>
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<tr>
<td>PLATE 9</td>
<td></td>
<td></td>
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<tr>
<td>PLATE 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PLATE 11</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NAME: ____________________________     DATE: ________________

DEPARTMENT: ______________________    SS#: ______________________

ADMINISTERED BY: ___________________    SCORE: ________________

COMMENTS: ___________________________________________________________________________________

______________________________________________________________________________________________

PASS / FAIL: ________________________________________________________________________________
### Extent of Testing for Patient Care

<table>
<thead>
<tr>
<th>Test</th>
<th>Diagnosis</th>
<th>Treatment</th>
<th>Screening w/Follow-up (Using confirmation test and/or patient assessment)</th>
<th>Screening w/out Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinalysis (Visual Dipstick w/ specific gravity)</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Urinalysis, Microscopic</td>
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<td>X</td>
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<tr>
<td>Urine Pregnancy, Qualitative</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Occult Fecal Blood</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Whole Blood Glucose</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Rapid Strep Group A</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wet Prep</td>
<td></td>
<td>X</td>
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<tr>
<td>Fern Test (performed only under direction of OB/GYN Lab)</td>
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<td>X</td>
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<tr>
<td>KOH</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td>Whole Blood Cholesterol</td>
<td></td>
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<td>X</td>
<td></td>
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<tr>
<td>Whole Blood A1C</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
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<td>Microalbumin</td>
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<td>Scabies Prep</td>
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<tr>
<td>Trichogram</td>
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<td>X</td>
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<td></td>
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<td>Glucose/Protein Dipstick</td>
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<td>i-STAT Glucose</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Test</td>
<td>Diagnosis</td>
<td>Treatment</td>
<td>Screening w/Follow-up (Using confirmation test and/or patient assessment)</td>
<td>Screening w/out Follow-up</td>
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<td>---------------------------</td>
</tr>
<tr>
<td>Microalbumin</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Monospot</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coaguchek PT-INR</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rapid Flu</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rapid RSV</td>
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<tr>
<td>BD Veritor for RSV</td>
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<tr>
<td>Polymedco OC Light FOB for occult blood</td>
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TEXAS TECH PHYSICIANS OF LUBBOCK
LUBBOCK, TEXAS

Point-of-Care Manual

Point-of-Care Testing by Clinic

UROLOGY - HSC
1. Urinalysis by dipstick

GASTROENTEROLOGY – HSC Pavilion
1. Occult Blood

PEDIATRICS – Medical Office Plaza
1. Rapid Strep
2. Occult Blood
3. Urinalysis by dipstick
4. Glucose – whole blood
5. H Flu – (seasonal)
6. RSV – (seasonal)
7. Hcg Pregnancy - urine

STUDENT HEALTH - TTU Wellness Center
1. Glucose – whole blood
2. Urinalysis by dipstick
3. Hcg Pregnancy - urine
4. Rapid Strep
5. Occult Blood
6. KOH

PEDIATRIC RAIDER CLINIC - Southwest
1. Urinalysis by dipstick
2. Rapid Strep
3. Occult Blood
4. Glucose
5. Hcg Pregnancy – urine
6. Rapid RSV – seasonal
7. Rapid Flu – seasonal
8. Monospot - seasonal

OBSTETRICS/GYNECOLOGY – Healthpoint/Southwest
1. i-STAT glucose
2. Urinalysis Dipstick
3. KOH
4. Hcg Pregnancy – urine
*Updated 06/20/2014

OBSTETRICS/GYNECOLOGY – Grand Expectations 26th and Ave Q
1. i-STAT glucose
2. Urinalysis Dipstick
3. KOH
4. Hcg Pregnancy – urine

OBSTETRICS/GYNECOLOGY – HSC Pavilion
1. i-STAT glucose
2. Urinalysis Dipstick
3. KOH
4. Hcg Pregnancy - urine

FAMILY MEDICINE CLINIC – HSC Pavilion
1. Urinalysis-by dipstick
2. Occult Blood
3. HeG Pregnancy - urine
4. Rapid Strep
5. Glucose – whole blood
6. Glucose/Protein dipstick – urine
7. KOH
8. Cholestech
9. Microalbumin
10. Rapid Flu - seasonal
11. Rapid RSV – seasonal
12. Monospot
13. Hemoglobin A1C
14. Coaguchek PT-INR
15. BD Veritor for RSV Detection

INTERNAL MEDICINE CLINIC – HSC Pavilion
1. Urinalysis by dipstick
2. Glucose – whole blood
3. Occult blood
4. Coaguchek PT-INR
5. Polymedco OC Light FOB for occult blood
6.

DERMATOLOGY CLINIC – HSC Pavilion
1. Rapid Strep
2. HeG Pregnancy – urine
3. Scabies
4. Trichogram
5. KOH

*Updated 06/20/2014
**PEDIATRIC CLINIC – HSC Pavilion**
1. Rapid Strep  
2. Urinalysis by dipstick  
3. Glucose – whole blood  
4. Hemoglobin A1C  
5. Occult blood  
6. H Flu – (seasonal)  
7. RSV – (seasonal)  
8. Urine Hcg

**PEDIATRIC CLINIC - HEALTHPOINT**
9. Urinalysis by dipstick  
10. Rapid Strep  
11. Occult Blood  
12. Glucose  
13. Hcg Pregnancy – urine  
14. Rapid RSV – seasonal  
15. Rapid Flu – seasonal  
16. Monospot

**CLINICAL RESEARCH - HSC**
1. Urinalysis by dipstick  
2. Glucose  
3. Hemocue  
4. Occult Blood  
5. Hcg Pregnancy – urine  
6. Hemoglobin A1C  
7. Coaguchek PT-INR

**SURGERY CLINIC – HSC Pavilion**
1. Occult Blood  
2. Glucose

**ENDOCRINOLOGY/ADULT – HSC Pavilion**
1. Glucose

**ENDOCRINOLOGY/PEDIATRIC – HSC Pavilion**
1. Glucose

**CARDIOLOGY CLINIC – HSC Pavilion**
1. PT-INR  
2. Glucose  
3. Urinalysis by dipstick

*Updated 06/20/2014*
## Normal Ranges for Test(s)

<table>
<thead>
<tr>
<th>TEST</th>
<th>Normal Reference Range</th>
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<tbody>
<tr>
<td><strong>Urinalysis, (Visual Dipstick):</strong></td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>Yellow/Colorless</td>
</tr>
<tr>
<td>Clarity</td>
<td>Clear</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>Negative</td>
</tr>
<tr>
<td>Uroblinogen</td>
<td>0.1 – 1.0 EU/dl</td>
</tr>
<tr>
<td>Protein</td>
<td>Negative</td>
</tr>
<tr>
<td>Nitrite</td>
<td>Negative</td>
</tr>
<tr>
<td>pH</td>
<td>4.5-8.0</td>
</tr>
<tr>
<td>Blood</td>
<td>Negative</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.003-1.025</td>
</tr>
<tr>
<td>Ketone</td>
<td>Negative</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>Negative</td>
</tr>
<tr>
<td>Glucose (mg/dl)</td>
<td>Negative</td>
</tr>
<tr>
<td><strong>Urine Microscopic:</strong></td>
<td></td>
</tr>
<tr>
<td>WBC</td>
<td>&lt; 5/HPF</td>
</tr>
<tr>
<td>RBC</td>
<td>&lt; 3/HPF</td>
</tr>
<tr>
<td>Casts</td>
<td>None/LPF</td>
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<tr>
<td>Crystals</td>
<td>None</td>
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<tr>
<td>Yeast</td>
<td>None</td>
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<tr>
<td>Epithelial Cells</td>
<td>0 – 3/HPF</td>
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<td>Trichomonas</td>
<td>None</td>
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<tr>
<td>Bacteria</td>
<td>None</td>
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<tr>
<td>Urine Pregnancy, Qualitative</td>
<td>Negative</td>
</tr>
<tr>
<td><strong>Occult, Fecal Blood</strong></td>
<td>Negative</td>
</tr>
<tr>
<td>Whole Blood Glucose (Fasting non-diabetic)</td>
<td>65-110mg/dl</td>
</tr>
<tr>
<td>Whole Blood Glucose (Random)</td>
<td>70-120mg/dl</td>
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<tr>
<td>Whole Blood Glucose (OB only)</td>
<td>&lt;95 mg/dl</td>
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<tr>
<td><strong>Rapid Beta Strep</strong></td>
<td>Negative</td>
</tr>
<tr>
<td><strong>Influenza Rapid</strong></td>
<td>Negative</td>
</tr>
<tr>
<td>RSV Rapid</td>
<td>Negative</td>
</tr>
<tr>
<td>Monospot</td>
<td>Negative</td>
</tr>
<tr>
<td><strong>Wet Mount:</strong></td>
<td></td>
</tr>
<tr>
<td>WBC</td>
<td>Rare/hpf</td>
</tr>
<tr>
<td>RBC</td>
<td>Rare/hpf</td>
</tr>
<tr>
<td>EPi</td>
<td>Rare/hpf</td>
</tr>
<tr>
<td>Other</td>
<td>Negative</td>
</tr>
<tr>
<td><strong>KOH</strong></td>
<td>Negative</td>
</tr>
<tr>
<td><strong>Cholestech LDX:</strong></td>
<td></td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>&lt;200mg/dl Desirable</td>
</tr>
<tr>
<td>HDL Cholesterol</td>
<td>&gt;35mg/dl Desirable</td>
</tr>
<tr>
<td>LDL Cholesterol</td>
<td>&lt;130mg/dl Desirable</td>
</tr>
<tr>
<td>TC/HDL Ratio</td>
<td>A Ratio of 4.5 or less is desirable</td>
</tr>
<tr>
<td>Triglyceride</td>
<td>&lt;200mg/dl</td>
</tr>
<tr>
<td><strong>Whole Blood HbA1C</strong></td>
<td>4.2% - 6.5%</td>
</tr>
<tr>
<td><strong>Whole Blood A1C NOW</strong></td>
<td>&lt;7%</td>
</tr>
<tr>
<td><strong>Microalbumin:</strong></td>
<td></td>
</tr>
<tr>
<td>Albumin</td>
<td>&lt;20 mg/dl Normal</td>
</tr>
<tr>
<td>Creatinine</td>
<td>100-30 mg/dl</td>
</tr>
<tr>
<td>Albumin/Creatinine Ratio</td>
<td>&lt;30 mg/dl</td>
</tr>
<tr>
<td>Test</td>
<td>Result</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Glucose</td>
<td>Negative</td>
</tr>
<tr>
<td>Protein</td>
<td>Negative</td>
</tr>
<tr>
<td>BD Veritor RSV</td>
<td>Negative</td>
</tr>
<tr>
<td>Polymedco OC Light FOB for occult blood</td>
<td>Negative</td>
</tr>
</tbody>
</table>

**PT/INR:** Expected values for patients taking oral anticoagulants depend on the patient’s specific condition, anticoagulant therapy and the target values established by the physician.
**Laboratory Requisitions:**

*Both Random Laboratory Testing and Urinalysis Laboratory Testing for specific clinics are now available through EMR. Paper copies of the Sample Requisitions are shown as follows:

<table>
<thead>
<tr>
<th>TTMC School of Medicine</th>
<th>Patient Name: _______________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lubbock, Texas</td>
<td>Medical Record Number:______________________</td>
</tr>
<tr>
<td><strong>Point-of-Care</strong></td>
<td>DOB: _____________________________________</td>
</tr>
<tr>
<td>Random Laboratory Testing</td>
<td>(or visit label)</td>
</tr>
<tr>
<td>Order/Report Form</td>
<td>Date Collected: _____________________   Time: ____________ Collector I.D. _______________</td>
</tr>
<tr>
<td></td>
<td>Physician: ______________________________   Location ________________________________</td>
</tr>
<tr>
<td></td>
<td>Time Testing Completed/Reported: ___________________________________________________</td>
</tr>
</tbody>
</table>

### TEST NAME

<table>
<thead>
<tr>
<th>TEST NAME</th>
<th>CPT CODE</th>
<th>RESULTS</th>
<th>ADULT NORMAL REFERENCE RANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Urine HCG - Screen</strong></td>
<td>81025QW</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td><strong>Occult-Fecal Blood</strong></td>
<td>82270QW</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td><strong>Whole Blood Glucose (Fasting, non-diabetic)</strong></td>
<td>82962QW</td>
<td>65 – 110 mg/dl</td>
<td></td>
</tr>
<tr>
<td><strong>Whole Blood Glucose (Random)</strong></td>
<td>82962QW</td>
<td>70 – 120 mg/dl</td>
<td></td>
</tr>
<tr>
<td><strong>Rapid Beta Strep (Group A)</strong></td>
<td>87880QW</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td><strong>Influenza Rapid</strong></td>
<td>87276QW</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td><strong>Rapid RSV</strong></td>
<td></td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td><strong>Wet Mount</strong></td>
<td>87210QW</td>
<td>(scan on low, report on high)</td>
<td></td>
</tr>
<tr>
<td>WBC</td>
<td></td>
<td>WBC 2 – 4/phf</td>
<td></td>
</tr>
<tr>
<td>RBC</td>
<td></td>
<td>RBC 0 – 3/phf</td>
<td></td>
</tr>
<tr>
<td>EPI</td>
<td></td>
<td>Epi 5 – 15/phf</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td><strong>KOH</strong></td>
<td>87210QW</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td><strong>Cholestech LDX</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>82465QW</td>
<td>&lt; 200 mg/dl desirable</td>
<td></td>
</tr>
<tr>
<td>HDL Cholesterol</td>
<td>83718QW</td>
<td>&gt; 35 mg/dl desirable</td>
<td></td>
</tr>
<tr>
<td>LDL Cholesterol</td>
<td>N/A</td>
<td>&lt; 130 mg/dl desirable</td>
<td></td>
</tr>
<tr>
<td>TC/HDL Ratio</td>
<td>N/A</td>
<td>A ratio of 4.5 or less is desirable</td>
<td></td>
</tr>
<tr>
<td>Triglyceride</td>
<td>84478QW</td>
<td>&lt; 200 mg/dl</td>
<td></td>
</tr>
<tr>
<td>Whole Blood Glucose</td>
<td></td>
<td>65 – 110 mg/dl</td>
<td></td>
</tr>
<tr>
<td>Whole Blood HA1C</td>
<td>83036QW</td>
<td>4.2% - 6.5%</td>
<td></td>
</tr>
<tr>
<td><strong>Microalbumin Urine</strong></td>
<td>87177QW</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td><strong>Scabies Prep</strong></td>
<td>87177QW</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td><strong>Whole Blood A1C NOW (Student Health)</strong></td>
<td>830360W</td>
<td>&lt; 7%</td>
<td></td>
</tr>
<tr>
<td><strong>Trichogram</strong></td>
<td>96902</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td><strong>Monosopot</strong></td>
<td></td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>
## Test Name: Urinalysis, Visual Dipstick

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Results</th>
<th>Adult Normal Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leukocytes</td>
<td>Trace</td>
<td>+ Small ++ Moderate +++ Large Negative</td>
</tr>
<tr>
<td>Nitrite</td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>Normal</td>
<td>2mg/dl 4mg/dl 8mg/dl 0.1 – 1.0 EU/dl 1mg Approx 1EU</td>
</tr>
<tr>
<td>Protein</td>
<td>Trace</td>
<td>30mg/dl 100mg/dl 300mg/dl Negative</td>
</tr>
<tr>
<td>pH</td>
<td>5.0 6.0 6.5 7.0 7.5 8.0 8.5</td>
<td>4.5 – 8.0</td>
</tr>
<tr>
<td>Blood</td>
<td>Negative</td>
<td>Non-Hemolyzed Trace Non-Hemolyzed Trace Hemolyzed Trace + Small ++ Moderate +++ Large Negative</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.000</td>
<td>1.005 1.010 1.015 1.020 1.025 1.003 - 1.025</td>
</tr>
<tr>
<td>Ketone</td>
<td>Trace</td>
<td>Small Moderate Large Negative</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>Negative</td>
<td>+ Small ++ Moderate +++ Large Negative</td>
</tr>
<tr>
<td>Glucose</td>
<td>Negative</td>
<td>100 mg/dl 500 mg/dl 1000 mg/dl 2000 mg/dl Negative</td>
</tr>
<tr>
<td>Color</td>
<td>Colorless</td>
<td>Straw Yellow Amber Yellow/Colorless</td>
</tr>
<tr>
<td>Clarity</td>
<td>Clear</td>
<td>Hazy Cloudy Turbid Clear</td>
</tr>
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</table>

## Test Name: Glucose/Protein, Visual Dipstick

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Results</th>
<th>Adult Normal Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>Normal</td>
<td>50 mg/dl 100 mg/dl 250 mg/dl 500 mg/dl 1000mg/dl Negative</td>
</tr>
<tr>
<td>Protein</td>
<td>Negative</td>
<td>Trace 30mg/dl 100mg/dl 500mg/dl Negative</td>
</tr>
</tbody>
</table>

## Test Name: Urinalysis, Microscopic

<table>
<thead>
<tr>
<th>Result</th>
<th>Reference Range</th>
<th>Results</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>0-5 5-10</td>
<td>&gt;10/HPF</td>
<td>EPITHELIAL CELLS 0-3 3-7 &gt;7 /HPF</td>
</tr>
<tr>
<td>RBC</td>
<td>0-3 3-10</td>
<td>&gt;10/HPF</td>
<td>Type</td>
</tr>
<tr>
<td>Casts</td>
<td>/LPF</td>
<td>NONE</td>
<td>Trichomonas</td>
</tr>
<tr>
<td>Yeast</td>
<td>NONE</td>
<td>OTHER</td>
<td>None</td>
</tr>
</tbody>
</table>

**Tested by:**
Date Prepared: 02/04/02
Author: Tina Anderson, MT (ASCP)
Date Effective: 03/01/02
Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

<table>
<thead>
<tr>
<th>Date</th>
<th>Signature/Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/18/08</td>
<td>Dale M. Dunn MD</td>
</tr>
<tr>
<td>06/17/09</td>
<td>Dale M. Dunn MD</td>
</tr>
<tr>
<td>06/16/10</td>
<td>Dale M. Dunn MD</td>
</tr>
<tr>
<td>06/16/11</td>
<td>Dale M. Dunn MD, MBA</td>
</tr>
<tr>
<td>06/21/12</td>
<td>Dale M. Dunn MD, MBA</td>
</tr>
<tr>
<td>06/19/14</td>
<td>Dale M. Dunn MD, MBA</td>
</tr>
</tbody>
</table>

Revised:


Risk Assessment: High

Complexity Level: Waived
I. **Title:** ASI ProPhase Plus

II. **Statement of Purpose:**
ASI ProPhase Plus is a single-step immunoassay for the qualitative determination of human chorionic gonadotropin (HCG) in urine for the early detection of pregnancy.

Human chorionic gonadotropin is a glycopeptide hormone produced by the placenta beginning shortly after fertilization. In normal pregnancy, HCG can be detected in serum and urine as early as 7 days following conception (1-5). At the time of the first missed menstrual period, HCG levels of 100 mIU/ml may be detected in the maternal urine, and peak levels are seen late in the first trimester of pregnancy (1-9). The early appearance of HCG in urine following conception has made it the marker of choice for the early detection of pregnancy.

III. **Principle Procedure:**
The immunochromatographic cassette device contains a unique set of dye-conjugated and immobilized antibodies, which produces a distinctive visual pattern in the result window when the HCG concentration of the test sample is 25 mIU/ml or greater. An elevated HCG concentration is detected in approximately four minutes or less.

Urine sample migrates through the absorbent area mixing with labeled antibody-dye conjugate; HCG present in the specimen binds to the conjugate forming an antibody antigen complex. As the reaction mixture flows through the test zone “T”, the complex binds to immobilized anti-HCG, producing a pink-rose color band. The appearance of the color band in the test zone indicates that HCG is present at or above the cutoff sensitivity of 25 mIU/ml. In the control zone “C”, unbound conjugate binds to immobilized reagents producing a pink-rose color band. The appearance of this band indicates that the test is functioning properly. The ASI ProPhase Plus test is standardized against the World Health Organization Second International Standard (61/6).

IV. **Reagents:**
The ASI ProPhase Plus test cassette contains a goat polyclonal antibody coated membrane and a pad containing mouse monoclonal IgG-dye conjugate in a protein matrix containing sodium azide as a preservative.

1. **Warnings and Precautions:** For In-Vitro Diagnostic Use
   A. Human urine should be handled as if capable of transmitting infectious agents. **Gloves should be worn whenever working with samples that are potentially biohazardous.** The CDC/NIH Health Manual “Bio-Safety in Microbiological
Laboratories” describes how these materials should be handled in accordance with good laboratory practice.

B. Do not pipette by mouth.
C. Do not smoke, eat, drink or apply cosmetics in areas where patient samples are handled.
D. Any cuts, abrasions or other skin lesions should be suitably protected.
E. Dispose of all used test components in a proper biohazard container.

2. Handling Procedural Notes:
A. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for the cassette or samples.
B. Do not use past the expiration date indicated on the cassette pouch.

3. Storage Instructions:
Store the kit contents at 15o-30oC (59o-86oF); do not freeze. Test cassettes must be at room temperature for use.

4. Indications of Deterioration:
Do not use the test cassette if the protective pouch has been punctured, if the device appears damaged, or if the membrane appears discolored or damaged.

V. Specimen Collection and Storage:
1. Urine specimens must be collected in clean glass, plastic, or wax coated containers free of preservatives.
2. Urine collected anytime may be used, however, the first morning urine usually contains the highest concentration of HCG.
3. If the sample is not to be tested immediately following collection, but is to be tested within 72 hours after collection, the sample should be refrigerated (2o-8oC; 36o-46oF). **It must be brought back to room temperature** (15o-30oC; 59o-86oF) before testing.
4. If a sample will not be tested until more than 72 hours after collection, it should be stored frozen (-20oC; - 4° F or below) for not more than two weeks. Prior to testing, frozen samples must be completely thawed, thoroughly mixed, and brought to room temperature (15o-30oC; 59o-86o F).

VI. Performance of the Test:
1. Materials provided:

<table>
<thead>
<tr>
<th></th>
<th>25 Test</th>
<th>375 Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foil Pouch, Containing One Each of:</td>
<td>25</td>
<td>15 x 25</td>
</tr>
<tr>
<td>ProPhase Test Cassette</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-Use Dropper</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moisture Absorbent Packet</td>
<td>1</td>
<td>15 x 1</td>
</tr>
<tr>
<td>Package Insert</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Additional Material Required:
A. Timing device
B. Specimen collection container
VII. Test Procedure:
  1. Preparation for the Assay
     A. Carefully read the instructions before beginning the test. Do not open the foil pouch until ready to perform the test.
     B. Allow the patient sample and controls to come to room temperature (15°-30°C; 59°-86°F).

VIII. Assay Protocol:
  1. Open a foil pouch by tearing at the notch and remove the test cassette and dropper. Place the test cassette on a clean, level surface.
  2. Fill the dropper with urine and hold it vertically above the sample well (marked “S”). Dispense.
  3. Read the result after four (4) minutes and no later than 30 minutes, then discard the cassette.

  NOTE: When performing ProPhase Plus HCG testing, if a pink-rose color migration is not observed with four (4) minutes after the addition of the 3 or 4 drops of urine to the SAMPLE WELL in the TEST CASSETTE, add an additional one (1) or two (2) drops to the SAMPLE WELL and read the result four (4) minutes after this second urine addition.

IX. Quality Control:
The use of positive and negative controls is recommended to insure proper kit performance. Quality control samples should be tested with each lot/kit. Each ASI ProPhase Plus test cassette contains a built-in quality control indicator, which causes a pink rose color line to appear in the control zone, marked “C”, if the test is functioning correctly. If no colored line appears in the control zone on the test strip, the test did not function properly.

X. Interpretation of Results:
  1. Negative: One pink-rose band appears in the control zone marked “C”, with no band in the test zone marked “T”. A negative result indicates that the concentration of HCG is below the detection sensitivity of the test and that the patient is not pregnant or it is too soon for the pregnancy to be detected.
  2. Positive: Two pink-rose bands appear, one in the test zone marked “T” and one in the control zone marked “C”. A positive result indicates that HCG has been detected at or above a concentration of 25 mIU/ml in the sample, a strong indicator that the patient is pregnant. The colored bands may vary in intensity.
  3. Invalid: If no pink-rose bands are visible, or if a band is visible only in the test zone marked “T” and not in the control zone marked “T” and not in the control zone marked “C”, then the result is invalid. An invalid result may be due to deterioration of the test reagents or to improper testing procedure. Carefully review the procedure and retest with a new cassette. Colored lines that appear after 30 minutes are not diagnostic and should be ignored.
XI. Common Questions:
1. Q. Within seconds after the urine sample is added, if a pink color covers the entire window region and there are a few vertical lines that appear darker than the rest of the window, does this indicate a positive?
   A. After the urine sample is added, you will see a pink liquid movement that starts from the bottom and gradually moves toward the top of the control zone of the cassette. You may see a few vertical streaks; however, this is completely normal. You should never use any vertical streaks as part of your interpretation of the test result; only horizontal bands can be considered. The appearance of horizontal rose-pink bands across both window regions indicates a positive result.

2. Q. If exactly 3 or 4 drops of urine are not used to perform the test, will it still give an accurate result?
   A. Three (3) or four (4) drops is the recommended sample size. However, as you can see from the note following the procedure description, five (5) or even six (6) drops can be tolerated without compromising the test results. If less than three (3) drops are added, the test may not work; this can easily happen if the user is not careful to eliminate air bubbles from the dropper before delivery of the urine into the sample well of the cassette.

3. Q. After a certain length of time can the test result change?
   A. A positive result will not change for several days after the test is completed. However, some reddish background might be noticed several hours after the test is performed. A negative result should not be read in the test zone more than thirty (30) minutes after the test is performed. After 30 minutes, some negative test might even appear to be weakly positive. This happens because the test chemicals keep reacting after the test is completed.

4. Q. How accurate is the test?
   A. There is a clinical data summary under the “Accuracy” section of this package insert; but it stops short of claiming 100% accuracy despite the fact that 100% is implied by the data, which contains no discrepancies. A claim of 100% accuracy cannot be made due to the potential for user error and other such error sources. It is acceptable to claim that the test is “over 99% accurate”.

XII. Limitations of the Procedure:
1. In addition to pregnancy, HCG has been detected in patients with both gestational and non-gestational trophoblastic disease. These diagnoses should be ruled out in the interpretation of HCG levels to establish a diagnosis of pregnancy.
2. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on HCG levels alone. Also, a spontaneous miscarriage may cause confusion in interpreting the test results.
3. A negative result from a urine specimen collected from a woman in very early pregnancy may be due to an unusually low concentration of HCG. In such cases, the test should be repeated on a fresh specimen obtained approximately two days later.
4. A negative result may be obtained from a urine sample that is too dilute (does not contain an adequate concentration of HCG). If pregnancy is still suspected, obtain a first morning urine specimen and retest.
5. Although the ASI ProPhase Plus test is very accurate in detecting pregnancy, a low incidence of false results can occur. If results are unexpected or inconsistent, consult with a physician.

6. As with all diagnostic tests, a definitive diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

XIII. Expected Values:
Urine HCG levels are estimated to be (1-3):
1. 10 – 30 mlU/ml seven to ten days post conception.
2. 37,000 – 50,000 mlU/ml eight to eleven weeks after last menstrual period.
3. Undetectable in healthy men or healthy non-pregnant women.

XIV. Performance Characteristics:
1. Sensitivity and Specificity: The ASI ProPhase Plus test will detect HCG in urine at a concentration of 25 mlU/ml or greater. This sensitivity has been confirmed with HCG standards up to 300,000 mlU/ml. The addition of LH (300 mlU/ml), FSH (1000 mlU/ml), and TSH (1000µl/ml) to negative (0ml/ml HCG) and positive (25 mlU/ml HCG urine showed no cross-reactivity.)

2. Interfering Substances: The following potentially interfering substances were added to urine specimens containing HCG levels of 0 and 25 mlU/ml:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Acetylsalicylic acid</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Ascorbic acid</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Atropine</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Caffeine</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Gentisic acid</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Glucose</td>
<td>2000 mg/dl</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>1 mg/dl</td>
</tr>
</tbody>
</table>

The ASI ProPhase Plus test was used to assay each preparation. In all cases, the expected results were obtained and none of the substances at the concentration tested interfered in the assay.

3. Accuracy: Different clinics and laboratories studied total of 176 blind clinical samples from suspected pregnant women. Samples were assayed with the ASI ProPhase Plus test and another commercially available one-step membrane test according to assay procedures. Both methods showed 99 negative and 77 positive results. The results demonstrated a 100% overall accuracy of the ASI ProPhase Plus test compared to the other commercially available test. A sensitivity of 100% and a specificity of 100% were obtained. However, a claim of 100% accuracy cannot be made due to the potential for user error and other error sources. It is acceptable to claim that the test is “over 99% accurate”.

Page 24 of 177
XV. Safety:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XVI. Performance Improvement:
A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

References:
Wampole PreVue Cassette Pregnancy Test Kit

Date Prepared: 07/14/04

Author: Karen Alderson, BSMT(ASCP), LVN

Date Effective: 07/21/04

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

<table>
<thead>
<tr>
<th>Date</th>
<th>Signature/Title</th>
</tr>
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Revised:

Risk Assessment: High

Complexity Level: Waived
I. **Title:** Urine HCG Pregnancy Test Procedure  
   Wampole PreVue Cassette Pregnancy Test Kit

II. **Purpose:**  
   It is the policy of Student Health Services to provide convenient, non-invasive pregnancy testing. **Wampole PreVue Cassette Pregnancy Test Kit** provides an assay for the qualitative determination of human chorionic gonadotropin (HCG) for the early detection of pregnancy.

   Human chorionic gonadotropin is a glycopeptide hormone produced by the placenta beginning shortly after fertilization. In normal pregnancy, HCG can be detected in serum and urine as early as 7 days following conception. At the time of the first missed menstrual period, HCG levels of 100 mIU/ml may be detected in the maternal urine and peak levels are seen late in the first trimester of pregnancy. The early appearance of HCG in urine following conception has made it the marker of choice for the early detection of pregnancy.

III. **Principle:**  
   The Wampole PreVue HCG Pregnancy Test is a chromatographic immunoassay (CIA) for the rapid qualitative determination of HCG in urine and serum. The membrane is precoated with anti-alpha HCG capture antibody on the test line region and goat anti-mouse on the control line region. During testing, the urine or serum specimen is allowed to react with colloidal gold particles coated with anti-beta HCG monoclonal antibody. The mixture then moves along the membrane chromatographically by capillary action. For a positive result, a pink colored line with a specific antibody-HCG-antibody colloidal gold particle complex will form on the membrane in the test line region. Absence of a pink colored line in the test line region serves as verification that sufficient volume has been added and that proper flow was obtained.

IV. **Specimen Requirement:**  
   Collect urine specimen in a clean glass, plastic, or wax-coated container free of preservatives. Although urine collected anytime may be used, the first morning urine usually contains the highest concentration of HCG. If the sample is not to be tested immediately following collection, but is to be tested within 72 hours, the sample should be refrigerated (2°-8°C or 36°-46°F). It should be brought back to room temperature (15°-30°C or 59°-86°F) before testing.

V. **Materials and Reagents:**  
   A. 25 Individual pouches with a cassette device and a pipette for each test
VI. **Quality Control:**
A. **Internal control:** *Wampole PreVue HCG Cassette Test Kit* contains an internal built in procedural control. The appearance of a red line in the reference/control region on the cassette confirms test was performed correctly and all reagents were reactive.
B. **External control:** External quality controls must be completed each time a test kit is opened. This control is completed using the Quantimetrix Control solution. One cassette is tested using 5 drops of solution from Quantimetrix Level 1 (Normal) control. This should produce a negative result. A second cassette is tested using 5 drops of Quantimetrix Level 2 (abnormal) control. This should produce a positive result.
C. The results of the control are recorded on the Urine Pregnancy Test Log. The staff performing the controls signs and dates when the controls are complete. If proper results are not noted, the test is repeated. If proper results are still not met, call Wampole Customer Service to report problem and ask for assistance. Documentation on back of Test Log will indicate the problem and what steps were taken to resolve it. No patient testing is performed until correct quality control results are noted.

VII. **Limitations of the Procedure:**
A. In addition to pregnancy, HCG has been detected in patients with both gestation and non-gestational trophoblastic disease. These diagnoses should be ruled out in the interpretation of HCG levels to establish a diagnosis of pregnancy.
B. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on HCG levels alone. Also, a spontaneous miscarriage may cause confusion in interpreting the test results.
C. A negative result from a urine specimen collected from a woman in very early pregnancy may be due to an unusually low concentration of HCG. In such cases, the test should be repeated on a fresh specimen obtained approximately two days later.
D. A negative result may be obtained from a urine sample that is too dilute (does not contain adequate concentration of HCG). If pregnancy is still suspected, obtain a first morning urine specimen and retest.
E. Although the *Wampole PreVue Cassette Pregnancy Test Kit* is very accurate in detecting pregnancy, a low incidence of false results can occur. If results are unexpected or inconsistent, consult with a physician.
F. As with all diagnostic tests, a definitive diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

VIII. **Testing Procedure:**
A. Collect a fresh urine specimen in a clean dry container.
B. Apply non-sterile latex gloves before performing procedure.
C. If refrigerated, allow cassette to warm to room temperature before testing.
D. Remove cassette and pipette from pouch and lay cassette on flat surface.
E. Use pipette from pouch and dispense 5 drops of urine specimen into the sample well of the cassette.
F. Wait 5 minutes for urine test to be completed. DO NOT interpret results after 5 minutes.
IX. Reporting of Results:
A. Record date, patient’s name, medical record number, performed by, and testing results on the Urine Pregnancy Test Log.
B. Inform the physician of results. The physician will document the results on the patient requisition and place in the patient’s chart. If test is performed through Nurse Clinic, Document on Pregnancy Progress Notes.

X. Interpretation of Results:
A. NEGATIVE - absence of red line in the test area but presence of a red line in the reference/control region on the test cassette.
B. POSITIVE - two visually detectable red lines in the test reference/control region on the test cassette.
C. INVALID - absence of red line (internal control) in the reference/control region on the test cassette. Test should be repeated.

XI. Storage and Handling:
A. Cassettes can be stored at room temperature between 35°-80°F until stated expiration date.
B. If cassettes are kept in refrigerator, allow cassette test device, in original pouch, to warm to room temperature before patient testing. A test device, which was out of pouch for 24 hours or became wet, should not be used.
C. Record kit lot#, date received, date in use, and date of expiration on the Urine Pregnancy Test Log.

XII. Safety:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XIII. Performance Improvement:
A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

References:
Wampole PreVue HCG Cassette Pregnancy Test Kit package insert.
Point-of-Care Manual

Blood Glucose Procedure

Date Prepared: 11/17/04
Author: Tina Anderson, MT (ASCP) Stacy Jackson, Phlebotomy Consultant
Date Effective: 11/24/04
Approved By: Dale M. Dunn MD Chief Medical Officer

Annual Review:

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Revised:

Risk Assessment: High

Complexity Level: Waived
I. **Title:** Blood Glucose Procedure

II. **Statement of Purpose:**
It is the policy of Texas Tech Physicians of Lubbock to provide instruments and reagent strips as a method of monitoring blood glucose in patients.

III. **Principle:**
A small drop of blood is applied to a test strip. A glucose oxidase reaction occurs between the blood and reagents in the test strip resulting in the formation of a blue color. This color is visible through the confirmation dot on the back of the test strip – the darker the blue, the higher the glucose level in the blood sample. This unit measures the color intensity and reports a glucose result.

IV. **Specimen:**

**Patient Preparation:**
Capillary blood can be obtained from puncturing the fingertip or heel of an infant using a lancing device. The puncture site should be cleaned and thoroughly dried before obtaining a blood sample.

**Type:**
Fresh whole blood – capillary, venous, arterial, and neonatal blood may be used. Venous and capillary blood may differ in glucose concentration by as much as 70 mg/dL, depending on the time of blood collection after food intake. Do not use serum or plasma samples. Anticoagulants such as heparin and EDTA may be used. Do not use preservatives that contain fluoride (grey top tubes).

**Handling Conditions:**
Test the blood sample as close as possible to the time the sample was collected. The test should be performed within 30 minutes of sample collection to minimize glycolysis. If using fresh whole blood in the absence of an anticoagulant, test immediately to prevent clotting from affecting the results.

When whole blood in a test tube is used (lavender or green topped tubes), care should be taken to uniformly distribute red cells throughout the tube before testing by gently inverting the tube several times.
V. Equipment and Materials:

**Equipment:**
- Blood Glucose Monitoring System and Operator’s Guide
- Lancing device (if obtaining a capillary sample)

**Materials:**
- Test Strips
- Glucose Control Solutions – HI & LOW

**Reagent Storage Requirements:**
- Store test strips tightly capped in their original bottle in a cool, dry place below 30˚C. Keep away from heat and direct sunlight. Do not refrigerate or freeze. Discard any unused portion 4 months after opening. Do not use after the expiration date printed on the bottle label.
- Store control and linearity solutions below 30˚C. Do not refrigerate or freeze. Discard any unused portion 3 months after opening. Do not use after the expiration date printed on the vial label.

VI. Quality Control:

Two levels of Glucose Control Solutions should be used to verify system performance:
- Within 24 hours of any patient testing.
- If a patient test has been repeated and the blood glucose results are still lower or higher than expected.
- When troubleshooting the system
- If you drop the unit

At room temperature, 95% (19 out of 20) of glucose control solution results should fall within the range printed on the test strip bottle label. Valid results depend on the correct test strip lot number (and corresponding code) being correctly entered in the bedside unit.

If test results fall outside the expected range, repeat the test. Results that fall outside the expected range may indicate:
- Procedural error
- Old or contaminated glucose control solution
- Incorrect test strip lot number entered in the unit.
- Debris in the lens area and test strip holder
- Test strip deterioration
- Unit malfunction
- Control solution outside 15-35˚C functional temperature range

VII. Procedure

A. Coding the Meter
1. Code numbers are used to calibrate the test strips with the meter for accurate results.
2. You must code the meter before using it for the first time and every time you change to another vial of test strips.
   a. Turn on the meter
b. Press the “M” button located on the top of the meter to change the code on the meter to match the code on the side of the test strip bottle.

c. Some meters require a “chip” be placed in the meter with each new lot number thus eliminating the need for coding.

B. Quality Control
1. Two Levels of Quality Control must be tested every 24 hours of patient testing.
2. Two Levels of Quality Control must be tested when a new vial of test strips is opened.
3. Two Levels of Quality Control must be tested when the operator suspects the meter or test strips are not working properly.
4. Quality Control Procedure
   • Insert test strip
   • Apply control solution – HI Control & LOW Control
   • Results will appear in 45 seconds

C. Specimen Collection Procedure
Always use a single-use sterile lancet. Avoid hand lotion, oils, dirt, or debris in or on the lancet.
1. Wash your hands.
2. Select appropriate puncture site. Capillary punctures should only be reserved for the distal segment of the middle and ring finger.
3. Clean the puncture site with 70% isopropyl alcohol.
4. Obtain 1 single-use sterile lancet.
5. Puncture the selected site.
6. Dispose of lancet in appropriate sharps resistant container.
7. Do not smear the blood sample on the test strip.

D. Test Procedure
1. Turn monitor on.
2. Insert test strip.
3. Apply sample.
4. Wipe away the first drop of blood. The first drop of blood contains tissue contaminants and should not be used for testing.
5. Gently massage the area to obtain a large round drop of blood and gently drop on test strip area.
7. Record the result on the Laboratory Result Form.

VIII. Reporting Results:
Reference Ranges:
1. Blood glucose levels for people without diabetes are as follows:

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<td>Before meals:</td>
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2. Expected values for neonates: 35-60 mg/dL
3. Any patient with a glucose value of <50mg/dL or >375mg/dL should have another specimen drawn and submitted to the Clinical Laboratory for result verification of high or low value. The clinic nurse or doctor will evaluate each result to determine if results require verification of the Clinical Laboratory.
IX. Limitations of the Procedure:
   1. Use only fresh whole blood. Do not use serum or plasma.
   2. Use an adequate amount of blood – just enough to completely cover the test circle on the test strip.
      • Too much blood may cause false high results, whereas too little blood may cause false low results.
   3. Extremes in hematocrit can affect test results. High hematocrits (above 55%) and low hematocrits (below 30%) on non-neonatal samples can cause false results.
   4. Blood glucose results obtained with test strips may be affected if excessive water loss or dehydration occurs. Severe dehydration can lead to many serious medical complications.
   5. Do not use blood collection tubes containing fluoride. Sodium fluoride interferes with test results.

X. Safety:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XI. Performance Improvement:
A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

References:
Point-of-Care Manual

QuickVue In-Line Strep A

Date Prepared: 02/04/02

Author: Tina Anderson, MT (ASCP)

Date Effective: 03/01/02

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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Revised:

Risk Assessment: High

Complexity Level: Waived
I. Title: QuickVue In-Line Strep A

II. Statement of Purpose:
The QuickVue In-Line Strep A test allows for the rapid detection of Group A streptococcal antigen directly from patient throat swab specimens. The test is intended for use as an aid in the diagnosis of Group A Streptococcal infection.

III. Statement of Principle:
Group A Streptococci are organisms that typically cause illnesses such as tonsillitis, pharyngitis and scarlet fever. These infections can lead to serious complications, including rheumatic fever and acute glomerulonephritis. Rapid diagnosis and appropriate antibiotic therapy of Group A streptococcal infections appear to be the best means of preventing these complications. The traditional means of detecting Group A Streptococcal infections involves 24-48 hour culture of throat swab specimens or other exudates, confirming beta-hemolytic Streptococci, is bacitracin susceptible, which provides a presumptive diagnosis of Group A Streptococcal disease.

It is also possible to identify Group A Streptococci by immunological means. The cell walls of Group A Streptococci share a common, group-specific, antigenic determinant. This determinant is a carbohydrate consisting of polymerase chains terminating in N-acetyl glucosamine residues. Antibodies against this carbohydrate antigen have been used in a variety of tests to identify the Group A organism. The QuickVue In-Line Strep test is a lateral-flow immunoassay utilizing an in-the-device antigen extraction. The test, which contains a highly specific and sensitive antibody reactive to the Strep A antigen, is specific to Group A with no cross-reactivity from other groups of Streptococci.

A throat swab specimen is collected and inserted into the swab chamber of the test cassette. The extraction solutions are mixed, resulting in a green color change, and added to the swab in the swab chamber in order for the antigenic component of the bacteria to be extracted.

Extraction begins instantaneously, after which the extracted solution flows from the swab chamber in the test strip by capillary action. The extracted sample migrates through a label pad consisting of a pink label containing rabbit polyclonal anti-strep A antibody and a blue control label. If the extracted solution contains Strep A antigen, the antigen will bind to the antibody on the pink test label which, in turn, will bind a second rabbit polyclonal anti-Strep A antibody spotted on the membrane, resulting in the formation of a pink-to-purple test line. A blue control line will also appear next to the letter “C” on the test cassette indicating that the reagents were mixed and added properly, proper volume of fluid entered the test cassette and capillary flow occurred. A blue control line should always appear in a properly functioning test cassette. If Strep A is not present, or present at very low levels, only a blue control line will be visible.
IV. **Reagents and Materials Supplied:**
   A. Individually packaged Test Cassettes (25)
      1. Membrane coated with rabbit polyclonal antibody to Strep A
   B. Extraction Solution Bottles (25)
      2. 4M Sodium Nitrite (0.6mL), and 0.2M acetic acid (0.65 mL) inside glass ampule
   C. Individually packaged sterile rayon-tipped swabs on solid green shafts (25)
   D. Positive Control Swabs (+) (1)
   E. Negative Controls Swabs (-) (1)
   F. Package Insert (1)
   G. Procedure Card (1)
   H. Extraction Kit (1)
      1. 5 tubes and 5 disposable droppers for use with Proficiency Testing Samples only.

V. **Warnings and Procedure:**
   A. For *In-Vitro* diagnostic use.
   B. Do not use beyond the expiration date printed on the outside of the box.
   C. Dispose of containers and used contents in accordance with Federal, State and Local requirements. 4
   D. The test cassette must remain sealed in the protective foil pouch until just prior to use.
   E. The extraction solution bottle contains an acidic solution. If the solution contacts the skin or eyes, flush with large volumes of water.
   F. The extraction solution bottle contains glass, break cautiously.
   G. If the extraction solution bottle is missing the glass ampule or the solution is green prior to the breaking of ampule, discard and use another extraction solution bottle.
   H. To obtain accurate results, package insert instructions must be followed.
   I. Store kit at room temperature, 59°-86°F (15°-30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

VI. **Specimen and Collection:**
The sterile rayon swabs supplied with this kit must be the only swabs used for specimen collection. These special swabs have green print on the paper wrapper and green shafts. Collect throat swab specimens by standard clinical methods. Depress the tongue with a tongue blade or spoon. Be careful not to touch the tongue, sides or top of the mouth with the swab.

Rub the swab on the back of the throat, on the tonsils, and in any other area where there is redness, inflammation or pus. Consult standard reference procedures such as the collection method described by Facklam. 5

Use *only* the rayon tipped swabs on solid green plastic shafts supplied in the kit to collect throat specimens. Other swabs, including other rayon swabs, are incompatible with this test due to their small tip size.

It is recommended that swab specimens be processed as soon as possible after collection. Swabs can be held in a clean, dry plastic tube or sleeve up to 4 hours at room temperature (15°-30°C) or 24 hours refrigerated (2°-8°C) before processing. Performance with transport
media has not been assessed, however the use of charcoal or agar medium is not recommended.

If a culture is desired, lightly streak the swab on a 5% sheep blood agar plate before using the swab in the QuickVue In-Line Strep A test. Do not perform the QuickVue In-Line Strep A test before streaking the swab, as the extraction solution will destroy the bacteria on the swab thereby rendering the organism incapable of successful culturing. Alternatively, throat swab specimens can be obtained by dual swabs or by two sequential swabs for the culture procedure.

VII. Quality Control:
A. Built-In Control Features
The QuickVue In-Line Strep A test contains built-in control features. The manufacturer’s recommendation for daily quality control is to document these controls for the first sample tested each day.

A control of the extraction procedure is provided by a color change from clear to green as the extraction solutions are mixed. The color change is an indication of extraction reagent integrity and is also an indication that the extraction procedure was correctly performed.

The two-color result format provides a clear-cut readout for positive and negative results. The appearance of a blue control line next to the letter “C” provides several forms of control. First, detection components for the specimen and internal control are processed concurrently using identical procedures; therefore, the appearance of the control line ensures that functional activity of the detection component is maintained. Secondly, the appearance of the control line also ensures that the foil pouch integrity has been maintained and the test cassette has been stored in such a manner as not to compromise its functionality. Third, the appearance of the control line indicates that proper volume of fluid entered the test cassette and capillary flow occurred. This would indicate that the test cassette was assembled properly by acting as a check for all membrane interfaces and proper positioning of components. If the control line does not develop within 5 minutes, the test result is invalid.

A negative background control is provided by the clearing of background color in the Result Window and indicates that there were no immunological interfering substances in the specimen. This area should be white to light pink within 5 minutes and not interfere with the reading of the test result. If background color remains in the result window, which interferes with reading the test result, the result may be invalid. In this case, contact Quidel Technical Support.

B. Positive and Negative Quality Control
External controls also may be used to demonstrate that the reagents and assay procedure perform properly. Positive and Negative control Swabs are supplied in the kit. The Positive Control Swab (+) is stored in the pink-capped tube; the Negative Control Swab (-) is stored in the blue-capped tube.
To test using a Positive or Negative control swab, remove the control swab from its container and insert it into the QuickVue In-Line Strep A test cassette swab chamber. Continue with the assay as instructed in the **Test Procedure** section.

To test using a liquid control (Catalog #00354), shake the control solution bottle vigorously. Hold the bottle vertically and place one free falling drop of liquid control on sterile swab provided in the kit. Insert the Swab into the QuickVue In-Line Strep A test cassette swab chamber. Continue with the assay as instructed in the **Test Procedure** section.

Quidel Recommends that positive and negative controls be run with every lot. If controls do not perform as expected, do not use the test results. Repeat the test or contact Quidel Technical Support.

**VIII. Test Procedure:**

**A. Important**
1. Gloves should be worn when handling human samples.
2. Do not use the extraction solution if it is green prior to breaking the ampule.

**B. Before Testing**
1. Only use the swabs provided in the kit.
2. Remove the test cassette from foil pouch and place on a clean, dry, level surface. Using the notch at the back of the chamber as a guide, insert the swab completely into the swab chamber.
3. Squeeze to crush the glass ampule inside the extraction solution bottle.

**C. Perform the Assay**
1. Vigorously shake the bottle five times to mix the solutions. Solution should turn green after the ampule is broken. **Solution must be used immediately.**
2. Remove the cap. Quickly fill the chamber to the rim (approximately 10 drops). **Begin timing. If the liquid has not moved across the result window in 1 minute, completely remove the swab and re-insert. If liquid still does not move across, retest with a new specimen, test cassette and extraction solution bottle. The test cassette should not be moved until the assay is complete.**

**D. Read Results at 5 minutes**
1. Some positive results may be seen earlier.

**IX. Interpretation of Results:**

**A. Positive Result**
The appearance of any pink-to-purple line next to the letter “T” in the result window, along with a blue control line next to the letter “C” means that the test is positive for Group A Streptococcus.

**B. Negative Result**
The appearance of only the blue Control Line next to the letter “C” in the result window means the test is negative. A negative QuickVue result means that the swab is a presumptive negative for Group A Streptococcus.

**C. Invalid Result**
If the blue control line does not appear next to the letter “C” at 5 minutes, the test is considered INVALID and the test result cannot be used. If this occurs, retest using a fresh swab and a new QuickVue test cassette or contact Technical Support.

*For a photographic example of test results, please see the procedure card.*
X. **Proficiency Testing Survey Procedure:**
The testing procedure for Proficiency Survey Swab specimens is outlined below. **This procedure must be followed to ensure accuracy** with the QuickVue test on Proficiency survey swab specimens because proficiency testing swab tips are smaller in size than the swabs provided for use with the kit.
A. Place a clean tube from the extraction kit in a test tube rack.
B. Squeeze to crush the glass ampule inside the extraction solution bottle as described in the TEST PROCEDURE section.
C. Dispense **8 DROPS** from the extraction solution bottle into the tube. Place the proficiency swab into the tube. Hold the bottom of the tube so the swab head is slightly compressed. Rotate the swab three (3) times.
D. WAIT ONE (1) MINUTE.
E. Express all the liquid from the swab head in the tube by rolling the swab against the inside of the tube and pressing slightly as it is withdrawn from the tube. Discard the swab.
F. Fill the disposable dropper to the fill line with the solution from the tube and add the contents into the test cassette swab chamber.
G. Read the result at 5 minutes. See INTERPRETATION OF RESULTS SECTION.

XI. **Limitations:**
The contents of this kit are for use in the **qualitative** detection of Group A Streptococcal antigen from throat swab specimens only. Failure to follow the test procedure and interpretation of test results may adversely affect performance and/or produce invalid results.

Respiratory infections, including pharyngitis, can be caused by Streptococcus from serogroups other than group A as well as other pathogens. The QuickVue In-Line Strep A test will not differentiate asymptomatic carriers of Group A Streptococcus from those exhibiting streptococcal infection. In rare cases, test specimens heavily colonized with Staphylococcus Aureus (>10^10) can yield false positive results.

Test results must always be evaluated with other data available to the physician. A negative test result might occur if the level of extracted antigen in a sample is below the sensitivity of the test. Additional follow-up testing using the culture method is recommended if the QuickVue test result is negative.

XII. **Expected Values:**
Group A Streptococci are responsible for about 19% of all upper respiratory tract infections, but the incidence varies by clinical setting. Streptococcal pharyngitis is seasonal in nature with the highest prevalence found during winter and early spring. The highest incidence of this disease is found in crowded populations such as military bases and in school-aged children, and is evenly distributed between males and females.

XIII. **Performance Characteristics:**
A. Clinical Sensitivity and Specificity
   1. The QuickVue In-line Strep A test will yield positive test results with specimens containing at least 5x10^5 Group A Streptococci organisms per test. A multi-center evaluation of the QuickVue Test was conducted to determine the clinical performance of the test relative to standard culture techniques. A total of 537 throat
Swabs specimens were collected from patients presenting with pharyngitis. Prior to performance of the QuickVue test, each swab specimen was inoculated onto a sheep blood agar plate containing a bacitracin disk and incubated at 37°C for 48 hours for culture evaluation. All cultures were confirmed for the presence of group A Strep using commercial latex agglutination assays.

Swabs were either tested in the QuickVue test immediately upon collection at the field site (fresh specimens) or frozen and shipped overnight to Quidel. Testing with the QuickVue test was performed by trained technicians and by users in the field with various levels of work experience and educational backgrounds.

Of the 537 total specimens, field users tested 301 fresh specimens while trained technicians at Quidel tested the other 236 frozen specimens. Ten (10) additional specimens tested resulted in uninterpretable results and were eliminated from the analysis.

In the field study, 240 specimens were found to be negative by SBA culture and 225 were also negative by the QuickVue test. Similarly, 61 specimens were found to be positive by SBA culture and 53 were also positive by the QuickVue test. Based on this data, specificity was 94% and sensitivity was 87% for the QuickVue Test, 95% confidence intervals were calculated to be 91%-97% and 78%-95% for specificity and sensitivity, respectively. Overall agreement between SBA culture and QuickVue was 92% (278/301).

In a separate study conducted at Quidel, 136 specimens were found to be negative by SBA culture and 135 were also negative by the QuickVue test; similarly, 100 specimens were found to be positive by SBA culture and 92 were also positive by the QuickVue test. Based on the data, specificity was 99% and sensitivity was 92% for the QuickVue test; 95% confidence intervals were calculated to be 96%-100% and 87%-97% for specificity and sensitivity, respectively. Overall agreement between SBA culture and QuickVue was 96% (227/236).

### XIV. Specimen Mix in Population:

<table>
<thead>
<tr>
<th>Culture Classification</th>
<th>Field Users</th>
<th>Trained Technicians</th>
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<tbody>
<tr>
<td></td>
<td>Correct Calls</td>
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<tr>
<td>Negative</td>
<td>225/240</td>
<td>94</td>
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<tr>
<td>1+</td>
<td>3/9</td>
<td>33</td>
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<tr>
<td>2+</td>
<td>7/9</td>
<td>78</td>
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<tr>
<td>3+</td>
<td>18/18</td>
<td>100</td>
</tr>
<tr>
<td>4+</td>
<td>25/25</td>
<td>100</td>
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<tr>
<td>Overall Agreement to Culture</td>
<td>278/301</td>
<td>92%</td>
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### XV. Physician’s Office Laboratory (POL) Studies:

An evaluation of the QuickVue In-Line Strep A test was conducted at four physicians offices using a panel of coded specimens. Physician’s office personnel with diverse educational backgrounds and work experience at different locations performed testing. The proficiency panel contained negative, low positive, moderate positive and high positive specimens. Each specimen level was tested in replicates of five at each site over a period...
of three days. The results obtained at each site ranged from 88% to 100% agreement with expected results. No significant differences were observed within run (five replicates), between runs (three different assay days), or between sites (four POL sites).

XVI. Cross-Reactivity:
Group C Streptococcus, Group G Streptococcus, S. aureus, N. subflava, H. influenza, C. albicans, N. meningitides, N. gonorrhoea, B. catarrhalis, E. faecalis, S. pneumoniae, and S. mutans were tested in the QuickVue In-Line Strep A test at levels exceeding 10^7/test and did not affect the expected test results.

XVII. Safety:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XVIII. Performance Improvement:
A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

XIX. Comments and Technical Assistance:
Quidel’s Technical Support number 800-874-1517 or (858) 552-1100, Monday through Friday, 7:00 am - 5:00 pm, Pacific time.

References:

**Point-of-Care Manual**

**Fecal Occult Blood**

<table>
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<td>Tina Anderson, MT (ASCP)</td>
</tr>
<tr>
<td>Date Effective:</td>
<td>03/01/02</td>
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<tr>
<td>Approved By:</td>
<td>Dale M. Dunn MD</td>
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<td>Chief Medical Officer</td>
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**Risk Assessment:** High

**Complexity Level:** Waived
Seracult Test for Fecal Occult Blood

I. Title: Seracult Test for Fecal Occult Blood

II. Statement of Purpose:
Seracult is a test procedure to detect the presence of occult blood in feces. This procedure can be an aid to the diagnosis of gastrointestinal bleeding or pathology (colorectal cancer). This test is for use as a preliminary screening aid and is not intended to be used for diagnosis or treatment. It is not a replacement for diagnostic procedures, such as proctosigmoidoscope examination, barium enema, or other radiological studies.

III. Statement of Principle:
The Seracult test is a simplified, standardized variation of the guaiac test for occult blood. It contains specially prepared guaiac impregnated paper and is ready for use without additional preparation.

When a small stool specimen containing occult blood is applied to Seracult test paper, the hemoglobin comes in contact with the guaiac. Application of developer (a stabilized hydrogen peroxide solution) creates a guaiac/peroxidase-like reaction, which turns the test paper blue within 60 seconds if occult blood is present.

The test reacts with hemoglobin released from lysed cells. When blood is present, hemolysis is promoted by substances in the stool, primarily water and salts.

IV. Specimen Required and Patient Preparation:
Small amount of stool specimen, approximately the size of a match-head. If possible, the patient should be placed on a meat-free low-peroxidase diet to reduce the possibility of false positive indications. This special diet should be started two days before testing and continued through the testing period. An alternative to this procedure is to omit the special diet for initial tests and to impose it on patients whose stools yield positive results and are to be retested. If any of the dietary restrictions and recommendations are known to cause discomfort, patients should be instructed to inform their physician. The patient should always consult the physician before discontinuing or interrupting any prescription medication.

<table>
<thead>
<tr>
<th>Patient May Consume</th>
<th>Patient Should NOT Consume</th>
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<tbody>
<tr>
<td>~ Generous amounts of cooked and uncooked</td>
<td>~ Rare and lightly cooked meats, particularly beef</td>
</tr>
<tr>
<td>vegetables such as lettuce, corn and spinach</td>
<td>~ Cauliflower, horseradish, red radishes, turnips,</td>
</tr>
<tr>
<td>~ Moderate amounts of high fiber food such as</td>
<td>broccoli and cantaloupe</td>
</tr>
<tr>
<td>bran cereal, peanuts and popcorn</td>
<td>~ Vitamin C in excess of 250 mg. per day</td>
</tr>
<tr>
<td>~ Plenty of fruits such as apples, plums, and</td>
<td>~ Iron rich supplements</td>
</tr>
<tr>
<td>grapes</td>
<td>~ Aspirin and other medications which may cause</td>
</tr>
<tr>
<td>~ Well cooked pork, poultry and fish</td>
<td>gastrointestinal irritation</td>
</tr>
</tbody>
</table>
V. Materials and Reagents:
A. Seracult Slides
   1. For In-Vitro diagnostic use only.
   2. Do not use after expiration date.
   3. Test is not valid, if the performance control test does not yield a blue color.
   4. Storage and stability - Store between 59°-86°F (15°-30°C). Stable until expiration date on the box. DO NOT refrigerate. Protect from heat, light, fluorescent light and ultra violet radiation. A light-blue discoloration of the normally light-amber paper may occur if slides are not stored under recommended conditions. This does not affect the performance of the test.

B. Seracult Developer
   1. The developer is an aqueous solution of approximately 5% hydrogen peroxide and 75% ethanol and is ready for use as packaged.
   2. For In-Vitro diagnostic use only.
   3. Do not use product after the expiration date imprinted on developer bottle.
   4. Do not ingest.
   5. The developer is flammable, keep away from open flame.
   6. The developer is an irritant. Avoid contact with eyes and skin; if contact occurs, flush the affected area with water.
   7. Keep bottle tightly capped when not in use to prevent evaporation.
   8. Storage and stability - Store between 59°-86°F (15°-30°C). Do not refrigerate or freeze. Keep away from heat and light. If properly stored, developer will remain stable until the expiration date printed on each bottle.

C. Swabs and/or applicators

VI. Performance Control Monitor:
A. The performance control test allows the user to verify the reactivity of the paper and developer used in each Seracult slide test. Any blue color developed in the performance control area acts as verification of correct product performance. (The shade or intensity of the blue color developed with the performance control test may not be indicative of the blue color that is obtained from a positive specimen test.)

B. The performance control test should only be performed after the patient specimen tests have been developed and interpreted to ensure the most objective interpretation of the patient specimen tests. If developer solution should accidentally cross over the barrier between the performance control area and the specimen test area, or if developer solution should inadvertently be applied to the performance control area while the specimen test area is being developed, the blue color developed in the performance control area should not be considered positive indication for the presence of occult blood.

C. A lack of blue color in the performance control area after proper development indicates that the slide test is not performing to product specifications. Specimen test results from a slide which fails the performance control test should be considered invalid and the test repeated.

D. Performance control should be recorded on the Point-of-Care Laboratory result form.

VII. Procedure:
A. Collect a small stool sample on one end of applicator.
B. Apply thin smear inside one test area.
C. Reuse applicator to obtain second sample from different part of stool. Apply thin smear inside second test area.

D. Close cover over smears.

E. Open flap on back side of slide and apply two drops of Seracult developer to guaiac paper directly over each smear.

F. Read results within 60 seconds.

VIII. Expected Results:
A. Results must be obtained by visual observation 30 to 60 seconds after the application of the developer solution. Any trace of blue color in the specimen test area is positive indication of occult blood. The absence of a blue color in the specimen test area indicates a test negative for occult blood. Since any developed blue color may fade after 2-4 minutes, it is imperative that the developed slide be read within the recommended time period.

IX. Reporting Results:
A. Patient results should be reported as a Positive for Occult Blood or a Negative for Occult Blood on the Point-of-Care Laboratory result form.

B. Performance Control Test should be reported on the Point-of-Care QC Log sheet.

X. Limitations:
A. Normal individuals following adequate pretest precautions will not have occult blood in their stool specimen. Proper pretest instructions should be given to patient. SEE SPECIMEN REQUIRED AND PATIENT PREPARATION.

B. Ingestion of high doses of vitamin C (ascorbic acid) in excess of 250 mg. per day has been linked to false negative results. Intake should be discontinued two days prior to and during the testing period.

C. Oral iron preparations such as iron-rich supplements have been associated with a higher than normal percentage of false positive indications in healthy patients. Ingestion of therapeutic iron should be discontinued two days prior to and during the testing period.

D. Certain oral medications may cause gastrointestinal irritation and bleeding. Medications such as aspirin, indomethacin, phenylbutazone, corticosteroids and reserpine should, with the consent of a physician, be discontinued two days prior to and during the testing period. The physician should always assess the advisability of any changes to a prescription medication regimen.

E. Dietary catalases and peroxidases derived from various meats and vegetables may contribute significantly to the incidence of false positive indications. For this reason, certain dietary restrictions (described in the preceding Patient Preparation section) are frequently recommended.

F. In-Vitro studies have shown Seracult test to be capable of detecting 2 ml to 4 ml of added blood in 100gm of feces-about twice the normal daily fecal blood loss in an adult.

G. Since bleeding from gastrointestinal lesions may be intermittent, collection of three consecutive stool specimens is recommended to increase the probability of detecting occult blood.

H. Patients with bleeding from other conditions that may show up in stool specimens (i.e. hemorrhoids or menstrual bleeding) are not appropriate test subjects while such bleeding is active.
I. Summary of the Seracult's test performance based on reported experience to date:
   1. Positive rate in screening situations has been approximately 3%-5%.
   2. False positive rate in patients receiving adequate preparation has been between 1% and 2%.

XII. Troubleshooting:
   A. Check expiration dates on the slides and developer.
   B. Test should be read during recommended time period.
   C. Check to ensure that the Gastroccult developer is not being used.
   D. Interfering substances may cause false results. See LIMITATIONS.

XIII. Maintenance:
   Not applicable.

XIV. Linearity:
   Not applicable.

XV. Calibration:
   Not applicable.

XVI. Safety:
   All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XVII. Performance Improvement:
   A. A Technical Supervisor/Director of Nursing or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
   B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

References:
Texas Tech Physicians of Lubbock
Lubbock, Texas

Point-of-Care Manual

Urinalysis By Multistix 10SG Reagent Strip

Date Prepared: 02/04/02
Author: Tina Anderson, MT (ASCP)
Date Effective: 03/01/02
Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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<td>Dale M. Dunn MD, MBA</td>
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Revised:

Risk Assessment: High
Complexity Level: Waived
I. Title: Urinalysis by Multistix 10SG Reagent Strip

II. Statement Of Purpose:
To establish guidelines for use of the Multistix Reagent Strips, including a description/reaction explanation for each reagent test area. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and urinary tract infection.

III. Principle of Test:
The Chemical Reactions of the Multistix are as follows:
A. Glucose: The test is based on a double sequential enzyme reaction. Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown.
B. Bilirubin: Colors through various shades of tan are produced when bilirubin couples with diazotized dichloroaniline in a strongly acid medium.
C. Ketone: Acetoacetic acid reacts with nitroprusside and causes the development of colors ranging from buff-pink to purple.
D. Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentration.
E. Blood: This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5',-tetramethylbenzidine. The resulting color ranges from orange through green; very high levels of blood may cause the color development to continue to blue.
F. pH: Colors range from orange through yellow and green to blue and indicate the entire pH range using a double indicator principle.
G. Protein: At a constant pH, the development of any green color is due to the presence of protein. This test is based on the protein-error-of-indicators principle.
H. Urobilinogen: A modified Ehrlich method is used. Pink to red color is produced when ρ-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium.
I. Nitrite: This test depends upon conversion of nitrate to nitrite by the action of Gram negative bacteria. Nitrite reacts with ρ-arsanilic acid to form a diazonium compound. This diazonium compound in turn couples with 1,2,3,4-tetra-hydrobenzo(h)-quinolin-3-ol to produce a pink color.
J. **Leukocytes:** Granulocytic leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product.

**IV. Specimen Requirements:**
A. Collect urine in a clean container and test it as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be done within an hour after collection, refrigerate the specimen **immediately.** Let the specimen return to room temperature and mix well before testing.
B. Optimum specimen is the first AM void. Nitrite results are optimized by using a most concentrated sample (first AM void) or one that has incubated in the bladder for at least four hours.
C. All specimens (unless specifically directed by the health care provider) should be collected clean-catch mid-stream. Clean-catch mid-stream specimens may be submitted for a culture as well as routine urinalysis testing.

**V. Materials and Reagents:**
Multistix are firm plastic strips to which several separate reagent areas are affixed for testing Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in urine. The reagent test areas on Multistix are ready to use upon removal from the bottle. The entire strip is disposable and requires no additional laboratory equipment for testing.

A. **Glucose:** 2.2% w/w glucose oxidase (1.3 IU); 1.0% w/w peroxidase (horseradish 3300 IU); 8.1% w/w potassium iodide; 69.8% w/w buffer; 18.94% w/w non-reactive ingredients.
B. **Bilirubin:** 0.4% w/w 2, 4-dichloroaniline diazonium salt; 37.3% w/w buffer; 62.3% w/w non-reactive ingredients.
C. **Ketone:** 7.1% w/w sodium nitroprusside; 92.9% w/w buffer.
D. **Specific Gravity:** 2.8% w/w bromthymol blue; 68.8% w/w poly (methyl vinyl ether/maleic anhydride); 28.4% w/w sodium hydroxide.
E. **Blood:** 6.8% w/w diisopropylbenzene dihydroperoxide; 4.0% w/w 3,3’,5,5’-tetramethylbenzidine; 48.0% w/w buffer; 41.2% w/w non-reactive ingredients.
F. **pH:** 0.2 w/w methyl red; 2.8% w/w bromthymol blue; 97.0% w/w non-reactive ingredients.
G. **Protein:** 0.3% w/w tetrabromphenol blue; 97.3% w/w buffer; 2.4% w/w non-reactive ingredients.
H. **Urobilinogen:** 0.2% w/w ρ-diethylaminobenzaldehyde; 99.8% w/w non-reactive ingredients.
I. **Nitrite:** 1.4% w/w ρ-arsanilic acid; 1.3% w/w 1,2,3,4-tetrahydrobenzofl(h)-quinoxalin-3-ol; 10% w/w buffer; 86.5% w/w non-reactive ingredients.
J. **Leukocytes:** 0.4% w/w derivatized pyrrole amino acid ester; 0.2% w/w diazonium salt; 40.9 w/w buffer; 58.5% w/w non-reactive ingredients.

**VI. Quality Control:**
A. Two levels of controls are performed with each new lot number.
B. Unopened Quantimetrix urine dipstick controls should be stored at 2º-8º C. Do not freeze. When stored at 2º-8º C, the controls are stable until the expiration date stated on the label. After initial use, controls can be stored at room temperature for one month. Make sure a 30-day expiration date is written on the control bottles.
C. Discard the controls if turbid or any evidence of microbial contamination.

D. Urine controls contain POTENTIAL BIOHAZARDOUS MATERIAL. Use gloves while testing controls.

E. Procedure
   1. Upon initial use, remove controls from refrigerator and allow them to come to room temperature. This should take about 15-30 minutes.
   2. Remove cap from Level I Control and invert bottle. While holding dipstick, gently squeeze the sides of the dropper bottle, and touch the tip of the bottle to the dipstick. Draw across the reagent pads, thoroughly saturating each pad. Do not aspirate excess control back into the bottle. Turn dipstick on its side and drain excess control onto absorbent material.
   3. Read the urine dipsticks visually according to PROCEDURE SECTION.
   4. Record results on the urine control log sheet. Control ranges are established per each lot number and each box of controls contains a package insert with acceptable ranges for controls. If controls are out of range, repeat controls. If controls still are not within range, obtain a new control and repeat testing.
   5. Repeat procedure for Level II Control.
   6. Wipe off dropper tips and recap controls. The controls can be stored at room temperature when not in use. Make sure a 30-day expiration date is on the control bottles.

VII. Procedure:

A. MACROSCOPIC EXAM:
   Determine and record the color and character of the urine.
   1. Color: The color of urine is due to the presence of urochrome, a urinary pigment. The intensity of color depends upon the concentration of urine.
      a. Straw usually indicates a diluted specimen.
      b. Yellow is usually indicative of a normal specimen.
      c. Amber usually indicates a concentrated specimen.

   2. Character: The normal character of urine is clear. Turbidity may be caused by:
      a. White blood cells
      b. Amorphous phosphates or urates
      c. Bacteria
      d. Uric acid crystals
      e. Epithelial cells
      f. Mucous or other substances

B. CHEMICAL EXAM by Multistix:
   1. Dip test areas of strip in fresh, well-mixed, uncentrifuged urine.
   2. Tap edge of strip against container to remove excess urine.
   3. Compare test areas closely with corresponding color charts on bottle at the times specified. Positive results may indicate the need for a complete urinalysis to be performed by the Clinical Laboratory. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.
4. **Time (after wetting) at which results are to be read:**
   a. Glucose at 30 seconds
   b. Bilirubin at 30 seconds
   c. Ketone at 40 seconds
   d. Specific Gravity at 45 seconds
   e. Blood at 60 seconds
   f. pH at 60 seconds
   g. Protein at 60 seconds
   h. Urobilinogen at 60 seconds
   i. Nitrite at 60 seconds
   j. Leukocytes at 2 minutes

5. **Interpretation of color reactions:**
   a. **Glucose:** Colors range from blue for negative through greens and browns for trace, 250 mg/dl, 500 mg/dl, 1000 mg/dl, and 2000 or more. Urine reducing substances by the Clinitest method are indicated in infants less than one year of age. Any value other than negative warrants further investigation.
   b. **Bilirubin:** Shades of brown indicate small, moderate and large. No bilirubin should be detected in normal urine by this method. Positive results indicate need for confirmation by Ictotest procedure.
   c. **Ketone:** Shades of buff-pink for negative through shades of purple indicating trace, small, moderate or large. Normal urine specimens ordinarily yield negative results with this reagent. Detectable levels of ketones may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. Fasting or starvation diets may cause ketones to appear in urine in large amounts before serum ketone is elevated.
   d. **Specific Gravity:** Test permits determination of urine specific gravity between 1.000 and 1.035. This test is not affected by nonionic urine constituents or by the presence of radiopaque dye.
   e. **Blood:** Shades of yellow for negative through yellow with green spots for non-hemolyzed trace, lime for hemolyzed trace and greens for small, moderate and large. The significance of the trace reaction may vary among patients and clinical judgment is required for assessment in an individual case. Development of green spots (intact erythrocytes) or green color (free hemoglobin/myoglobin) on the reagent area within 60 seconds indicates the need for further investigation.
   f. **pH:** Colors range from orange through yellow and green to blue for the numeric range of 5.0 to 8.5.
   g. **Protein:** Colors range from yellow for negative through yellow-green and green to green-blue for positive results. Positive results indicate need for confirmation by Sulfasalicylic Acid test or SSA.
   h. **Urobilinogen:** Color varies from yellow to pink-red with increasing concentrations of urobilinogen. Color blocks representing 0.2 to 8.0 mg/dl are provided (1mg/dl is approximately equal to 1 Ehrlich Unit/dl). A result of 2.0 mg/dl represents the transition from normal to abnormal and the patient and/or urine specimen should be evaluated further.
   i. **Nitrite:** Any degree of a pink color indicates a positive reaction. No nitrite is detected in urine.
j. **Leukocytes:** Buff color indicates a negative result, beige through purple indicates positive results of trace through large. Normal urine specimens generally yield negative results; positive results (small or greater) are clinically significant. Individually observed trace results may be of questionable clinical significance; however, trace results observed repeatedly may be clinically significant. Positive and repeated trace results indicate the need for further testing of the patient and/or urine specimen.

VIII. **Storage and Handling:**
A. The reagent strips must be kept in the bottle with the cap tightly closed to maintain reagent reactivity. Do not remove desiccant from bottle.
B. Multistix should be stored at temperatures under 30ºC (86º F).
C. DO NOT store in refrigerator.
D. Avoid exposing Multistix to moisture, direct sunlight, heat, acids, alkali, or volatile fumes.
E. Do not touch test areas of the reagent strip.
F. Dip test areas in urine completely, but briefly, to avoid dissolving out reagents.
G. Read test results carefully at the times specified, in a good light and with the test area held close to the appropriate color chart on the bottle label. Because this test is usually read and requires color differentiation, it should not be interpreted by people who are color blind or visually impaired.
   **CAUTION:** *Do not use Multistix strip if any of the unused reagent areas are not similar in color to the negative color blocks on the color chart.*
H. Multistix and urine control bottles must be labeled with open date and expiration date.

X. **Test Limitations:**
A. **Glucose:** The test is specific for glucose; no substance excreted in urine other than glucose is known to give a positive result. However, false positives may be caused by oxidizing cleaning agents. False negatives may be caused by high doses of ascorbic acid (Vitamin C).
B. **Bilirubin:** Ingestion of large quantities of ascorbic acid lowers the sensitivity of the test. Medications that turn the urine red may cause false positives.
C. **Ketone:** False positives may occur in presence of phenylketones.
D. **Specific Gravity:** Chemical nature of the strip may cause slightly different results than other methods when elevated amounts of urine constituents are present and highly buffered alkaline urines may cause lower results than other methods. The presence of moderate quantities of protein(100-750 mg/dl) may cause elevated values.
E. **Blood:** Elevated specific gravity may reduce the reactivity of the blood test. Capoten (Captopril) may also cause decreased reactivity. Certain oxidizing contaminants, such as hypochlorite, may cause false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction.
F. **pH:** If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "runover" may occur, in which the acid buffer from the protein reagent will run into the pH area, causing a false lowering of the pH result.
G. **Protein:** False positives are found with phenazopyridine, blood substitutes and when detergent residue contaminates the container or urine.
H. **Urobilinogen:** False positives may be caused by phenazopyridine. Reaction may be falsely decreased if formalin is present.
I. **Nitrite:** High levels of ascorbic acid decrease sensitivity and medication that turns the urine color red may cause false positives.

J. **Leukocytes:** Elevated glucose concentrations (>3mg/dl) or high specific gravity may cause decreased test results. The presence of cephalixin or cephalothin or high concentrations of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity and high levels of the drug may cause a false negative reaction.

XI. **Safety:**
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XII. **Performance Improvement:**
A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

**References:**
Multistix Package Insert, Diagnostics Division of Bayer Corporation, Elkhart, IN, Revised 9/95.
Quantimetrix Package Insert, Quantimetrix Corporation, Redondo Beach, CA, 4/96.
TEXAS TECH PHYSICIANS OF LUBBOCK
LUBBOCK, TEXAS

Point-of-Care Manual

Thermo Electron Pocketchem UA

Date Prepared: 06/16/04

Author: Karen Alderson, BSMT(ASCP), LVN

Date Effective: 07/17/04

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

Date                  Signature/Title
06/18/08               Dale M. Dunn MD
06/17/09               Dale M. Dunn MD
06/16/10               Dale M. Dunn MD
06/16/11               Dale M. Dunn MD, MBA
06/21/12               Dale M. Dunn MD, MBA
06/19/14               Dale M. Dunn MD, MBA

Revised:


Risk Assessment: High

Complexity Level: Waived
I. **Title: Thermo Electron Pocketchem UA**

II. **Purpose:**
The PocketChem UA is a portable automated dipstick reader intended for use in routine urinalysis. It is intended for use with AUTION sticks 10TA for the semi-quantitative measurement of Glucose, Protein, Bilirubin, Urobilinogen, pH, Specific Gravity, Blood, Ketones, Nitrite and Leukocytes in urine specimens. The PocketChem UA is a reflectance spectrophotometer utilizing three wavelengths: 565, 632, and 755nm. The device can be operated attached to the printer or detached as a battery-operated, hand-held unit. Specimens to be tested should be clean, fresh (within 4 hours) urine samples. Results are obtained within 60 seconds. The onboard software automates the operation of the device and monitors critical functional parameters.

III. **Chemical Principles:**

**Glucose:** This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxidase from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of the hydrogen peroxide with imine quinone dye producing a tan to purple/brown color range.

**Protein:** This test is based on a protein-error reaction. At a constant pH, the development of any green to green-blue color indicates the presence of protein. Results range in colors from yellow (negative reaction) through yellow-green, green and green-blue (positive reaction).

**Bilirubin:** This test is based on the Azo-coupling reaction (the coupling of bilirubin with Diazonium salt). The color reaction ranges in intensities of reddish-browns.

**Urobilinogen:** This test is based on the Azo-coupling reaction (the coupling of urobilinogen with Diazonium salt). The color reaction ranges in intensities of pink/purple browns.

**pH:** This test is based on the mixed pH indicator principle that will show a range of colors covering the entire urinary pH range. The color reaction ranges from yellow through greens to blue.
**Specific Gravity:** This test is based on the Cation extraction principle with the combination of Cation, Phosphoric Acid (EHPA), and pH indicator. In the presence of an indicator for ionic concentration, colors will range according to the color reaction of the pH indicator: a range from blue-green in urine with low ionic concentration through green and yellow-green in urines with greater ionic concentration.

**Blood:** This test is based on the measurement of activity of pseudoperoxidase in hemoglobin, which catalyzes the reaction of Cumene Hydroperoxide (CHP) and 3,3’,5,5’ Tetramethylbenzidine (TMBZ). The color reaction ranges from light green through green-blue with very high levels of blood often continuing to blue. Non-hemolysis will be indicated in a spotted blue-green color with the light green background.

**Ketones:** This test is based on the Legal Reaction – a color reaction indicating intensity of reaction between ketones and sodium nitroprusside in an alkaline medium. The color reaction will range from a buff-pink color indicating a negative reading to a purple color indicating a positive reading.

**Nitrite:** This test is based on the Griess Reaction and measures the conversion of nitrate (derived from the diet) to nitrite by the action of gram-negative bacteria in the urine. Nitrite in the urine reacts with Sulfanilamide in an acid medium (Diazo compound). This compound couples with Naphthyl ethylenediamine dihydrochloride (NEDA-2HCL) to produce pink coloration.

**Leukocytes:** This test measures the activity of esterase in leukocytes, where the esterase hydrolyzes TAI which can couple with MMB to create variations of pink-buff to purple coloring.

**IV. Specimen Requirements:**

**A. Specimen:**
- **Acceptable:** Fresh urine specimens collected in a clean, dry container. Volume of urine must be sufficient to cover all reagent pad areas when dipped.

- **Unacceptable:** Specimens collected in urine preservatives or contaminated with skin cleaners/antiseptics containing chlorhexidine.

**B. Specimen Storage:** Specimens should be refrigerated, if not, run within 1 hour. Specimens should be run within 4 hours of collection.

**C. Handling precautions:** Handle specimen with universal precautions.
V. Materials and Reagents:
A. Reagents and Materials Provided:

<table>
<thead>
<tr>
<th>Component</th>
<th>Storage/Content</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>PocketChem Analyzer</td>
<td>Operate on level surface temperature 10º-30ºC, Humidity 20%-80%</td>
<td>1/ea</td>
</tr>
<tr>
<td>AUTION Sticks 10TA</td>
<td>Store at room temperature (15º-30ºC), out of sunlight, humidity, and heat. Keep tightly capped when not in use. Keep desiccant strip in container, do not use after expiration date</td>
<td>100</td>
</tr>
<tr>
<td>User Manual</td>
<td></td>
<td>1/ea</td>
</tr>
<tr>
<td>Package Insert</td>
<td></td>
<td>1/ea</td>
</tr>
<tr>
<td>AC Adapter</td>
<td></td>
<td>1/ea</td>
</tr>
<tr>
<td>Check Strip Set</td>
<td></td>
<td>1/ea</td>
</tr>
<tr>
<td>Thermal Printer Paper</td>
<td></td>
<td>1/ea</td>
</tr>
</tbody>
</table>

Note: Reagent strips are for In-Vitro use. They have been determined to be non-hazardous under the guidelines issued by OSHA.

B. Materials required but not provided:
1. When reading AUTION 10TA sticks visually, a watch or timer is required.

V. Quality Control:
A. External Quality Control:
1. PocketChem UA/AUTION Sticks 10TA
   a. For best results, performance of the PocketChem UA should be confirmed by testing known negative and positive specimens or controls. Water should not be used as a negative control.
   b. These controls are intended to monitor instrument/strip reagent pad failure. Additional controls may be tested in accordance with guidelines or requirements of local, state, and/or federal regulations and accrediting organizations.
      Controls should be tested as follows:
      1. At the start of the day
      2. When opening a new bottle of strips
      3. Whenever the results are in doubt
      4. When training new instrument operators.
2. PocketChem UA Analyzer
   a. The check strip provided serves as an electronic control to confirm normal/negative readings for all analytes. The check strip is intended for troubleshooting purposes only when the instrument has been dropped, exposed to temperatures outside the normal operating ranges or when errors E001, E002, or E003 occur.
   b. When the external control or check strip measurements fail to meet the requirements for failed test, patient results should not be reported. Call Thermo Electron Point-of-Care and Rapid Diagnostics technical support at 800-637-3717, #2 if you experience any of these problems.
VII. Limitations of Procedure:
A. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method. Substances that can cause abnormal urine color such as azo dyes (Pyridium, Azo Gantrisin, Azo Gantanol, nitrofurantoin, Macrodantin, Furadantin, etc. may alter the accuracy of the overall results).

<table>
<thead>
<tr>
<th>Test</th>
<th>Substances which may cause false negative results</th>
<th>Substances which may cause false positive results</th>
<th>Other Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>-Ascorbic acid&gt; 25mg/dl -Urine with high SG</td>
<td>Hypochlorite, chlorine</td>
<td>NA</td>
</tr>
<tr>
<td>Protein</td>
<td>Urine with high SG</td>
<td>-Increased hemoglobin -Contrast medium -High molecular substances -Disinfectants, antiseptics -Detergents, skin cleaners -Alkaline urine pH&gt;8</td>
<td></td>
</tr>
<tr>
<td>Bilirubin</td>
<td>-Ascorbic acid&gt;25mg/dl -Nitrite -Indican may produce orange color</td>
<td>-Urobilinogen -Iodine metabolites</td>
<td>Unstable in sunlight</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>Formalin</td>
<td>Carbapenem</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>None</td>
<td>None</td>
<td>Alkalinity increases with specimen aging</td>
</tr>
<tr>
<td>SG</td>
<td>Alkaline urine</td>
<td>-Low pH&lt;5 -Protein &gt;300mg/dl</td>
<td></td>
</tr>
<tr>
<td>Blood</td>
<td>-Urine with elevated SG -Urine with inc. protein -Ascorbic acid&gt;25mg/dl -Capoten/Captopril</td>
<td>-Oxidizing substances -Microbial peroxidase found in UTI's</td>
<td>Urine not refrigerated within 1 hour</td>
</tr>
<tr>
<td>Ketones</td>
<td>None</td>
<td>-Highly pigmented urine -L-DOPA, PKU, Sulfa -Aldose reductive antienzymes</td>
<td></td>
</tr>
<tr>
<td>Nitrite</td>
<td>Ascorbic acid&gt;25mg/dl</td>
<td>None</td>
<td>Urine not refrigerated within 1 hour of collection</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>-Glucose&gt;500mg/dl -Protein&gt;300mg/dl -Low pH&lt;5 -Increased SG -Tetracycline in high levels -Keflex, Cephalothin -Inc axalic acid</td>
<td>Formaldehyde</td>
<td>Urine not refrigerated within 1 hour of collection</td>
</tr>
</tbody>
</table>
VIII. Testing Procedure:
A. Routine Test Procedure
   1. Prepare sample: ensure sample volume is adequate to cover all reagent pads. Mix sample well. Prepare tissue to blot excess urine.
   2. Prepare the test strip: take out only the necessary number of strips from the test strip container. Close the cap.
   3. Press <START> to turn on PocketChem analyzer. When READY screen appears the analyzer is ready for test measurement. Press <START> again to begin test measurement cycle.
   4. Dip a test strip into the sample during the sampling interval defined by the analyzer-timing buzzer.
   5. Remove excess sample.
   6. Set the test strip onto analyzer strip holder while the test strip icon is blinking.
   7. The strip holder is pulled into the analyzer automatically and the measurement begins.
   8. When measurement is complete the results are displayed and the strip holder slides out of the analyzer. Discard the used test strip.
   9. Analyzer is ready for new sample analysis. If no further samples to test, press <START> for 2-3 seconds to turn off power.
B. Procedure Notes
   Nitrite test results are optimized by using a first morning specimen or one that has incubated in the bladder for four hours or more. It is important to use fresh urine for optimal results for Bilirubin and Urobilinogen as these components are very unstable when exposed to room temperature and light. Prolonged exposure to urine at room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the Protein test area. Urine containing Glucose may decrease pH as organisms metabolize the Glucose. Bacterial growth from contaminating organisms may cause false positive Blood reactions from the peroxidases produced. In random urine specimens from females, a positive result for Leukocytes may be due to a source external to the urinary tract. Contamination of the urine specimen with skin cleaners/antiseptics containing chlorhexadine may effect Protein test results.

When measurement or printing trouble occurs, the PocketChem Analyzer displays error codes. Refer to Troubleshooting Section of Operating Manual for specific information.

IX. Reporting of Results:
A. Results with AUTION 10TA Strips are obtained in clinically mindful units directly from the color guide on the product package when reading the Strips visually. With use of PocketChem UA analyzer the reagent pads are "read" by the instrument and the results are printed.
B. When abnormal measurement result is recognized, (*) is printed before the name of the analyte. The results are given semi-quantitative ranks and concentration in units (SI or usual).
C. Record results on patient result form and record in patient chart.
X. Reference Ranges:

- Glucose…………………………………………………….. Negative
- Protein……………………………………………………… Negative
- Bilirubin……………………………………………………. Negative
- Urobilinogen……………………………………………….. 0.2 – 1mg/dl
- pH………………………………………………………….. 6.0 – 7.0
- Specific Gravity……………………………………………..1.010 – 1.025
- Blood……………………………………………………….  Negative
- Ketones…………………………………………………….. Negative
- Nitrite………………………………………………………. Negative
- Leukocytes…………………………………………………. Negative

XI. Critical Value Criteria:

All laboratory tests are subject to random error. If the test result is questionable or if clinical signs and symptoms appear inconsistent with test results, re-assay the sample or confirm the results with another method. Send to UMC Clinical Laboratory for confirmation on all questionable results. Notify physician of any confirmed critical value.

XII. Storage and Handling:

A. Store at room temperature between 15°-30°C. Do not store testing strips in direct sunlight.

B. All unused strips must remain in the original bottle. Transferance to any other container may cause strips to deteriorate and become unreactive. Do not remove desiccant packet from bottle. Remove each strip from bottle immediately before it is to be used for testing. Replace cap immediately and tightly after removing reagent strip. Do not touch the area of the reagent strip. Work areas and specimen containers should be free of detergents and any other contaminating substances.

C. Important: Protection against ambient moisture, light and heat is essential to guard against altered reagent reactivity. Discoloration or darkening or reagent areas may indicate deterioration. If this is evident or if test results are questionable or inconsistent with expected findings then the following steps are recommended:

1. Confirm that the product is within the expiration date shown on the label.
2. Check performance against known positive and negative control materials.
3. Retest with fresh product.
4. If proper result is not obtained, consult product representative.

XIII. Safety:

All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.
XIV. **Performance Improvement:**
   A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
   B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

XV. **Training/Competency Evaluations:**
   All testing personnel will be trained prior to reporting patient results. An initial competency exam of "return demonstration" will be given and repeated annually thereafter. The Charge Nurse/Nurse Manager of each Clinical Department will maintain documentation.

**References:**
Thermo Electron Corporation Point-of-Care and Rapid Diagnostics.
Texas Tech Physicians of Lubbock
Lubbock, Texas

Point-of-Care Manual

Cholestech LDX Lipids and Glucose Procedure

Date Prepared: 02/04/02

Author: Tina Anderson, MT (ASCP)

Date Effective: 03/01/02

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

Date | Signature/Title
--- | ---
06/18/08 | Dale M. Dunn MD
06/17/09 | Dale M. Dunn MD
06/16/10 | Dale M. Dunn MD
06/16/11 | Dale M. Dunn MD, MBA
06/21/12 | Dale M. Dunn MD, MBA
06/19/14 | Dale M. Dunn MD, MBA

Revised:

Risk Assessment: High

Complexity Level: Waived
I. Title: Cholestech LDX Lipids and Glucose Procedure

II. Principle:
The Cholestech LDX System combines enzymatic methodology and solid-phase technology to measure total cholesterol, HDL Cholesterol, triglycerides, and glucose.

III. Specimen Collection:
Samples used for testing can be whole blood from a finger stick (collected in a lithium heparin coated capillary tube) or vein puncture.

IV. Specimen Requirements:
The sample volume is 30–60 ml of whole blood. For clinically significant results, the subject must fast 12 hours before being tested for triglycerides and glucose.

V. Criteria for Unacceptable Specimens:
1. Hemolysis and/or tissue fluid present in the finger stick whole blood may cause poor results.

VI. Materials/Reuseants:
1. Cholestech LDX Analyzer and power supply
2. Cholestech LDX test cassettes
3. Alcohol swabs and gauze for cleaning puncture site
4. Lancets for capillary blood collection
5. Cholestech LDX capillary tubes (with lithium heparin anticoagulant)
6. Cholestech LDX capillary plungers
7. Latex gloves
8. Biohazard waste containers
9. Quality control material (as required by manufacturer)
10. Cholestech mini-pet pipette and tips or micropipetter that will deliver 35-60 ml for use with venipuncture samples and quality control material.
11. Vacuum collection tubes, needles and any tube holders if sample is to be collected by venipuncture.

VII. Quality Control:
1. Controls are analyzed in the same manner as the patient sample.
2. Controls should be tested on each new shipment of cassettes.
3. Controls should be tested on each new lot of cassettes received.
4. Controls should be tested if the user thinks cassettes may not have been stored properly.
5. Quality control should be run routinely to demonstrate that the system is performing accurately.
6. A high and low control for each analyte should be tested. Cholestech controls work well and should be used with the Cholestech LDX System. If other controls are used, then ranges will need to be set for the Cholestech LDX System.

7. If quality control fails, repeat procedure and record all controls, even the ones that are out of range.


VIII. Procedure:

1. Let the cassette sit at room temperature for 10 minutes.
2. Remove the cassette from its pouch. Do not touch the black bar or brown strip.
3. Put the cassette on a flat surface.
4. [Note: Gloves must be worn when working with blood samples.]
5. Press Run.
7. Once the self-test is complete the cassette drawer will open. The screen will read [LOAD Cassette and Press Run].
8. Place the sample into the cassette well.
9. Use Cholestech LDX capillary tube for fingerstick samples.
10. Use the Cholestech mini-pet pipette for other sample.
11. [Finger stick samples must be applied within five (5) minutes or the blood will clot.]
12. Keep the cassette flat after the sample has been applied. Place the cassette into the drawer of the analyzer at once.
13. The black bar must face the analyzer.
14. The brown stripe must be on the right.
15. Press [Run]. The drawer will close.
16. During testing, the screen will read:
   - Test Name
   - Test Running
17. Put everything that touched the blood sample or control in a biohazard waste container.
18. When test is complete, the analyzer will beep. The screen will read:
   - Test Name = ### or Test Name = ###
   - Warnings
19. Press [Data] to show more results.
20. When the results are outside the measuring range, the screen will read:
   - Test Name > ### or Test Name < ###.
21. If there is a problem with the test, a message will appear on the screen. See the Cholestech L.D.X User Manual if this happens.
22. When the drawer opens, remove the cassette.
23. Put in a biohazard waste container.
24. Leave the analyzer drawer empty when not in use.

IX. Linearity:

1. Total Cholesterol 100 – 500 mg/dl
2. HDL Cholesterol 12 – 100 mg/dl
3. Triglycerides 45 – 650 mg/dl
4. Glucose 50 – 500 mg/dl
5. If the triglycerides are > 400 mg/dl, the estimated LDL will not be calculated. If the total cholesterol, HDL cholesterol, or triglycerides result is outside the measuring range, the LDL will appear as N/A.
6. If the triglycerides are > 650, the HDL result may not be accurate and will appear as N/A.
7. [Samples with total cholesterol, HDL cholesterol, triglyceride or glucose values outside the measuring range should be sent to the UMC Clinical Laboratory for testing.]

8. The glucose test is specific for D-glucose. Other sugars that may be present in the blood do no react in the glucose test. (i.e. fructose, lactose).

9. This test/analyzer is [Not to be used on newborns.]

X. Interfering Substances:
1. Fluoride, oxalate, citrate and EDTA anticoagulants will interfere with total cholesterol, HDL cholesterol, triglyceride and glucose test and should not be used.
2. Blood collection tubes whose stoppers have been lubricated with glycerol should not be used.
3. Hand creams and soaps with glycerol may cause falsely high triglyceride results.

XI. Reporting Results:
1. Record results on the patient log sheet and the patient result form.
   a. Staple the print out to patient result form.

XII. Reference Range:
1. Total cholesterol 100 – 500 mg/dl
2. HDL cholesterol 15 – 100 mg/dl
3. Triglycerides 45 – 650 mg/dl
4. Glucose 50 – 500 mg/dl

XIII. Criteria For Handling Critical Values:
All laboratory tests are subject to random error. If the test result is questionable or if clinical signs and symptoms appear inconsistent with test results, re-assay the sample or confirm the results with another method. Send to UMC clinical laboratory for confirmation on all questionable results as well as those outside the linear range of the analyzer.

XIV. Safety:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XV. Performance Improvement:
A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.
XVI. **Review and Update Procedures and Review of Quality Control:**
   The Medical Director and/or designee review this procedure annually. The Point of Care Coordinator or designee will review and sign the QC logs monthly.

XVII. **Training and Competency Evaluation:**
   All testing personnel will be trained prior to reporting patient results by the Point of Care Coordinator. An initial competency exam of “return demonstration” will be given and repeated annually thereafter. The Nurse Manager of the Clinical Department will maintain documentation.

**References:**
Cholestech LDX Procedure Manual.
Cholestech GDX-A1C Procedure

Date Prepared: 07/14/04
Author: Karen Alderson, BSMT(ASCP), LVN
Date Effective: 07/28/04
Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

<table>
<thead>
<tr>
<th>Date</th>
<th>Signature/Title</th>
</tr>
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<tbody>
<tr>
<td>06/18/08</td>
<td>Dale M. Dunn MD</td>
</tr>
<tr>
<td>06/17/09</td>
<td>Dale M. Dunn MD</td>
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</tr>
<tr>
<td>06/19/14</td>
<td>Dale M. Dunn MD, MBA</td>
</tr>
</tbody>
</table>

Revised: ___________________________ ___________________________

Risk Assessment: High
Complexity Level: Waived
I. **Title: Cholestech GDX-A1C Procedure**

II. **Statement of Purpose:**
A. Diabetes Mellitus is a leading cause of kidney failure, blindness, and amputation in adults. It is also a major risk factor for heart disease, stroke, and birth defects, and shortens average life expectancy by up to 15 years. It is well-accepted that in patients with diabetes there is a direct between blood sugar levels and complications associated with the disease. In a number of studies, such as the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study, it was shown that a reduction in blood sugar levels significantly delays the onset and slows the progression of the most serious complications of diabetes.

B. The measurement of A1C is recommended for monitoring the long-term care of people with diabetes. The concentration of A1C within red blood cells reflects the average level of blood sugar (glucose) over the previous 2-3 months. The higher the blood sugar level, the higher A1C.

III. **Principle:**
The Cholestech GDX A1C Test is for the measurement of hemoglobin A1C (A1C). This test is indicated for monitoring the average blood glucose levels of people with diabetes as an indicator of overall blood glucose control.

IV. **Reagents/Storage:**
A. Cholestech GDX A1C Test Cartridges are intended for use with the Cholestech GDX System (Catalog No. 12-319).

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Product Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-321</td>
<td>Cholestech GDX A1C Test Cartridges, 12/package</td>
</tr>
<tr>
<td></td>
<td>includes the following:</td>
</tr>
<tr>
<td></td>
<td>● This package insert</td>
</tr>
<tr>
<td></td>
<td>● 12 Cholestech GDX A1C Test Cartridges, each cartridge containing 3 tubes</td>
</tr>
<tr>
<td></td>
<td>● 13 MicroSafe ™ Pipettes</td>
</tr>
</tbody>
</table>

NOTE: Active ingredients: M-amino-phenylboronic acid coupled to 6% beaded agarose ~100 µg.
B. Required items, available from Cholestech

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Product Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-319</td>
<td>Cholestech GDX System</td>
</tr>
<tr>
<td>11-814</td>
<td>Lancets</td>
</tr>
</tbody>
</table>

C. Storage Instructions

Cholestech GDX A\textsubscript{1}C Test Cartridges are stable until the expiration date when stored between 59º and 77ºF (15-25ºC). Do not freeze.

V. Specimen Requirements

A. Blood Collection

The Cholestech GDX A\textsubscript{1}C Test is carried out on a fingerstick blood sample.

To collect the capillary blood sample, hold the MicroSafe Pipette horizontally. Touch the tip to the blood sample. Do not squeeze. The pipette will fill automatically to the black fill line.

To expel the sample, place the tip of the MicroSafe Pipette into the liquid of the sample tube and squeeze the bulb.

B. Contents

1 Cholestech GDX Analyzer
1 Power Supply Transformer and Plug for U.S. Power Supply
1 Analyzer User Manual
1 Quick Reference Guide
1 Instructional CD-ROM
1 Warranty Card
1 10 µL Minipet Pipette
50 Pipette tips
1 Cholestech GDX Optics Check Cartridge (packaged separately)

C. The Cholestech GDX Analyzer must be stored at a temperature between 50 and 95ºF (10º-35ºC). It is important to prevent dust and dirt from getting into the Analyzer. So keep the Analyzer covered.

Make sure the Cholestech GDX Optics Check Cartridge is protected from sunlight during storage. Store the Optics Check Cartridge at a humidity of less than 60%.

VI. Specimen Collection

The Cholestech GDX A1C test is carried out on a fingerstick blood sample.

VII. Quality Control

A. A Cholestech GDX Optics Check Cartridge is supplied with the Cholestech GDX Analyzer to ensure that the Analyzer is working correctly. The Optics Check Cartridge should be run every day the Analyzer is used. If you are concerned that your test result may not be correct, also run an Optics Check Cartridge.
Cholestech GDX A1C Controls are available from Cholestech. One set of controls has normal and abnormal A1C control samples. These controls must be run:

- With each new shipment of test cartridges (even if cartridges are from the same lot previously received).
- With each new lot of test cartridges.

If the controls do not give results within the range stated on the pack, contact Cholestech Technical Service.

B. The Cholestech GDX Analyzer and A1C Test Cartridges have been manufactured to deliver and A1C result. This is calibrated to the recommendations of the Diabetes Control and Complications Trial (DCCT).

This result is traceable to NGSP (National Glycohemoglobin Standardization Program), an internationally accepted method of standardization. The DCCT was a landmark multicenter clinical study that conclusively linked elevated A1C levels to the complications associated with diabetes. The result of the test can be used by your doctor to monitor your disease. Further information on calibration can be found in the Cholestech GDX Analyzer User Manual.

VIII. Test Procedure

Cholestech GDX Analyzer has been specifically designed for use with Cholestech GDX A1C Test Cartridges. A full description of the Analyzer, together with operating instructions, can be found in the Cholestech GDX Analyzer User Manual. Analyzer has been programmed with factory set calibration. It does not need servicing.

Connect the Cholestech GDX Analyzer to the power supply using the 12-volt DC power pack. The Analyzer requires a warm-up period. During this period the Hourglass icon will be displayed. When the Cartridge icon replaces the Hourglass icon, go to Section 3.6, Step 1.

Running an A1C Test

STEP 1: Unpack a Cholestech GDX A1C Test Cartridge. Hold the cartridge by the white rim only, and place it into the Analyzer. Push it down until it clicks into place. The Analyzer will then check that the test cartridge is OK. During this time the Hourglass icon will appear on the display.

When this check is complete, a beep is heard and the light will flash at Position 1. The Analyzer will show the Identification Number icon with a test identification number. This unique identification number will be stored in the Analyzer's memory with the test result. You can access this information at a later date if required (see instructions in the Cholestech GDX Analyzer User Manual). Write down the identification number with your test result.

STEP 2: Hold the white rim of the test cartridge and rotate it clockwise through 90º to Position 1. The test cartridge will click into its new position. The first sample tube will rise from the cartridge. Remove the sample tube from the test cartridge and unscrew the cap.
Stick your finger. Hold the MicroSafe Pipette next to the blood drop on your finger, leaving the pipette in contact with the blood until the blood reaches the fill line. Do not squeeze the bulb while filling the capillary as this will lead to an overfilled MicroSafe Pipette. Do not cover the air hole before sampling is complete, as this will cause incorrect filling of the pipette.

Place the tip of the MicroSafe Pipette of blood into the liquid of the sample tube. Squeeze the bulb to release the blood. Replace the cap and mix the contents by gently turning upside down 5 times. Start the wait time by IMMEDIATELY PRESSING the round enter button. A 60-second countdown will appear on the display.

**STEP 3:** The end of the countdown is indicated by a beep. The Insert/Mix and Pour Tube icons will appear on the display. Mix the contents of the tube by turning upside 3 times. Remove the cap. Pour the entire contents into the gray funnel of the test cartridge.

**STEP 4:** The Analyzer senses the sample. No button press in necessary.

A 50-second countdown will appear on the display.

At the end of the countdown, the Hourglass icon will appear.

A beep will sound. The light will flash at Position 2 and the Rotate Cartridge icon will appear on the display.

*NOTE: Some liquid may stay in the funnel at the end of the 50-second countdown. Continue and turn the cartridge to Position 2. Wait until the liquid disappears from the funnel before adding the contents of the second tube.*

**STEP 5:** Hold the white rim of the cartridge and turn it clockwise to Position 2. The test cartridge will click into its new position and the second tube will rise from the cartridge.

- Remove the tube from the cartridge.
- Unscrew the cap.
- Pour the entire contents into the funnel of the test cartridge.
- Press the button.

A 40-second countdown will appear on the display. The liquid will gradually disappear into the test cartridge.

**STEP 6:** At the end of the countdown, a beep is heard. The light will flash at Position 3. The ? Cartridge icon will appear on the display.

Hold the white rim of the test cartridge and turn it clockwise to Position 3. The cartridge will click into its new position. The third tube will rise from the cartridge.

When prompted by the Pour Tube icon, remove the tube from the cartridge. Pour the entire contents into the funnel. Again, the Analyzer senses the liquid. The beep continues for up to 20 seconds while the Analyzer takes a reading. The final 80-second countdown will then appear on the display.
STEP 7: At the end of the countdown, the Hourglass icon will appear on the display.

**Do not turn the cartridge** until the beep sounds and the Rotate Cartridge icon appears on the display.

Do not turn the cartridge before the beep sounds.

Turn the test cartridge clockwise to Position O.

Remove it from the Analyzer.

The test cartridge can be thrown away. When the test cartridge is removed, the Analyzer displays the percentage $\text{HbA}_{1C}$ (A1C) value for the sample.

Push the enter button to clear the display.

IX. **Reporting Results**

A. Upon completion of test, results will appear in the Display Window. The number displayed is the percentage of Hemoglobin $\text{A}_{1C}$ (A1C) in the test sample.

B. Record results on the patient log sheet and patient result form.

X. **Limitations**

Understanding the Results

If your result is above 7% A1C, you should discuss these results with your doctor. This means that your day-to-day glucose levels are above recommended levels. Your doctor will tell you what you need to do to bring your daily blood glucose levels down. This may be a change of diet, increased exercise, or a different treatment.

XI. **Safety**

A. ● Do not use the test components beyond the expiration date.
   ● After completion of the test, all components should be disposed of carefully.
   ● Store the test cartridges according to the instructions on the box.

B. All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XII. **Performance Improvement:**

A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.

B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager
C. The Cholestech GDX Analyzer requires a 12-volt (±5%) DC supply regulated at greater than 250 milliamps. This is provided. There are no user-serviceable parts.

If the Cholestech GDX Analyzer is dirty, clean it carefully with a lint-free cloth dampened with aqueous solutions containing 5% hypochlorite or alcohol. Take care not to get liquid in the space for the cartridge. Do not use more aggressive chemicals such as acetone.

The Cholestech GDX Analyzer has been fully tested according to Electrical Safety Regulations (BS EN 61326:1998).

XII. Troubleshooting
A. The Cholestech GDX Analyzer has been programmed to detect any Analyzer or test problems. An error code will appear on the display if any mistakes arise during the test.

Look at the following table to see the cause of the error code and the possible correction.

<table>
<thead>
<tr>
<th>Error Code</th>
<th>Cause</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Test abandoned by the user.</td>
<td>N/A</td>
</tr>
<tr>
<td>2</td>
<td>Test cartridge is not in the Analyzer.</td>
<td>Analyzer has failed to detect a test cartridge. This may be due to an Analyzer problem, or the cartridge is damaged.</td>
</tr>
<tr>
<td>3</td>
<td>Cartridge has not been turned in time.</td>
<td>It is essential to follow the instructions without long delays between steps. The Analyzer measures time intervals between steps and will error if the time taken is too long.</td>
</tr>
<tr>
<td>4</td>
<td>The cartridge is in the wrong position.</td>
<td>The cartridge has been moved when not told to do so. It is essential to follow the instructions for use.</td>
</tr>
<tr>
<td>5</td>
<td>Too long has been taken to do the step.</td>
<td>The Analyzer measures time between steps and will error if the time taken is too long.</td>
</tr>
<tr>
<td>6</td>
<td>The sample has not been added.</td>
<td>The Analyzer measures time intervals between steps and will error if the time taken is too long. It is essential to follow the instructions for use.</td>
</tr>
<tr>
<td>7</td>
<td>Enter button has been pressed too early.</td>
<td>The analyzer measures time intervals between steps and will error if the time taken is too long or too short. It is essential to follow the instructions for use.</td>
</tr>
<tr>
<td>8</td>
<td>Internal Analyzer check is incorrect.</td>
<td>The cartridge may be damaged or dirty. To check that the Analyzer is running correctly, run the <strong>Optics Check Cartridge</strong>.</td>
</tr>
<tr>
<td>9</td>
<td>Internal Analyzer check is incorrect.</td>
<td>The cartridge may be damaged or dirty. To check that the Analyzer is running correctly, run the <strong>Optics Check Cartridge</strong>.</td>
</tr>
<tr>
<td>10</td>
<td>Internal Analyzer check is incorrect.</td>
<td>This may be due to an insufficient blood sample, or failure of the liquid to flow through the funnel. Do the test again and make sure that the pipette is filled correctly.</td>
</tr>
<tr>
<td>11</td>
<td>Internal Analyzer check is incorrect.</td>
<td>This may be due to too much blood. Do the test again and make sure that the pipette is filled correctly.</td>
</tr>
<tr>
<td>12</td>
<td>Internal Analyzer check is incorrect.</td>
<td>This may be due to an insufficient blood sample, or failure of the liquid to flow through the funnel. Do the test again and make sure that the pipette is filled correctly.</td>
</tr>
<tr>
<td>13</td>
<td>Internal Analyzer check is incorrect.</td>
<td>Do the test again and make sure that the pipette is filled correctly.</td>
</tr>
<tr>
<td>14</td>
<td>Internal Analyzer check is incorrect.</td>
<td>Do the test again.</td>
</tr>
</tbody>
</table>
B. In the event of technical difficulty or Analyzer failure, contact: Technical Assistance, Toll Free (U.S.) (800) 733-0404 or (510) 732-7200

References:
A. Cholestech package insert.
Point-of-Care Manual

Cholestech LDX-II Procedure

Date Prepared: 07/14/04

Author: Karen Alderson, MT, M (ASCP) LVN

Date Effective: 07/28/04

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

<table>
<thead>
<tr>
<th>Date</th>
<th>Signature/Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/18/08</td>
<td>Dale M. Dunn MD</td>
</tr>
<tr>
<td>06/17/09</td>
<td>Dale M. Dunn MD</td>
</tr>
<tr>
<td>06/16/10</td>
<td>Dale M. Dunn MD</td>
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<tr>
<td>06/16/11</td>
<td>Dale M. Dunn MD, MBA</td>
</tr>
<tr>
<td>06/21/12</td>
<td>Dale M. Dunn MD, MBA</td>
</tr>
<tr>
<td>06/19/14</td>
<td>Dale M. Dunn MD, MBA</td>
</tr>
</tbody>
</table>

Revised:

Risk Assessment: High

Complexity Level: Waived
I. **Title:**  Cholestech LDX-II Procedure

II. **Statement of Purpose:**
The Cholestech LDX-II allows for measurement of
- Total Cholesterol
- Total Cholesterol and HDL Cholesterol
- Total Cholesterol and Glucose
- Lipid Profile (Total Cholesterol, HDL Cholesterol, and Triglycerides)
- Total Cholesterol, HDL Cholesterol, and Glucose
- Lipid Profile and Glucose
- ALT (Alanine Aminotransferase)

These tests are intended for use as an aid in patient diagnosis and treatment.

III. **Principle:**
A. The Cholestech LDX System uses reflectance photometry (the amount of light reflected from a solid surface) to measure the amount of substances in blood. The Analyzer measures color changes of the four reagent pads. The amount of color formed is converted by the Analyzer to mg/dL and the results are shown on the Liquid Crystal Display (LCD) screen.

B. Each test cassette has two parts: the main body and the reaction bar. The main body contains a sample well where the blood sample is dispensed and a brown magnetic stripe. The magnetic stripe contains the test names, instructions to the Analyzer for running the tests on the cassette, and calibration information for converting the color reading to analyte concentration. The reaction bar holds the reagent pads which contain the chemicals for each test.

After a blood sample is placed into the sample well, it moves into the separation system where the red blood cells are separated from the plasma. The plasma is transferred to the reagent pads on the reaction bar for testing. The color of the white pad changes during the test. The more of the substance that is present, the darker the color of the pad. Depending on the test cassette being used, some pads may remain white.
IV. Reagents and Materials

- Cholestech LDX Analyzer
- Power Supply
- Optics Check Cassette
- User Manual
- Procedure Manual
- Warranty Card
- Accessory Tray
- Capillary Tubes
- Capillary Plungers
- Lancets
- MiniPet Pipette
- Pipette Tips
- Printer and Cable Assembly
- Training Video

In addition to these supplies, you may need the following materials that are not provided with your Cholestech LDX Analyzer:

- Cholestech LDX Test Cassettes
- Cholestech Level 1 and 2 Controls
- Biohazardous waste containers
- Alcohol swabs
- Gloves
- Gauze sponges
- Vacuum collection tubes, needles and tube holders if the sample is to be collected by venipuncture.

V. Special Requirements

1. Cholestech LDX Capillary tube (fingerstick)
2. MiniPet Pipette (venous blood)

VI. Specimen Collection

A. Performing a Fingerstick

IMPORTANT: A warm hand and good blood flow from the puncture site are essential in order to collect a good capillary sample.

1. The patient should sit quietly for five minutes before the blood sample is collected.
2. Put a capillary plunger into the end of a Cholestech capillary tube with the red mark. Set it aside.
3. Choose a spot on the side of one of the center fingers of either hand. To help increase blood flow, the fingers and hands should be warm to the touch. To warm the hand, you can:
   a. Wash the patient's hand with warm water, or…
   b. Apply a warm (not hot) compress to the hand for several minutes, or…
   c. Gently massage the finger from the base to the tip several times to bring the blood to the fingertip.
4. Clean the site with an alcohol swab. **Dry thoroughly with a gauze pad before pricking the finger.**
5. Firmly prick the selected site with a lancet.
6. Squeeze the finger gently to obtain a large drop of blood. Wipe away this first drop of blood, as it may contain tissue fluid.
7. Squeeze the finger gently again while holding it downward until a second large drop of blood forms. **Do not milk the finger.** The puncture should provide a free-flowing drop of blood.
8. Hold the capillary tube horizontally by the end with the plunger. Touch it to the drop of blood without touching the skin. The tube will fill by capillary action up to the black mark. Do not collect air bubbles. If it is necessary to collect another drop of blood, wipe the finger with gauze then massage again from base to tip until a large drop of blood forms.

9. Fill the capillary tube within 10 seconds.

10. Wipe off any excess blood and have the patient apply pressure to the puncture until the bleeding stops.

B. **Follow these suggestions to help you consistently perform good fingersticks:**

<table>
<thead>
<tr>
<th>Suggestion</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform a deep and firm puncture.</td>
<td>An adequate puncture is crucial to obtaining a free-flowing drop of blood.</td>
</tr>
<tr>
<td>Keep the patient's hand below the level of his or her heart.</td>
<td>This will improve the blood flow.</td>
</tr>
<tr>
<td>Hold the capillary tube at a slight descending angle to the drop of blood.</td>
<td>This will make the capillary tube fill faster.</td>
</tr>
<tr>
<td>Fill the capillary in under 10 seconds.</td>
<td>This will ensure proper mixing of blood and anticoagulant, which prevents clotting.</td>
</tr>
<tr>
<td>Dispense blood from the capillary tube in less than five minutes.</td>
<td>After five minutes, the blood will begin to clot in the capillary tube.</td>
</tr>
<tr>
<td>If blood stops flowing, wipe finger firmly with gauze.</td>
<td>You can improve blood flow by reopening the puncture.</td>
</tr>
</tbody>
</table>

**WARNING:** Squeezing the finger excessively may cause inaccurate test results.

C. **Using Your MiniPet Pipette**

*Use this procedure to apply a venous whole blood, proficiency, or control sample to the cassette. Any pipette that can deliver 35-50µL may be used.*

1. Firmly attach the pipette tip to the end of the MiniPet Pipette. Use a new tip for each sample.
2. To fill the pipette, push the plunger down as far as you can. Place the pipette tip into the sample and slowly release the plunger. Confirm that no air bubbles are in the pipette tip.
3. Place the pipette tip into the cassette sample well. Dispense the sample by pressing the plunger down. Move the pipette tip out of the sample well before releasing the plunger again.
4. Remove the pipette tip and put it into a biohazardous waste container.
IMPORTANT: if the plunger is released before the pipette tip is removed from the sample well, the sample may be drawn back into the pipette tip.

IMPORTANT: Hold the cassette horizontally at all times after applying the sample.

For additional information about proper handling of blood specimens, see the product insert for the test cassette you are using.

D. Using Venous Whole Blood for ALT Testing
   ● Collect blood into a heparin (green-top) tube.

   Note: Do not use tube with any other additives because it may cause inaccurate results.
   ● Whole blood should be used within 30 minutes. The blood sample may be taken directly from the tube after mixing.
   ● Use a 35 µL, top place whole blood into the cassette.
   ● Samples should be at room temperature before testing.
   ● Mix all samples by inverting gently 7-8 times before testing.
   ● Do not use the Cholestech capillary tubes for measuring venous whole blood.

VII. Quality Control
A. Choosing Quality Control Material
   The quality control materials (controls) sold by Cholestech are those recommended for use with the Cholestech LDX System.
   If you decide to use other controls, you will need to determine their precision and expected ranges on the Cholestech LDX System.

B. Handling Controls
   ● Read the product insert that comes with each box of controls to find out how to use and store them.
   ● Check the expiration date before using. Do not use control material past its expiration date.
   ● Mix controls well before use. Hold the top and bottom of the bottle and gently turn it upside down seven to eight times to mix.
   ● Check the control assay sheet for the correct sample setting for running controls.
   ● Verify that the lot number on the control vial and the assay sheet are the same.

C. External Quality Control
   External controls must also be used to demonstrate that the reagents and assay procedure perform properly.
   Liquid ALT Level 1 and Level 2 Controls are available from Cholestech. Controls must be tested.
   ● With each new shipment of cassettes (even if cassettes are from the same lot previously received).
   ● With each new lot of cassettes.
   ● As otherwise required by your laboratory's standard quality control procedures.
● If you are not running the Cholestech LDX under CLIA-waived status, or if your local or state regulations require more frequent testing of quality control material, then quality control must be performed in compliance with those regulations.

D. Good Laboratory Practice principles suggest that external controls must be run whenever the laboratory director has any question about test system integrity or operator technique (e.g., when reagents may have been stored or handled in a way that can degrade their performance or when operators have not performed a particular test in recent weeks).

E. If the controls do not perform as expected, repeat the test or contact Cholestech Technical Service before testing patient samples.

**The quality control results should be in range before testing patient samples.**

**Please call Cholestech Technical Service at 800-733-0404 if you have any questions about quality control.**

F. **Control Range**
   Results for Cholestech controls should be within the ranges included with the control. The expected ranges for each lot of controls are calculated using several Cholestech LDX Analyzers and test cassette lots.

G. **Results Within Control Range**
   If results for all analytes are within the expected ranges, patient samples may be tested and the results reported.

H. **External Quality Control for CLIA-Waived ALT Testing**
   External controls must also be used to demonstrate that the reagents and assay procedure perform properly.

   Liquid ALT Level 1 and 2 Controls are available from Cholestech. Controls must be tested:

   ● With each new shipment of cassettes (even if cassettes are from the same lot previously received).
   ● With each new lot of cassettes.
   ● As otherwise required by your laboratory's standard quality control procedures.
   ● If you are not running the Cholestech LDX under CLIA-Waived status, or if your local or state regulations require more frequent testing of quality control material, then quality control must be performed in compliance with those regulations.

   Good laboratory practice principles suggest that external controls must be run whenever the laboratory director has any question about test system integrity or operator technique (e.g., when reagents may have been stored or handled in a way that can degrade their performance or when operators have not performed a particular test in recent weeks).
If the controls do not perform as expected, repeat the test or contact Cholestech Technical Service (800-733-0404) if you have any questions regarding the manufacturer's instructions for quality control.

Control Range:
Results for Cholestech controls should be within the range on the assay sheet included with the control. The expected ranges for each lot of controls are calculated using several Cholestech LDX Analyzers and test cassette lots.

Results Within Control Range:
If results for all analytes are within the expected ranges, patient samples may be tested and the results reported.

I. **Results Outside the Control Range**

If results of one or both levels of control tested are outside the established ranges:

1. Verify that you have the correct assay sheet for the control being tested.
2. Check that the expiration date for the test cassette and quality control materials have not passed.
3. Verify that the lot number on the control vial and the assay sheet are the same.
4. Retest the control level that is out of range using a new sample from the same control vial. Pay careful attention to possible errors in technique.
   a. If the control is within acceptable limits, patient samples may be tested and results reported.
   b. If the control is outside the acceptable limits, test with a sample of control from a new vial.
      - If results are in range, continue testing patient samples.
      - If the control is still outside the acceptable limits, contact Cholestech Corporation Technical Service. Do not use the Analyzer for testing patient samples until the problem is solved.

VIII. **Test Procedure**
   A. **Cholestech LDX Optics Check**

A Cholestech LDX Optics Check Cassette is initially supplied with the Analyzer. It should be used to check the optical system of the Analyzer. Store the Cholestech LDX Optics Check Cassette at room temperature in the case provided. Do not touch the reaction bar or allow it to become wet, dirty or scratched. Do not use a damaged or expired Cholestech LDX Optics Check Cassette.

Run the Cholestech LDX Optics Check Cassette:

- Once each day before patient samples are tested.
- After the Cholestech LDX System has been moved or serviced.

**Optics Check Cassette Test Procedure**
Do not use a Cholestech LDX Optics Check Cassette that has become damaged or altered in any way.
1. Press the **RUN** button. After verifying the Selftest OK message, the drawer will open. This message will appear:

```
Load cassette and press RUN.
```

2. Place the Optics Check Cassette into the cassette drawer.

**IMPORTANT:** Do not place any blood sample on the cassette.

3. Press the **RUN** button again and the Analyzer will automatically perform the optics check. The words Optics Check and four numbers will appear on the screen, one for each optical channel in the Analyzer.

```
Optics Check
ch#1-ch32-ch#3-ch#4
```

4. Check to see that the numbers are within the acceptable range (80-105), which is printed on the Optics Check Cassette. Record the results in the Optics Check Log each day.

5. If the numbers are outside the printed range, this message will appear.

```
Optics Test Fail
ch#1-ch32-ch#3-ch#4
```

The analyzer will be temporarily disabled until another optics check has been run that falls within range. If necessary, call Cholestech Technical Service for assistance.

**B. Running a Test**

For more information, see the test cassette product inserts. The Quick Reference Guide gives a brief summary of the procedure.

1. If the cassettes have been refrigerated, allow them to come to room temperature at least 10 minutes) before opening.

2. Make sure the Analyzer is plugged in and has warmed up.

3. Remove the cassette from its pouch. Hold the cassette by the short sides only. **Do not touch the black bar or the brown magnetic stripe.** Place the cassette on a flat surface.

**IMPORTANT:** Gloves should be worn whenever working with samples that are potentially biohazardous.
4. Press **RUN**. The analyzer will do a self-test, and the screen will display:

   Self-test running.

   Self-test OK.

5. The cassette drawer will open, and the screen will display:

   Load cassette and press RUN.

6. Depending on the sample type, use the Cholestech LDX Capillary Tube (fingerstick) or MiniPet Pipette (venous or control material) to place sample into the test cassette sample well. (See "Performing a Fingerstick" and "Using Your MiniPet Pipette," pages 19-22, for additional information.)

   **IMPORTANT**: A fingerstick sample must be applied within five (5) minutes after collection or the blood will clot.

7. Keep the cassette level after the sample has been applied. *Immediately* place the cassette into the drawer of the Analyzer. The black reaction bar must face toward the Analyzer. The brown magnetic stripe must be on the right.

8. Press **RUN**. The drawer will close. During the test, the screen will display:

   ![Test Name(s)] Running****

9. Put everything that came into contact with the blood sample or control material into a biohazardous container.

10. When the test is complete, the Analyzer will beep, and the screen will display:

    ![Test Name(s)]=#### units/date/warnings

11. Press **DATA** to view the calculated results.

12. When the results are outside the measuring range of the test, the screen will display:

    ![Test Name] > ###

13. If there is a problem with the test, a message will appear on the screen. (See the *Troubleshooting & Maintenance* section, pages 38-43, for further instructions.)
14. When the drawer opens, remove the cassette, and put it in a biohazardous waste container. Leave the Analyzer drawer empty when not in use.

15. Record the results on the appropriate form.

16. To run another test cassette, press RUN once.

   Load cassette and press RUN.

17. Repeat step 3, and steps 6 through 15.

18. Otherwise, after four minutes a beep will sound and the screen will display:

   System timeout
   RUN to continue

   IMPORTANT: If the Run button is not pushed within 15 seconds, the drawer will close and the screen will go blank.

19. If necessary, press the DATA button to view the results from the last cassette tested.

IX. Reporting
   A. Record results on the patient log sheet and the patient result form.
      1. Staple the printout to the patient result form.

X. Limitations
   A. A fingerstick sample must be applied within five (5) minutes after collection or the blood will clot.
   B. Squeezing the finger excessively during collection may cause inaccurate test results.

XI. Maintenance/Cleaning
   No maintenance is required other than routine cleaning.
   
   ● Clean the outside of the Cholestech LDX Analyzer case with a clean, damp cloth. If necessary, a mild detergent or disinfectant (such as a 5% bleach solution) may be used. **Do not** immerse the Analyzer in water or other cleaning fluid. **Do not** use any abrasive cleaner.
   ● When necessary, clean inside the cassette drawer with a cotton swab moistened with water, a 70% isopropyl alcohol solution, a 5% bleach solution, or disinfectant. Dry with a second (unused) cotton swab.

XII. Precautions
   Analyzer Precautions and Warnings
   ● Always Press STOP. Make sure that the cassette drawer is closed and the screen is blank before unplugging the power supply.
   ● Do not remove the ROM pack while the Analyzer is plugged in.
● Do not allow any liquid, except the sample in a cassette, inside the Analyzer case. If a liquid is spilled on the Analyzer, unplug the power supply and call Cholestech Technical Service at once.
● The Analyzer drawer must be left empty when not in use. Do not store cassettes in the Analyzer. The Analyzer must be handled carefully to avoid damage when moving when moving from site to site. Carry only one Analyzer in a Cholestech LDX Carrying Case. Do not use the Cholestech LDX Carrying Case to ship the Analyzer. Do not use the Cholestech LDX Carrying Case for air travel as checked baggage. The Analyzer should be shipped in its original box.
● There are no user adjustments in the Analyzer. Do not remove the cover of the Analyzer this will void the warranty agreement.
● Do not attach any printer or computer to the Analyzer unless using the cable recommended by Cholestech.
● Keep fingers clear of the cassette drawer when it moves in or out of the Analyzer.

Testing Precautions
● Use a pipette the will deliver a 35-50µL volume for venous samples. Do not use the capillary tubes for venous blood, proficiency testing or quality control material.
● Use only heparin (green-top) tubes to collect anticoagulated blood for testing. Any other anticoagulant may not give accurate results.
● Use proper technique when collecting blood by the fingerstick method to ensure that a suitable sample is obtained.
● Collect fingerstick sample into capillary tube within 10 seconds and place in cassette within 5 minutes.
● Treat all patient samples and quality control material as if capable of transmitting infectious diseases. All containers, capillary tubes and other materials that have come in contact with blood or quality control materials must be discarded into a biohazardous waste container.
● Capillary fingerstick blood samples must be placed in the cassette within five minutes after sample collection, of the blood will clot producing inaccurate results.
● Squeezing the fingerstick puncture site excessively may cause erroneous test results due to hemolysis of dilution of the specimen with tissue fluids.

Test Cassette Precautions
● Protect the cassettes from magnetic fields that could damage the magnetic stripe (e.g., magnetic stirrers).
● Do not open the cassette pouch until ready to perform a test.
● The cassette must be placed flat in the cassette drawer.
● The Cholestech LDX may give falsely low glucose values when performed at altitudes above 5,000 feet.

XIII. Safety:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.
XIV. **Performance Improvement:**

   A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.

   B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

**References:**

Point-of-Care Manual

Hemoglobin A1C Procedure

Date Prepared: 02/04/02

Author: Tina Anderson, MT (ASCP)

Date Effective: 03/01/02

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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Revised:

Risk Assessment: High

Complexity Level: Waived
Title: Hemoglobin A<sub>1c</sub> Procedure

II. Principle/Purpose:
A. The DCA2000® Analyzer quantitatively measures the percent concentration of Hemoglobin A<sub>1c</sub>.
B. Hemoglobin A<sub>1c</sub> is a quantitative method for measuring the percent concentration of hemoglobin A1c in blood. The term glycosylated hemoglobin (A1c) refers collectively to a series of stable compounds that are formed between hemoglobin and sugars. Their concentrations are increased within erythrocytes of patients with diabetes mellitus. The level of hemoglobin A<sub>1c</sub> is proportional to the level of serum glucose over a period of two months. Thus, hemoglobin A<sub>1c</sub> is considered to be an indicator of the mean daily blood glucose concentration over the preceding two months.

The measurement of hemoglobin A1c concentration is recommended for monitoring the long-term care of persons with diabetes. The American Diabetes Association recommends measurement of hemoglobin A1c levels two to four times per year, less frequently in patients with stable control. The aim of therapy by clinicians is to maintain patient glucose levels at constant normal or near normal levels in the blood.

III. Specimen Collection:
A. Fill the capillary with whole blood.
B. Hold to capillary holder at an angle.
C. Touch only the tip of the capillary to a small drop of blood on the finger until the capillary is filled.
D. See Operating Manual for additional instructions.

IV. Specimen Requirements:
Whole Blood

V. Criteria for Unacceptable Specimens:
A. Do not run sample if the capillary is not completely filled.
B. Do not run sample if the capillary holder has air bubbles.
C. Do not run sample if more than five minutes has elapsed with the blood in the capillary holder.
D. Do not report results if the patient’s hemoglobin is less than 7g/dl.
E. Do not report results if the patient’s hemoglobin is greater than 24g/dl.
F. Do not report results if the patient has high triglycerides (the instrument will report “Error 107”).

VI. Materials/Reagents:
A. Calibration card (provided in DCA 2000® Hemoglobin A<sub>1c</sub> Reagent Kit). System must be calibrated for each new lot number of reagent cartridges.
B. DCA 2000\textsuperscript{®} Hemoglobin A\textsubscript{1}C Reagent Kit
C. Patient Sample, DCA 2000\textsuperscript{®} Hemoglobin A\textsubscript{1}C Control Kit of other control
D. Lint-free tissue
E. Clock or timer

VII. Quality Control:
A. Frequency:
   1. Run a normal and abnormal control under the following conditions:
      a. At the beginning of each week (Monday – Friday/Saturday) of use before client
         samples are tested and reported.
      b. With each new lot number of reagent kits.
      c. With each new shipment of reagents.
      d. Each time a calibration card is scanned.
      e. To train and confirm acceptability for new analysts.
      f. When results do not match the client’s clinical condition or symptoms.
   2. The manufacturer will establish the acceptable control range with each lot of
      controls purchased. If the bar code on the control card (included in the DCA 2000+
      HbA\textsubscript{1}C Control Kit) was scanned before running the control, the instrument will
      automatically indicate (via the display screen) whether the control result is within or
      out-of-limits. Otherwise the acceptable range for that lot number is on the
      manufacturer’s package insert.
   3. If control results are out-of-limits, do not proceed with specimen analysis. Check
      reagent cartridges, instrument, environmental conditions and technique. Correct
      any problems and then re-assay controls to verify that control results are with
      acceptable limits. Document all actions on the QC Log and Corrective Action
      Report form.
   4. All QC data must be stored for a minimum of two (2) years

B. Running the Controls
   1. Controls are analyzed in the same manner as the patient sample.
   2. A specially designed control bar code (that enters the control lot number, etc) is
      provided with DCA2000\textsuperscript{®} HbA\textsubscript{1}C controls.
   3. Locate the dot (on the instrument) next to the bar code track.
   4. Locate the bar code on the control card (Note: The control card is double-sided; one
      side for normal, the other side for abnormal. Make sure you are using the correct side
      of the control card for the particular DCA2000 control level in use.)
      C1=Normal
      C2=Abnormal
   5. Hold the control card so that the bar code faces right.
   6. Insert the control card into the bar code track (above dot). Hold card gently against
      the right side of the track.
   7. Quickly (within 1 second) and smoothly slide the card down past the dot.
   8. A beep sounds to signal a successful scan.
   9. If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to the
      Troubleshooting Section (section 6) of the DCA 2000 Operating Manual.
   10. Press Enter.
   11. Locate the bar code on the reagent cartridge.
   12. Hold the reagent cartridge so the bar code faces right.
   13. Insert the reagent cartridge (above dot) into bar code track.
   14. Quickly (within 1 second) and smoothly slide the reagent cartridge down past the dot.
   15. A beep sounds to signal a successful scan.
   16. If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to
   17. Open the cartridge compartment door.
   18. Hold the reagent cartridge so that the barcode faces right.
   19. Insert the reagent cartridge into the cartridge compartment until a subtle snap is
heard/felt.
   (Hint: The reagent cartridge is designed to fit only one way into the instrument. Do
not force cartridge into instrument).
20. Using a smooth, slow, continuous motion, pull flexible plastic pull-tab completely out
of reagent cartridge.
22. [Note] If “Control Out of Range” is displayed, press escape to display value of out of
range control.
23. Record the displayed result before removing the reagent cartridge.
24. Remove the reagent cartridge
   a. Open cartridge compartment door.
   b. Locate the button on the right side of the cartridge compartment. Push and hold it
down with your right hand.
   c. With your left hand, gently push the plastic tab on the cartridge to the right; this
action releases (unlocks) cartridge.
   d. Pull the reagent cartridge out of the compartment.
   e. Repeat procedure; record all controls, even the ones that are out of range.
   f. Document corrective action.

VIII. Procedure:
   A. Patient Testing:
1. All cartridges must be labeled with patient’s name before testing.
2. Never perform/collection more than one patient at a time. Complete testing prior to
collection and testing of next patient.
3. Locate the dot (on the instrument) next to the bar code track.
4. Locate the bar code on the reagent cartridge.
5. Hold the reagent cartridge so that the bar code faces right.
6. Insert the reagent cartridge (above dot) into bar code track.
7. Quickly (within 1 second) and smoothly slide the reagent cartridge down past the dot.
8. A beep sounds to signal a successful scan.
9. If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to
Troubleshooting, Section 5 of the DCA 2000 Operators Manual.
10. Open the cartridge compartment door.
11. Hold the reagent cartridge so that the bar code faces right.

12. Insert the reagent cartridge into the cartridge compartment until a subtle snap is
heard/felt. (Hint: The cartridge is designed to fit only one way into the instrument.
Do not force cartridge into instrument).
13. Using a smooth, slow, continuous motion, pull flexible plastic pull-tab completely out
of reagent cartridge.
15. Dispose of flexible plastic pull-tab.
   a. Five (5) seconds after the door is closed, a beep sounds and the assay begins.
   [Note: If you accidentally close the door before you pull the flexible pull-tab, you
have five (5) seconds to re-open the door; the display returns to “LOAD Cartridge.”
You may now pull the tab or correct existing problem(s).]
16. Record the displayed results on the patient log sheet and the patient result form
[before] removing the reagent cartridge.
17. Remove the reagent cartridge.
   a. Open cartridge compartment door.
   b. Locate the button on the right side of the cartridge compartment. Push and hold it
down with your right hand.
   c. With your left hand, gently push the plastic tab on the cartridge to the right; this
action releases (unlocks) cartridge.
   d. Pull the reagent cartridge out of the compartment. [Hint: If the displayed test
result was not recorded, use the MENU to recall up to 16 test results].
18. The displayed test result requires no further calculation. HbA1C concentrations in the following range are reported: 2.5% to 14%.

IX. **Linearity:**
The test is linear from 2.5 % to 14%.

X. **Interfering Substances:**
1. See criteria for rejection of specimen
2. Substantial amounts of fetal hemoglobin
3. Hemolytic anemia
4. Polycythemia

XI. **Reporting Results:**
1. Record results on the patient log sheets and the patient result form.
2. Staple the print out to patient result form.
3. Results preceded by a less than sign ( < ):
   a. Report as less than 2.5% HbA1C.
   b. This method does not provide for re-assay using a large sample
4. Results preceded by a greater than sign ( > ):
   a. Report the results as being more than 14% HbA1C.
   b. This method does not provide for re-assay using a diluted sample.

XII. **Reference Range:**
4.2% to 6.5%.

XIII. **Criteria for Handling Critical Values:**
All laboratory tests are subject to random error. If the test result is questionable or if clinical signs and symptoms appear inconsistent with test results, re-assay the sample or confirm the results with another method. Send to UMC Clinical Laboratory for confirmation on all questionable results as well as those outside the linear range of the analyzer.

XIV. **Safety:**
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XV. **Performance Improvement:**
A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

XVI. **Review and Update Procedures and Review of Quality Control:**
The Medical Director and/or designee review this procedure annually. The Point of Care Coordinator or designee will review and sign the QC Logs monthly.

XVII. **Training and Competency Evaluation:**
Each testing personnel will be trained prior to reporting patient results. An initial
competency exam of “return demonstration” will be given and repeated annually thereafter. The Nurse Manager of the Clinical Department will maintain documentation.

References:
Date Prepared: 07/14/04
Author: Karen Alderson, BSMT(ASCP), LVN
Date Effective: 07/21/04
Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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Revised: __________________________

Risk Assessment: High
Complexity Level: Waived
Title: Hemoglobin A\textsubscript{1C} NOW Procedure

II. Statement Of Purpose:
The Hemoglobin A\textsubscript{1C}NOW test provides quantitative measurement of the percent of glycated hemoglobin levels in capillary (fingerstick) or venous whole blood samples. The test is for professional use to monitor glycemic control in people with diabetes.

III. Statement of Principle:
Metrika has developed an enabling technology called MODM (Micro Optical Detection Method) that incorporates microelectronics, optics and dry-reagent chemistry strips within a self contained, integrated, single use monitor. An unmeasured whole blood mixture (diluted) is directly applied to the sample port, and results are displayed in numeric form on the monitor’s liquid crystal display after 8 minutes. Having no switches or buttons, the monitor self-activates upon addition of the sample.

The A\textsubscript{2}CNOW monitor utilizes both immunoassay and chemistry technology to measure HbA\textsubscript{1C} and total hemoglobin respectively. Upon the addition of a diluted blood sample, blue microparticles conjugates to anti-HbA\textsubscript{1C} antibodies migrate along reagent strips. The amount of blue microparticles captured on the strips reflects the amount of HbA\textsubscript{1C} in the sample.

For the total hemoglobin (Hb) portion of the test, the sample diluent converts Hb to met Hb. The intensity of met Hb color measured on the reagent strips is proportional to the concentration of hemoglobin in the sample. Test results are expressed as \%HbA1c.

Calibration of the A\textsubscript{1C} NOW is performed with a set of blood samples that have been value assigned by a National Glycohemoglobin Standardization Program (NGSP) certified laboratory using NGSP reference material. Total Hb calibration values for those samples are obtained with at Total Hb analyzer. The calibration of the A\textsubscript{1C} NOW test is thus traceable to the NGSP Certified Network Method.

IV. Reagents and Materials:
A. A\textsubscript{1C} NOW monitors – each monitor includes the following chemistries: antibody to HbA\textsubscript{1C} antigen conjugate that binds to the antibody and membranes.
B. Sample Dilution Kit – each Sample Dilution Kit contains the following:
   1. Capillary (1)
   2. Tube (1), containing 0.69 mL of buffered detergent solution with ferricyanide
3. Transfer Pipette (1)
4. Tube Holder (1)
C. Product insert
D. Procedure card
E. Patient result labels
F. Materials requires but not supplied
   1. Fingerstick sample: lancet or other blood finger collection device
   2. Venous sample: EDTA tube, venous collection supplies
   3. Gauze pad or cotton ball
   4. Bandage

V. Warnings and Precautions:
B. A1C NOW parts must be kept at temperatures below 120° F (49°C) during shipment. If the temperature indicator on the box flap has changed color or if you suspect this temperature has been exceeded, it is recommended that external controls be tested. Please call Metrika for more information.
C. For In-Vitro diagnostic use only.
D. Handle and dispose of all samples and pipettes following appropriate biohazard procedures.
E. The A1C NOW monitor should not be used if it is cracked or broken, or if the foil patch is damaged.
F. The Dilution Buffer contains ferricyanide in a buffered detergent solution. DO NOT INGEST. In case of contact with skin or eyes flush the area with large amounts of water.
G. Carefully read and follow the "Procedure" section to ensure proper test performance.
H. Do not reuse any portion of the test.

VI. Specimen Collection:
A. Fingerstick Procedure – have the patient wash their hands in warm water, or clean a finger with alcohol. Make sure the finger is completely dry. Perform the lancing procedure to obtain a large drop of blood (1 ml).
B. Venous Draw Procedure – obtain a blood sample by standard venipuncture technique in an EDTA tube. Mix the sample well before testing.

VII. Quality Control:
A. Before using this kit, check the temperature dot located on the box flap. If the dot has not changed color the product is okay to use. If the temperature dot has changed color this product should not be used. Call Metrika Technical Support toll free at 877-212-4968 for further information.
B. Each A1C NOW monitor performs over 25 internal chemical and electronic quality control checks, including potential hardware and software errors. The monitor has been programmed to report an error code if these quality checks are not passed.
C. If external quality control testing is desired, commercial controls may be purchased from other vendors. Please contact Metrika Customer Service for recommendations.
D. Metrika recommends that external controls be tested at the following times:
   1. Whenever laboratory or room conditions have been above 29°C if stored at room temperature.
   2. To perform training or retraining of testing personnel.
3. Whenever A1C NOW results do not match other clinical findings or symptoms.

E. Good laboratory practices include a complete quality control program. This entails proper sample collection and handling practices, ongoing training of testing personnel, on-going evaluation of control results, proper storage of test kits, etc. A permanent record of control results should be retained.

VIII. Test Procedure:

A. Always run the test with all parts of the test kit at room temperature. If the monitoring kit has been recently at high temperatures or in the refrigerator, allow all parts to come to room temperature for at least 1 hour before running the test. Leave the parts in their sealed pouches while doing this. Avoid running the test in direct sunlight on hot or cold surfaces or near sources of heat or cold.

B. Stand up the tube holder by squeezing the folded sides. Unscrew the cap of the tube and place the tube in the tube holder.

C. Collect sample by fingerstick or venous draw (see specimen collection)

D. Hold the tip of the capillary horizontally against the blood drop and allow the capillary to fill to the line with blood. The blood will stop when it reaches the line. Do not squeeze the bulb at this step. Note: a standard laboratory precision pipette may be used to transfer 10 uL from an EDTA tube into the tube, instead of the capillary.

E. Check capillary – if under filled, add more blood to fill to the line. If slightly overfilled or excess blood is present, touch tip to gauze or cotton ball to remove small amount of blood. Do not squeeze the capillary bulb while removing excess blood.

F. Drop the capillary tip first into the liquid in the tube. Add the blood to the tube by squeezing the bulb firmly. Squeeze and release the bulb two to three times to rinse out the blood and empty the capillary. All of the blood must be added to the tube.

G. Remove the cap from the tube. Squeeze the top bulb of the transfer pipette and place the open end into the liquid just slightly above the bottom of the tube. Release the bulb to fill the barrel of the transfer pipette. The barrel must be filled. Extra sample may collect in the overflow bubble. If there is not enough sample in the transfer pipette, squeeze the sample back into the tube and refill the transfer pipette as described above.

H. Hold the transfer pipette slightly above the sample well of the monitor. Add all of the sample ALL AT ONCE by squeezing the bulb firmly. Extra sample will stay in the overflow bubble. DO NOT touch the sample well with the transfer pipette.

I. After the diluted sample has been added, the window of the monitor will show “----four dashes. The window will next show how much time is left before the result will be reported. This will take 8 minutes. Do not handle the monitor after adding sample. The monitor may be picked up after the result is displayed.

J. “QC OK” will appear in the window, followed by the %HgA1C result after the countdown is over the QC OK message and the %HbA1C result will alternate back and forth. Results will continue to be displayed for about one week.

K. If any quality control checks do not pass, and error message (QC 1 to QC 99) will appear in the window instead of a number. If any Out of Range situations arise, a message (OR1 to OR6) will appear in the window. If this happens, see “troubleshooting”.

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IX. **Interpretation of Results:**
   A. Results are displayed in the display window after 8 minutes and will remain for about one week. Record the test result immediately on the patient label provided to prevent possible loss of patient date. Results are expressed as % (percent) HgA1C.

   B. Percent HbA1C results monitor glucose control over the last three months. About 50% of the HgA1c result is from the past 30 days of glucose levels; about 25% is from the past 30-60 days and about 25% is from the past 60-120 days.

   C. Depending on the test methodology used, laboratory methods show that the reference range of the HgA1C test is approximately 4.0-6.5% HgA1C and 6% to 9% in people with well to moderately controlled diabetes. Levels can be as high as 20% in people with poorly controlled diabetes.

   D. Reference range studies conducted by Metrika using the A1C NOW monitor showed the normal range to be 3.9-6.5 HgA1C in the non-diabetic population tested. Reference ranges should be determined by each laboratory to conform to the population being tested.

X. **Proficiency Testing:**
   The testing procedure for Proficiency testing should follow the same procedure as directed for patient testing.

XI. **Limitations:**
   A. This test is NOT for the screening or diagnosis of diabetes.
   B. A1C NOW is a single-use, disposable test. Do not reuse the monitor.
   C. If the patient has high levels of Hemoglobin F, Hemoglobin S, Hemoglobin C, or other hemoglobin variants, the A1C NOW may report incorrect results.
   D. Any cause of shortened red cell survival (e.g. hemolytic anemia or other hemolytic diseases, pregnancy, recent significant blood loss etc.) will reduce exposure of red cells to glucose. This results in a decrease HbA1C values. Percent HbA1C results are not reliable in patients with chronic blood loss and consequent variable erythrocyte life span.
   E. This test is designed to be run at 18°-28° C (64°-8° F) and 15-80% humidity. Using the monitor outside this temperature range will give an error code.
   F. This test is not a substitute for regular doctor visits and blood glucose monitoring.
   G. As with any laboratory procedure, a large discrepancy between clinical impression and test results usually warrants investigation.

XII. **Expected Values:**
   A. The expected normal range for % HbA1C using the A1CNow system was determined by testing blood samples from 118 presumptively non-diabetic individuals (fasting glucose levels <127 mg/dL) across three US sites. The population included 33 males and 85 females, and an age range from 19 to 76 with a mean age of 43. The mean %HbA1C result was 5.2% +/- 0.71% (1SD). The 95% confidence limits were 3.9% to 6.5%. These values are similar to those reported in the literature. Each laboratory should determine its own reference range to conform to the population being tested.
B. The expected %HbA1C valued for patients with diabetes will depend on physician discretion. The American Diabetes Association’s most recent Clinical Practice Recommendation for diabetes specifies a treatment goal of less that 7% and suggests additional action when the GbA1C level is above 8%.

XIII. Reporting Results:
Record results on the patient result form and post to patient chart.

XIV. Safety:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XV. Performance Improvement:
A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

XVI. Performance Characteristics:
A. Precision – Precision testing was done under a specialized protocol. Following the protocol, two whole blood samples, one of approximately 6% HbA1C (low) and one of approximately 9% HbA1C (high) were tested over 20 days and four funs per day, for a total of 80 assays per level. The overall imprecision (including with-day and between-day) was 2.03% CV at the low level and 3.66% CV at the high level. This performance meets the requirements of NGSP certification.
B. Accuracy – Accuracy studies were conducted with 287 diabetic and nondiabetic subjects across three US sites. Fingerstick sampling was performed on each subject for testing with the A1C NOW and venous blood was collected from each subject for comparative testing by the NGSP using a NGSP-certified method. A1C NOW results were compared to the NGSP reference results and found to meet the requirements of NGSP certification.

References:
Metrika Package Insert, Sunnyvale CA, 94085-4022.
Point-of-Care Manual

Chemstrip 2 GP Procedure

Date Prepared: 09/22/04

Author: Karen Alderson, BSMT(ASCP), LVN

Date Effective: 10/01/04

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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Revised:

Risk Assessment: High

Complexity Level: PPM
I. Title: Chemstrip 2 GP Procedure

II. Statement of Purpose:
A. The Chemstrip 2 GP urine test is a two-parameter test strip to measure glucose and protein in the urine. These measurements are useful in the evaluation of renal, urinary, and metabolic diseases.
B. Chemstrip 2 GP urine test strips are inert plastic strips to which are attached different reagent pads for determining glucose and protein in urine. The test pads are uniquely attached to the strip with a nylon mesh which holds the reagent pad in place, protects the pad, and provides for rapid and even wetting of the entire test pad. To prevent urine runover, certain of the test pads have an inert, absorbent paper located between the test pad and the strip.
C. Chemstrip 2 GP urine test strips are packaged in a vial with a tightly fitting cap which contains a drying agent. Each test strip is stable and ready for use when removed from the vial. No additional instrumentation is required.

III. Principle of Procedure:
A. Glucose: Glucose detection is based on the enzymatic glucose oxidase/peroxidase (GOD/POD) method. This method was first described by Keston in 1956 for the determination of blood glucose and applied by Comer to a test paper for glucose in urine. The glucose test of this strip is a further development of this test principle. The reaction utilizes the enzyme glucose oxidase to catalyze the formation of gluconic acid and hydrogen peroxide from the oxidation of the glucose. In turn, a second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with the chromogen Tetramethylbenzidine to form a green dye complex. A positive reaction is indicated by a color change from yellow to green.1,2

B. Protein: The detection of proteins is based on the so-called "protein error of pH indicators" (Sörensen, 1909). The indicator 3',3",5',5" –tetrachlorophenol-3,4,5,6-tetabromosulfophthalein used in this test is a more recent development. A positive reaction is indicated by a color change from yellow to light green/green.3,4,5

IV. Reagents:
A. Materials provided: 1 vial containing 100 Chemstrip© GP urine test strips. A visual comparison color scale for reading test results is printed on the vial label.

B. Material required but not provided: a timer and a clean specimen collection container. It is also recommended that commercial control products be used for quality control checks.
V. Specimen Requirements/Collection:
Specimen collection and preparation: Chemstrip© 2 GP urine test strips may be used on many freshly voided urine specimens or on urines collected under special conditions such as first-morning specimens and post-prandial urines. The urine must be collected in a clean container and should be tested as soon as possible after collection. Do not centrifuge or use preservatives. If testing cannot be performed within one hour after collection, the specimen should be refrigerated at 2-8°C immediately and returned to room temperature before testing. Mix urine thoroughly before testing. Urine should be collected in a container which will allow complete immersion of the reagent pads on the test strip.

VI. Quality Control:
Quality control for this procedure consists of following good laboratory techniques and ensuring that reagents have been properly stored and specimens handled according to instructions. The analyst should be aware of the sources of error outlined under Limitations. External Quality Control should be performed and documented with each new lot number. If the expected results are not obtained and repetition of the assay excludes errors in technique, the following steps should be taken:
1. Check the expiration date stamped on the vial label.
2. To verify that Chemstrip© 2 GP urine test strips have not been exposed to heat extremes or moisture, open a new vial of strips and retest.
3. Contact the Roche Diagnostics Technical Service Center, 1-800-428-4674, 24 hours a day, 7 days a week.

VII. Test Procedure:
Assay:
1. Briefly (no longer than 1 second) dip test strip into the urine. Ensure that the chemically impregnated pads on the test strip are totally immersed.
2. Draw the edge of the strip along rim of specimen container to remove excess urine.
3. Turn the test strip on its side and tap once on a piece of absorbent paper to remove any remaining urine, and to prevent the possible mixing of chemicals.
4. After 60 seconds, read the test by holding the strip close to the color blocks and matching carefully, ensuring that the strip is properly oriented to the color chart on the vial label.

Color changes that occur after 2 minutes from immersion are not of diagnostic value. Color changes that occur only along the edge of the test pad should be ignored. Careful removal of excess urine (steps 2 and 3) should eliminate this effect.

VIII. Results:
Results are obtained by direct visual comparison with the color scale printed on the vial label. No calculations are necessary.
IX. Reporting Results:
A. Reporting results should be recorded on the Point of Care Laboratory Result Form.
B. Performance Control Test should be performed with each new lot# and recorded on the POC QC Log Sheet.

X. Limitations:
The limitations including interfering substances for each reagent are shown below.

Glucose Test: the effect of ascorbic acid (vitamin C) retained in the urine due to ingesting vitamin tablets, antibiotics, or fruit juices has been eliminated at glucose concentrations of 100mg/dl and above so that false negative readings may only rarely occur, even at high concentrations of ascorbic acid. False-positive readings may be produced by strong oxidizing cleaning agents in the urine container.

Expected Values:
Glucose: due to the test's sensitivity, glucose should not be detectable in normal urine. Therefore, any positive reaction should be followed by further diagnostic evaluation of the patient, such as a quantitative blood glucose or a glucose tolerance test.

Protein Test: false positive results may be found:
1. In strongly basic urine (pH 9 or higher).
2. During therapy with phenazopyridine.
3. When infusions of polyvinylpyrrolidone (blood substitutes) are administered.
4. When residues of disinfectants containing quaternary ammonium groups of chlorhexidine are present in the urine container.

Expected Values:
Protein: a color change from yellow to light green/green will occur if protein is present in urine. The concentrations given on the vial label correspond favorably with the albumin concentration in urine. Pathological proteinuria will usually produce persistent values above 30mg/dL. Clinical significance of the trace result should be determined by additional testing.

XI. Troubleshooting/Precautions:
Warning: avoid contact with skin and mucous membranes; flush affected areas with copious amounts of water. Get immediate medical attention for eyes or if ingested. Exercise the normal precautions required for handling all laboratory reagents.

Storage and Stability: store at temperatures under 30ºC (86ºF). Do not freeze. Chemstrip© urine tests are stable in the original capped vial until the listed expiration date. In order to avoid exposure to moisture, the vial must be closed immediately after removal of a strip, using the original stopper which contains a drying agent.

XII. Performance Improvement:
A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

XIII. Safety:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

References:
1. Keston, A. Abstracts of papers presented at the 129th meeting of the American Chemical Society, p.31c, Dallas, April, 1956.
4. US patent No. 4,013, 416.
Point-of-Care Manual

QuickVue Influenza Test

Date Prepared: 11/03/04

Author: Tina Anderson, MT (ASCP)

Date Effective: 11/17/04

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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Revised:


Risk Assessment: High

Complexity Level: Waived
I. Title: QuickVue Influenza Test

II. Purpose:
The QuickVue Influenza Test allows for the rapid qualitative detection of influenza type A and type B antigens directly from nasal swab, nasal wash and/or nasal aspirate specimens. The test is intended for use as an aid in the rapid diagnosis of acute influenza virus infection. The test is not intended to detect influenza C antigens. Negative test results should be confirmed by cell culture.

Influenza is a highly contagious, acute viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA viruses known as influenza viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with most serious epidemics. Type B viruses produce a disease that is generally milder than that caused by type A. Type C viruses have never been associated with a large epidemic of human disease. Both A and B viruses can circulate simultaneously, but usually one type is dominant during a given session.1

III. Principle:
The QuickVue Influenza Test involves the extraction of influenza A and B viral antigens. The patient specimen is placed in the Extraction Reagent Tube, during which time the virus particles in the specimen are disrupted, exposing internal viral nucleoproteins. After extraction, the Test Strip is placed in the Extraction Reagent Tube where nucleoproteins in the specimen will react with the reagents in the Test Strip.

If the extracted specimen contains influenza antigens, a pink-to-red Test Line along with a blue procedural Control Line will appear on the Test Strip indicating a positive result. If influenza type A or type B antigens are not present, or are present at very low levels, only a blue procedural Control Line will appear.

IV. Reagents:

2-Test Sampler Kit, Catalog Number 00325
10-Test Kit, Catalog Number 00324

- Individually Packaged Reagent Trays, 2 or 19 each containing:
  - Test Strip (1): Mouse monoclonal anti-influenza A and anti-influenza B antibodies
  - Extraction Reagent Solution (1 vial with 250 μL): Salt solution
  - Extraction Tube (1): Lyophilized buffer with detergents and reducing agents
  - Disposable Dropper (1)
  - Sterile Swab (1)
  - Procedure Card (1)
Positive Influenza Type A Control Swab (1): Swab is coated with non-infectious recombinant influenza A antigen
Positive Influenza Type B Control Swab (1): Swab is coated with non-infectious recombinant influenza B antigen *(not included with 2-Test Sampler)*
Negative Control Swab (1): Swab is coated with formalin-inactivated, non-infectious *Streptococcus C* antigen *(not included with 2-Test Sampler)*
Direction Insert (1)

**25-Test Kit, Catalog Number 003617**
- Shelf box containing:
  - Individually Packaged Test Strips (25): Mouse monoclonal anti-influenza A and anti-influenza B antibodies
  - Extraction Reagent Solution: (25 vials with 250 µL each): Salt solution
  - Extraction Tubes (25): Lyophilized buffer with detergents and reducing agents
  - Disposable Droppers (25)
  - Sterile Swabs (25)
  - Positive Influenza Type A Control Swab (1): Swab is coated with non-infectious recombinant influenza A antigen
  - Negative Control Swab (1): Swab is coated with formalin-inactivated, non-infectious *Streptococcus C* antigen
  - Direction Insert (1)
  - Procedure Card (1)

**MATERIALS NOT SUPPLIED**
- Specimen containers
- Timer or watch

**V. Specimen Requirements:**
A. Nasal swab sample
B. Nasal wash or aspirate sample

**VI. Specimen Collection:**
A. Nasal swab sample:
   *For proper test performance, use the swabs supplied in the kit.*
   To collect a nasal swab sample, insert the sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab a few times against the nasal wall.
B. Nasal Wash or Aspirate Sample:
   *For Older Children and Adults:*
   With the patient's head hyper-extended, instill about 2.5 ml of sterile, normal saline into one nostril with a syringe. To collect the wash, place a clean, dry specimen container directly under the nose with slight pressure on the upper lip. Tilt the head forward and allow the fluid to run out of the nostril into the specimen container. Repeat for the other nostril and collect the fluid into the same specimen container.
C. For Younger Children:
   The child should sit in the parent's lap facing forward, with the child's back against the parent's chest. The parent should wrap one arm around the child in a manner that will restrain the child's body and arms.
Fill an aspiration bulb or bulb syringe with up to 2.5 ml of sterile, normal saline (depending on the size of the child), and instill the saline into one nostril while the head is tilted back. Release the pressure on the bulb to aspirate the specimen back into the bulb. Transfer the specimen into a clean, dry specimen container. Repeat the process for the child's other nostril and transfer the specimen into the same specimen container.

D. SAMPLE TRANSPORT AND STORAGE
Samples should be tested as soon as possible after collection. Do not use any kind of transport media to store or transport samples. Samples may be stored refrigerated (2º-8ºC), or at room temperature (15º-30ºC), in a clean, dry, closed container for up to eight hours prior to testing.

VII. Quality Control:

Built in Control Features
The QuickVue Influenza Test contains built-in procedural control features. The manufacturer's recommendation for daily control is to document these built-in procedural controls for the first sample tested each day.

The two-color result format provides a simple interpretation for positive and negative results. The appearance of a blue procedural Control Line provides several forms of positive control by demonstrating sufficient capillary flow has occurred and the functional integrity of the Test Strip was maintained. If the blue procedural Control Line does not develop at 10 minutes, the test result is considered invalid.

A built-in negative control is provided by chat cleaning of red background color, verifying that the test has been performed correctly. Within 10 minutes, the result area should be white to light pink and allow the clear interpretation of the test result. If background color appears and interferes with interpretation of the test result, the result is considered invalid. Should this occur, review the procedure and repeat the test with a new Test Strip.

External Quality Control
External controls may be also used to demonstrate that the reagents and assay procedure perform properly.

Quidel recommends that positive and negative controls be run every 25 tests, and as deemed necessary by your internal quality control procedures.

If the controls do not perform as expected, repeat the test or contact Quidel Technical Support before testing patient specimens.

External positive and negative control swabs are supplied in the kit and should be tested using the Swab Procedure with each new lot number/kit that is opened for patient testing.

VIII. Test Procedure
A. Nasal Swab Procedure
   1. Dispense all of the Extraction Reagent Solution from the Reagent Tube. Gently swirl the Extraction Tube to dissolve its contents.
2. Place the patient swab sample into the Extraction Tube. Roll the swab at least three (3) times while pressing the head against the bottom and side of the Extraction Tube.

3. Roll the swab head against the inside of the Extraction Tube as you remove it. Dispose of the used swab in accordance with your biohazard waste disposal protocol.

4. Place the Test Strip into the Extraction Tube into with the arrows on the Test Strip pointing down. Do not handle or move the Test Strip until the test is complete and ready for reading.

5. Read result at ten (10) minutes. Some positive results may appear sooner.

B. Nasal Wash/Nasal Aspirate Procedure
   1. Fill the dropper to the top/uppermost notch with nasal wash or nasal aspirate sample.
   2. Add entire contents of the dropper to the Extraction Tube. Swirl the Extraction Tube gently to dissolve its contents.
   3. Place the Test Strip into the Extraction Tube with the arrows on the Test Strip pointing down. Do not handle or move the Test Strip until the test is complete and ready for reading.
   4. Read result at ten (10) minutes. Some positive results may appear sooner.

IX. Interpretation of Results:
   A. Positive Result:
      At ten minutes, ANY shade of a pink-to-red Test Line forms AND the appearance of a blue procedural Control Line indicates a positive result for the presence of influenza A and/or B viral antigen.
   B. Negative Result:
      At ten minutes, the appearance of ONLY the blue procedural Control Line indicates the sample is negative for influenza A and B viral antigen. A negative result should be reported as a presumptive negative for the presence of influenza antigen.
   C. Invalid Result:
      If at ten minutes, the blue procedural Control Line does not appear, even if any shade of a pink-to-red Test Line appears, the result is considered invalid. If at ten minutes, the background color does not clear and it interferes with the reading of the test, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new Test Strip.

X. Reporting Results:
   A. Patient results should be reported as positive for the presence of influenza A and/or B viral antigen, or presumptive negative for the presence of influenza antigen.

XI. Limitations:
The contents of this kit are to be used for the qualitative detection of influenza A and B antigen from nasal wash and nasal aspirate specimens. This test does not differentiate between influenza types A and B.
Failure to follow the Test Procedure and Interpretations of Test Results may adversely affect test performance and/or invalidate the Test Result.

Test Results must be evaluated in conjunction with other clinical data available to the physician.

A negative test result may occur if the level of antigen in a sample is below the detection limit of the test, or from improper sample collection.

Negative test results are not intended to rule-out other non-influenza viral infections.

Interfering Substances:
Whole blood, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the QuickVue Influenza Test at the levels tested: whole blood (2%); three OTC mouthwashes (25%); three OTC throat drops (25%); three OTC nasal sprays (10%); 4-Acetamidophenol (10mg/mL); Acetylsalicylic Acid (20mg/mL); Chlorpheniramine (5mg/mL); Epinephrine (20mg/mL); Guaiacol glycercyl ether (20mg/mL); Oxymetazoline (10mg/mL); Phenylephrine 100mg/mL); and Phenylpropanolamine (20mg/mL).

XII. Troubleshooting:

WARNINGS AND PRECAUTIONS

● The QuickVue Influenza Test is for In-Vitro diagnostic use.
● Do not use the kit contents beyond the expiration date printed on outside of the box.
● Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents. Discard used material in a proper biohazard or sharps container.
● The Test Strip must remain sealed in the protective foil pouch until use.
● The Extraction Reagent Solution contains a salt solution. If the solution contacts the skin or eye, flush with copious amounts of water.
● To obtain accurate results, you must follow the Direction Insert.

Kit Storage and Stability
Store the kit at room temperature, 59º-86ºF (15º-30ºC), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

Test Procedures
Expiration Date: check expiration on each individual test package (tray or outer box) before using. Do not use any test past the expiration date on the label.

XIII. Safety:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.
XIV. Performance Improvement:

A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.

B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

Assistance:
If you have any questions regarding the use of this product, please call Quidel's Technical Support Number 800-874-1517 (toll-free) or 858-552-1100, Monday through Friday, between 7:00 a.m. and 5:00 p.m., Pacific Time. If outside the United States contact your local QUIDEL office or distributor.

References:
Thermo Biostar Acceava Strep A

Date Prepared: 09/29/04

Author: Karen Alderson, MT, M (ASCP) LVN

Date Effective: 10/01/04

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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Revised:

Risk Assessment: High

Complexity Level: Waived
I. **Title:** Thermo BioStar Acceava Strep A Laboratory Procedure

II. **Statement of Purpose:**
The Thermo BioStar Acceava Strep A Test allows for the rapid detection of Group A Streptococcus antigen directly from patient throat swab specimens. The test is intended for use as an aid in the diagnosis of Group A Streptococcus infections.

III. **Principle of Procedure:**
The Thermo BioStar Acceava Strep A test uses color immunochromatographic dipstick technology with rabbit antibodies coated on the nitrocellulose membrane. In the test procedure, a throat swab is subjected to a chemical extraction of a carbohydrate antigen unique to Group A Streptococcus. The Test Stick is then placed in the extraction mixture and the mixture migrates along the membrane. If Group A Streptococcus is present in the sample, it will form a complex with the anti-group A Streptococcus antibody conjugated color particles. The anti-group A Streptococcus capture antibody will then bind the complex and a visible blue Test Line will appear to indicate a positive result.

IV. **Reagents:**

A. **Reagents and Materials Provided:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Storage/Content</th>
<th>Quantity Provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Sticks</td>
<td>Store at Room Temperature (15º to 30ºC)</td>
<td>50</td>
</tr>
<tr>
<td>Test Tubes</td>
<td>Store at Room Temperature (15º to 30ºC)</td>
<td>50</td>
</tr>
<tr>
<td>Sterile Swabs</td>
<td>Store at Room Temperature (15º to 30ºC)</td>
<td>50</td>
</tr>
<tr>
<td>Reagent 1</td>
<td>2 M Sodium Nitrite</td>
<td>1 Bottle</td>
</tr>
<tr>
<td>Reagent 2</td>
<td>0.3 M Acetic Acid</td>
<td>1 Bottle</td>
</tr>
<tr>
<td>Positive Control</td>
<td>Nonviable Group A Streptococci, 0.1% Sodium Azide</td>
<td>1 Bottle</td>
</tr>
<tr>
<td>Negative Control</td>
<td>Nonviable Group C Streptococci, 0.1% Sodium Azide</td>
<td>1 Bottle</td>
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<tr>
<td>Package Insert</td>
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B. **Materials required, but not provided:** a timer and/or watch.
C. Storage and Stability:
Store test sticks and reagents tightly capped at 15º to 30ºC (59º to 86ºF). Do not use Test Sticks or reagents after expiration date.

V. Specimen Requirements:

<table>
<thead>
<tr>
<th>A. Specimen: Acceptable:</th>
<th>Pharyngeal swab collected with a sterile swab.</th>
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<tbody>
<tr>
<td>Unacceptable:</td>
<td>Specimens collected from other sources than the throat or nasopharynx.</td>
</tr>
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</table>

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<thead>
<tr>
<th>B. Swabs: Acceptable:</th>
<th>Sterile rayon swab supplied with kit. Swabs from other suppliers have not been validated.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unacceptable:</td>
<td>Swabs with wooden shafts, calcium alginate, or cotton tips.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. Transport Media: Acceptable:</th>
<th>Modified Stuart's liquid transport media.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unacceptable:</td>
<td>Those that contain charcoal or semi-solid transport media.</td>
</tr>
</tbody>
</table>

| D. Specimen Storage: Process swabs as soon as possible after collection. Swabs may be stored at room temperature (15º to 30ºC) or refrigerated (2º to 8ºC) for up to 24 hours. |
|-------------------------------|-------------------------------------------------------------------------------------|

| E. Culture: If a culture is also required, streak the culture plate with the swab before starting the Thermo BioStar Acceava Strep A Test procedure. |
|-------------------------------|-------------------------------------------------------------------------------------|

| F. Handling precautions: Follow your laboratory safety guidelines in the collection, handling, storage, and disposal of controls and patient specimens. |
|-------------------------------|-------------------------------------------------------------------------------------|

VI. Quality Control:

A. Internal Procedural Controls
The Thermo BioStar Acceava Strep A Test provides three levels of procedural controls with each test run. For daily quality control, Thermo Biostar recommends documenting these controls on each day of testing.

- The color of the liquid changes from pink to light yellow as you add Extraction Reagent 2 to Extraction Reagent 1. This is an internal extraction reagent control. The color change means that you mixed the extraction reagents properly. The color change also means that the reagents are functioning properly.

- The red Control Line is an internal control. The Test Stick must absorb the proper amount of sample and the Test Stick must be working properly for the red Control Line to appear. For the Test Stick to be working properly, the capillary flow must occur.

- A clear background is an internal background negative control. If no interfering substances are in the specimen and the Test Stick is working properly, the background in the Control Line area will clear. A discernible result will be seen.
B. External Quality Control Testing

- Each kit contains Positive and Negative Control material. The Controls are for external quality control testing. Use the Controls to test that the extraction reagents and the Test Sticks are working. Also use the Controls to test that you are able to correctly perform the test procedure. If you choose, you may use Group A and non Group A Streptococcus ATCC reference strains as controls. Some commercial controls may contain interfering additives. Therefore, Thermo BioStar recommends that you do not use other commercial controls with the Acceava Strep A Test.

- In addition to your laboratory's standard QC procedures, Thermo BioStar recommends that Positive and Negative controls be run every 25 tests (twice per kit), and as deemed necessary by your internal laboratory procedures.

VII. Procedure:

**Extraction Procedure**

1. Just before testing, add 3 drops of Reagent 1 (pink to light red) and 3 drops of Reagent 2 to the Test Tube. (The solution should turn light yellow).

2. Immediately put the swab into the Test Tube and thoroughly "mix and mash" by stirring and pinching swab through tube.

3. Let stand 1 minute.

4. Express as much liquid as possible from the swab by squeezing the sides of the Tube as the swab is withdrawn.

5. Discard the swab.

**Assay Procedure**

1. Remove Test Stick(s) from the container; recap the container immediately.

2. Place the Absorbent End of the Test Stick into the extracted sample.

3. Read the results at 5 minutes. A positive result may be read as soon as the blue Test Line and the red Control Line appear. Weak positive and negative results require the 5 minutes.

**Procedure Notes**

*Note:* A blue or red line that appears uneven in color density is considered a valid result. In cases of moderate or high positive specimens, some blue color behind the Test Line may be seen; as long as the Test Line and Control Line are visible, the results are valid.

VIII. Reporting and Interpreting Results:

**Positive Result:** A blue test and a red Control Line is a positive result for the detection of Group A Streptococcus antigen. Note that the blue line can be any shade of color.
**Negative Result:** A red Control Line but no blue Test Line is a presumptive negative result.

**Invalid Result:** If no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. If this occurs, repeat the test on a new Test Stick or contact Thermo BioStar Technical Support at 800-637-3717.

**Expected Results**
Approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci. Streptococcal pharyngitis displays a seasonal variation and is most prevalent during winter and early spring. The highest incidence of this disease is found in crowded populations such as military bases and in school-age children.

**V. Limitations:**
- The Thermo BioStar Acceava Strep A Test has been categorized as CLIA waived only for the application of qualitative detection of Group A Streptococcal Antigen from throat swabs. The application for the confirmation of presumptive Group A Streptococcal colonies recovered from culture is not waived.

- The results obtained with this kit yield data that must be used only as an adjunct to other information available to the physician. The Acceava Strep A Test is a qualitative test for the detection of Group A Streptococcal antigen. This test does not differentiate between viable and nonviable Group Streptococci.

- The Thermo BioStar Acceava Strep A Test should be used only with throat swabs, or other colonies taken directly from a plate. The use of swab specimens taken from the other sites or the use of other samples such as saliva, sputum or urine has not been established. The quality of the test depends on the quality of the sample; proper throat swab specimens must be obtained.

- This test does not differentiate between carriers and acute infection. Pharyngitis may be caused by organisms other than Group Streptococcus.

- A negative result may be obtained if the specimen is inadequate or antigen concentration is below the sensitivity of the test. A negative Thermo BioStar Acceava Strep A Test shall be followed up with testing using the culture method.

**Cross Reactivity**
The following organisms tested at levels of approximately $1 \times 10^8$ organisms/test were all found to be negative when tested with the Acceava Strep A Test.

<table>
<thead>
<tr>
<th>Streptococcus Group B</th>
<th>Cornybacterium diphtheria</th>
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<tbody>
<tr>
<td>Streptococcus Group C</td>
<td>Serratia marcescens</td>
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<tr>
<td>Streptococcus Group F</td>
<td>Candida albicans</td>
</tr>
<tr>
<td>Streptococcus Group G</td>
<td>Klebsiella pneumoniae</td>
</tr>
<tr>
<td>Streptococcus pneumoniae</td>
<td>Pseudomonas aeruginosa</td>
</tr>
</tbody>
</table>
X. **Troubleshooting:**  
**Remedial Actions**  
- If the red Control Line does not appear, the test may be invalid. If the background does not clear and interferes with the test result, the test may be invalid. Call Thermo BioStar's Technical Support at 800-637-3717 if you experience either of these problems.

XI. **Safety:**  
- Thermo BioStar Acceava Strep A is intended for *in-vitro* diagnostic use.  
- **Reagent 2 contains an acid.** If the solution comes in contact with the skin or eyes, flush with large volumes of water.  
- The Positive and Negative Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. Large quantities of water must be used to flush discarded control material down a sink.

All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XII. **Performance Improvement:**  
A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.  
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

XII. **Performance Characteristics:**  
- Clinical Evaluation

In a multi-center evaluation, a total of 639 throat swabs were collected from patients presenting with pharyngitis. Each swab was inoculated to a sheep blood agar plate, then tested by the Acceava Strep A Test. Plates were incubated for 18-24 hours at 35º-37ºC at 5-10% CO₂ with a Bacitracin disk. Presumptive GAS colonies were confirmed with commercially available Strep A testing kits.
Of the 639 total specimens, 464 were found to be negative by culture and 454 were also negative by the Acceava Strep A Test, for a specificity of 97.8%. Of the 175 specimens found to be positive by culture, 168 were also positive by the Acceava Strep A Test, for a sensitivity of 96.0%. The 95% confidence intervals were calculated to be 96.6-99% for specificity and 94.4-97.6% for sensitivity. Overall agreement between culture and the Acceava Strep A Test was 97.3% (622/639). The results are summarized below:

<table>
<thead>
<tr>
<th>Culture Classification</th>
<th>Acceava/Culture</th>
<th>% Correct</th>
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</thead>
<tbody>
<tr>
<td>Negative (Specificity)</td>
<td>454/464</td>
<td>97.8%</td>
</tr>
<tr>
<td>1+ (less than or + 10 colonies)</td>
<td>3/6</td>
<td>50.0%</td>
</tr>
<tr>
<td>2+ (11-50 colonies)</td>
<td>9/13</td>
<td>69.2%</td>
</tr>
<tr>
<td>3+ (&gt;50 colonies)</td>
<td>44/44</td>
<td>100.0%</td>
</tr>
<tr>
<td>4+ (predominant growth)</td>
<td>112/112</td>
<td>100.0%</td>
</tr>
<tr>
<td>Total Positive (Sensitivity)</td>
<td>168/175</td>
<td>96.0%</td>
</tr>
<tr>
<td>Total (Overall Agreement)</td>
<td>622/639</td>
<td>97.3%</td>
</tr>
</tbody>
</table>

In addition, the Acceava Strep A Test was used to confirm the identification of Group A streptococcus on blood agar plates. As a culture confirmation test, the Acceava Strep A Test was 100% sensitive (62/62) and 100% specific (39/39).

- **POL Studies**

An evaluation of the Acceava Strep A test was conducted at three physicians offices where testing was performed by personnel with diverse educational backgrounds. Each site tested the randomly coded panel consisting of negative (6), low positive (3) and moderate positive (3) specimens for three days. The results obtained had >99% agreement (107/108) with the expected results.

**References:**


3. CDC, Biosafety in Microbiological and Biomedical Laboratories, 2nd Ed., HHS Publication No. 8808395, 4-6, 1988.


7. Thermo BioStar Acceava STREP A Test Package Insert, 10/01 (05118.09)
Texas Tech Physicians of Lubbock
Lubbock, Texas

Point-of-Care Manual

Binax NOW* RSV Test

Date Prepared: 08/16/05

Author: Karen Alderson BSMT, M(ASCP), LVN

Date Effective: 08/16/05

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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<td>Dale M. Dunn MD, MBA</td>
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Revised:

Risk Assessment: High

Complexity Level: Waived
I. Title: Binax NOW* RSV Test

II. Purpose:
The BinaxNOW RSV Test is a rapid immunochromatographic assay for the qualitative detection of respiratory syncytial virus (RSV) fusion protein antigen in nasal wash and nasopharyngeal swab specimens from symptomatic patients. This test is intended for in vitro diagnostic use to aid in the diagnosis of respiratory syncytial virus infections in neonatal and pediatric patients under the age of 5 years. It is recommended that negative results be confirmed by cell culture.

RSV is a common cause of upper and lower respiratory tract infections in the major cause of bronchiolitis and pneumonia in infants and children. Infections and outbreaks due to RSV typically occur yearly in the fall, winter and spring. While RSV can cause significant respiratory illness in older children and adults, the disease tends to be milder in these populations than in infants and young children.

Rapid identification and diagnosis of RSV has become more important due to the availability of effective antimicrobial therapy. Rapid identification can lead to reduced hospital stays, reduction in antimicrobial use and reduction in the cost of hospital care.

The BinaxNOW RSV Test provides a simple, rapid method for the diagnosis of RSV using nasal wash and nasopharyngeal swab specimens. The easy-to-use format and rapid results allow for its use in “STAT” testing where it can provide invaluable information to assist with treatment and hospitalization decisions.

III. Principle:
The Binax NOW RSV Test is an immunochromatographic membrane assay used to detect RSV fusion protein antigen in nasal wash and nasopharyngeal swab specimens. Anti-RSV antibody, the Sample Line, is adsorbed onto nitrocellulose membrane. Control antibody is adsorbed onto the same membrane as a second stripe. Both anti-RSV and control antibodies are conjugated to a visualizing particles that are dried onto an inert fibrous support. The resulting conjugate pad and the striped membrane are combined to construct the test strip. This test strip is mounted on the right side of a cardboard, book-shaped hinged test device.

Swab samples (controls and patients) require a preparation step, in which the sample is eluted off the swab into an appropriate solution. Nasal wash samples do not require any preparation.
To perform the test, the sample to be tested is added to the white pad at the top of the testing strip, and the test device is closed. RSV antigen present in the sample reacts to bind anti-RSV conjugated antibody. The resulting antigen-conjugate complexes are captured by immobilized anti-RSV antibody, forming the Sample Line. The Control Line is blue in a device that has not been tested.

Test results are interpreted by the presence or absence of visually detectable pink-to-purple colored lines. A positive test, read at 15 minutes, will include the detection of both a Sample line and a Control Line. A negative test result, read at 15 minutes, will produce only a Control Line, indicating that RSV antigen was not detected in the sample. Failure of the Control Line to appear, or the Control Line remaining blue, indicates an invalid assay, whether the Sample Line is present or not.

IV. Reagents:
Test Devices: A membrane coated with mouse antibody specific for RSV antigen and with control line antibody conjugates in a hinged test device. The membrane of an untested device contains a blue line oat the control line area.
Transfer Pipettes: fixed volume (100 ml) transfer pipettes used to transfer sample to the test devices. Use only pipettes provided by Binax or a calibrated pipette capable of delivering 100 ml sample volume.
Positive Control Swab: Inactivated RSV dried onto swab
Negative Control Swab: Inactivated Streptococcus Group A dried onto a swab
Elution Solution Vials for Control Swabs: Vials containing a fixed volume (0.5ml) of elution solution used to prepare the Control Swabs. Do not use other elution solutions with the Binax Now test.

Materials Not Provided:
Clock, Timer or stopwatch, nasal wash collection containers, nasopharyngeal swabs, transport media

V. Specimen Requirements:
A. Nasopharyngeal Swabs
B. Nasal Washes

VI. Specimen Collection:
A. Nasopharyngeal Swab Sample:
Polyester, rayon, foam and cotton nasopharyngeal swabs, all with flexible shafts, have been evaluated and found to be acceptable for use in the NOW* test. Add swab specimens to the 0.5 – 3.0 ml of a suitable liquid transport system within one hour of collection. If immediate testing is not possible, eluted liquid swab samples can be stored at room temperature for up to 4 hours or at 2 – 8 degrees C for up to 48 hours, before testing. Allow samples to warm to room temperature and swirl gently before testing.
B. Nasal Washes:
Collect wash samples in standard collection cups. Use procedures appropriate for the age of the patient. If immediate testing is not possible, washes can be stored at room temperature for up to 4 hours or at 2 – 9 degrees C for up to 24 hours, before testing. Allow samples to warm to room temperature and swirl gently before testing.

Wash samples can be placed in up to 3 ml of a suitable liquid transport system prior to testing in the NOW* test. Use of transport media will result in dilution of
wash samples. This dilution may lower the overall test sensitivity.

VII. Quality Control:

Daily Quality Control:
The NOW* RSV test has built-in procedural controls. For daily quality control, Binax suggests that you record these controls for each test run.

Procedural Controls:
A. An untested device has a blue line at the “Control” position. If the test flows and the reagents work, this blue line will always turn pink in a tested device.
B. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 15 minutes. Background color should not hinder reading of the test

Positive and negative controls:
NOW* test kits contain Positive and Negative Control Swabs. These swabs will monitor for substantial reagent failure. The Positive Control will not ensure precision at the assay cut-off. Test these swabs once with each new test kit opened.

VIII. Test Procedure:
A. Remove device from the pouch just prior to testing and lay flat on a work bench.
B. Fill pipette by firmly squeezing the top bulb and placing pipette tip into liquid sample. Release bulb while tip is still in sample. This will pull liquid into the pipette. Make sure there are no air spaces in the lower part of the pipette.
C. See arrow on test device to find white sample pad. Slowly add entire contents (100 ml) of pipette to the middle of this pad by squeezing the top bulb.
D. Immediately peel off adhesive liner from the test device. Close and securely seal the device. Read result in window 15 minutes after closing the device. Results read before or after 15 minutes may be inaccurate.

IX. Interpretation of Results:
A. Positive Result: For a Positive Sample, the blue control line turns to a pink-to-purple color. Second pink-to-purple sample line appears above it.
B. Negative Result: For a negative sample, the blue control line in the lower half of the window turns a pink-to-purple color. No other line appears.
C. Invalid Result: A test is invalid if the control line remains blue or is not present at all. Repeat invalid tests with a new test device. Call Binax Technical Service if the problem persists.

US: 1-800-257-9525

X. Reporting Results:
A. Positive Result: Positive for RSV antigen. A positive result may occur in the absence of viable virus.
B. Negative Result: Negative for RSV antigen. Infection due to RSV cannot be ruled out. The antigen in the sample may be below the detection limit of the test. Binax suggests culture of negative samples.
XI. **Limitations:**

The Binax NOW* RSV test detects both viable and non-viable RSV. Test performance depends on antigen load in the specimen and may not correlate with cell culture performed on the same specimen.

Inadequate specimen collection or low levels of virus shedding may result in suboptimal performance and may yield false negative results.

A negative test does not exclude infection with RSV nor is it intended to rule out other microbial-caused respiratory infections. Therefore, the results obtained with the NOW* RSV test should be used in conjunction with clinical findings to make an accurate diagnosis.

Binax test performance has not been evaluated in patients who have been treated with palivizumab. However, an analytical study has demonstrated that palivizumab interferes with the ability of the Binax NOW* test to detect RSV.

The potential for interference from anti-microbials and interferon has not been established. Monoclonal antibodies may not detect all antigenic variants or new strains of RSV.

XII. **Troubleshooting/Warnings/Precautions:**

A. The Binax NOW* RSV test is for In-Vitro diagnostic use only  
B. Do not use the kit contents beyond the expiration date.  
C. The testing device must remain sealed in the protective foil pouch until use.  
D. Store the kit at room temperature (59-86 degrees F, 15 – 30 degrees C). The Binax NOW* RSV test kit and reagents are stable until the expiration dates marked on their outer packaging and containers.  
E. Do not mix components from different kit lots  
F. The white sample pad at the top of the test strip contains reagents that extract the target antigen from the virus. To ensure optimum performance, add the sample SLOWLY to the MIDDLE of this pad such that all of the sample volume absorbs into the pad.  
G. Invalid results can occur when an insufficient volume of specimen is added to the test device. Make sure to deliver a complete volume.  
H. If the pipette becomes clogs when drawing specimen into the transfer pipette, expel the specimen back into the container by squeezing the top bulb and redraw the specimen into the pipette.  
I. Use Universal Precautions in the collection, handling, storage and disposal of patient samples and used kit contents. Discard used material in a proper biohazard or sharps container.

XIII. **Safety:**

All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention for transmission of blood /body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.
XIV. **Performance Improvement:**
   A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends
   B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits with corrective action, expired kits) will be submitted to the Nurse Manager.

XV. **Assistance:**
   If you have any questions regarding the use of this product, please call Binax NOW* RSV Technical Support ph# 1-800-257-9525 or fax 207-730-5710.

XVI. **References:**
Clearview Monospot Test

**Date Prepared:** 04/21/2010

**Author:** Karen Spees BSMT, M(ASCP), LVN

**Date Effective:** 04/21/2010

**Approved by:** Dale M. Dunn MD, MBA  
Chief Medical Officer

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**Revised:**

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**Distribution:** 04/21/2010  Electronic

**Risk Assessment:** High

**Complexity Level:** Waived
I. TITLE: CLEARVIEW MONOSPOT

II. PURPOSE:
The Clearview Monospot test is a rapid chromatographic immunoassay for the qualitative
detection of Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma to
aid in the diagnosis of infectious Mononucleosis.

III. PRINCIPLE:
Bovine erythrocyte extracted antigen is coated on the test line region of a cassette. The sample
reacts with the bovine erythrocyte extracted antigen coated particles that have been applied to the
label pad. This mixture migrates chromatographically along the length of the test strip and
interacts with the coated bovine erythrocyte extracted antigen. If the sample contains IM
antibodies, a colored line will appear in the test line region indicating a positive result. If the
sample does not contain IM heterophile antibodies, a colored line will not appear in this region
indicating a negative result. To serve as a procedural control, a colored line will always appear at
the control line region, indication that the proper volume of specimen has been added an
membrane wicking has occurred.

IV. SPECIMEN REQUIREMENTS:
A. The Clearview MONO test can be performed using whole blood (from venipuncture or
fingerstick), serum or plasma. The whole blood samples may be collected in sodium or potassium
heparin, sodium or potassium EDTA, sodium or potassium citrate and sodium oxalate following
standard laboratory procedures.

B. Testing should ideally be performed immediately after the sample has been collected. Do not
leave the sample at room temperature for prolonged periods. Whole blood collected by
venipuncture should be stored 2-8 C for up to 3 days. Bring samples to room temperature prior to
testing.

V. MATERIALS and REAGENTS:
Test Cassette
Disposable pipettes
Disposable heparinized capillary tubes and dispensing bulbs
Positive control (1 mL; Diluted human plasma containing 0.09% IM heterophile antibodies,
0.09% sodium azide)
Negative control (1 mL; Diluted human plasma, 0.09% sodium azide
Sample Buffer
Directional Insert
Sample container (for venipuncture whole blood)
Lancet (for fingerstick whole blood only)
Centrifuge (for serum or plasma only)
Timer
VI. QUALITY CONTROL:
A. Internal Quality Control: internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.
B. External Quality Control: quality control requirements must be performed in accordance with local, state and federal regulations or accreditation requirements. Optimally, Inverness Medical recommends that positive and negative external controls be run with each new lot and with each new untrained operator. External positive and negative controls are not recommended if they have not been validated with this product.

VII: PROCEDURE:
A. Directions for use:
1. Allow the test cassette, sample, buffer and controls to reach room temperature (15-30 C) before testing.
2. Remove the test cassette from the foil pouch and use it as soon as possible. For best results, perform the test immediately after opening the pouch.
3. Place test cassette on a clean and level surface.
4. For whole blood (Venipuncture) samples: hold the pipette upright and add 2 drops of whole blood (about 50 ul) to the sample well (S) of the test cassette. Then add 1 drop of the sample buffer to the sample well (S). Start the timer.
5. For whole blood (Fingerstick) samples: add one capillary tube of blood (about 50 ul) to the sample well (S) of the test cassette. Then add 1 drop of sample buffer to the sample well.
6. For Serum or Plasma samples: hold the pipette upright and add 1 drop of serum of plasma (about 25 ul) to the sample well (S) of the test cassette. Then ad 1 drop of sample buffer to the well.
7. Wait for the red line(s) to appear. The result should be read at 5 minutes. The background should be clear before the result is read. Do not read the result after 10 min.
B. Interpretation of results:
1. Positive: Two distinct red lines appear. One line should be in the control line region (C) and another line should be in the test line region (T). A positive result means that IM heterophile antibodies were detected in the sample.
2. Negative: One red line appears in the control line region (C). No apparent red or pink line appears in the test line region (T). A negative result means that IM heterophile antibodies were not found in the sample or are below the detection limit of the test.
3. Invalid: No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test cassette. If the result is still invalid, stop using the test kit and contact Inverness Medical Technical Support at (877) 441-7440.

VIII: STORAGE AND HANDLING
The kit can be stored at room temperature or refrigerated (2-30C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. Do not freeze. Does not use beyond the expiration date.
IX. LIMITATIONS:

A. The Clearview MONO test is for *in vitro* diagnostic use only. The test should be used for the detection of IM heterophile antibodies in whole blood, serum or plasma samples only. Neither the quantitative value nor the rate of increase in Mononucleosis antibody concentration can be determined by this qualitative test.

B. The Clearview MONO test will only indicate the presence of IM heterophile antibodies in the sample and should not be used as the sole criteria for the diagnosis of Mononucleosis infection.

C. Grossly hemolysed samples will yield invalid results.

D. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

E. **This assay has not been established for patients less than 18 years of age.** A heterophile antibody response is observed in approximately 80-90% of adults and children with EBV-caused IM.

X. SAFETY:

All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precaution (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XI. PERFORMANCE IMPROVEMENT:

D. A Technical Supervisor/Director of Nursing or designee will review the QC and maintenance records on a regular basis, checking for completion of records and QC trends.

E. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

XII. TRAINING/COMPETENCY EVALUATION:

Each testing personnel will be trained prior to reporting patient results. An initial competency exam of “return demonstration” will be given and repeated annually thereafter. The Nurse Manager of each clinical department will maintain documentation.

XIII. REFERENCES:

Inverness Medical Innovations: Clearview MONO package insert 2008
Point-of-Care Manual

Clinitek Microalbumin Test

Date prepared: 7/16/03

Author: Karen Alderson M (ASCP) LVN

Date Effective: 07/16/03

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

Date                Signature/Title
06/17/09         Dale M. Dunn MD
06/16/10         Dale M. Dunn MD
06/16/11         Dale M. Dunn MD, MBA
06/21/12         Dale M. Dunn MD, MBA
06/19/14         Dale M. Dunn MD, MBA

Revised:

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Distribution:
07/13/06 Electronic

Risk Assessment: HIGH

Complexity Level: WAIVED
I. TITLE: CLINITEK MICROALBUMIN PROCEDURE

II. PURPOSE:
Microalbumin reagent strips contain reagent areas that test for albumin and creatinine in urine. An albumin/creatinine ratio is also determined, which allows for the use of single-void specimens. This test can be used in screening samples for microalbumin; positive results should be confirmed with quantitative methods for albumin. Test results may aid clinicians in the detection of patients at risk of developing kidney damage. Microalbuminuria has been reported to be an early predictor of the development of glomerular damage and the absence of overt nephropathy. Patients with diabetes and hypertension are the primary risk groups.

III. PRINCIPLE:

Albumin: This test is based on dye binding using a high affinity sulfonephthalein dye. At a constant pH, the development of any blue color is due to the presence of albumin. The resulting color ranges from pale green to aqua blue.

Creatine: This test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzine dihydroperoxide and 3,3',5,5'-tetramethylbenzdine. The resulting color ranges from orange through green to blue.

III. SPECIMEN REQUIREMENTS:
A. Collect urine in a clean container and test the specimen as soon as possible. Boric acid at a concentration on 1.0 g/L is the only urine preservative that is recommended. If testing can not be done within 2 hours after voiding, refrigerate the specimen immediately and let it return to room temperature before testing. Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation with resultant loss of albumin. Specimens may be stored at 0 – 8 degrees Celsius for one week or at –20 degrees Celsius for one month without significant effect on results with this test.
B. Any single-void urine specimen, when evaluated in conjunction with the albumin to creatinine ratio, can be used to discriminate between normal and abnormal levels of microalbuminuria.
C. First morning specimens are recommended. Urinary albumin fluctuates day to day; therefore, testing three urine samples over a three to six month period may increase the predictive value, where two positive samples are predictive of incipient nephropathy. Twenty-four our or timed collections may also be used with this test to determine the albumin excretion rate.

V. MATERIALS AND REAGENTS:
A. Clinitek microalbumin reagent strips are for in vitro use. They have been determined to be nonhazardous under the guidelines issued by OSHA in 29 CFR 1910.1200 (d).
B. **Albumin** = 1.9% w/w bis (3’3’’-diiodo-4’4’’-dihydroxy-5’5’’- dinitrophenyl)-3,4,5,6-tetrabromosulfonephthalein; 94.2% w/w buffer; 3.9% w/w nonreactive ingredients.

C. **Creatinine** = 2.5% w/w copper sulfate; 4.5% w/w diisopropylbenidine; 56.4% w/w buffer; 34.6% w/w nonreactive ingredients.

VI. **QUALITY CONTROL:**

A. For best results, confirm performance of reagent strips at the start of each day and whenever a new bottle is first opened, by testing with commercially available negative and positive controls that include values for microalbumin and creatinine. Each laboratory should establish its own goals for adequate standards of performance and should question handling and testing procedures if these standards are not met.

VII. **LIMITATIONS OF PROCEDURE:**

A. The presence of hemoglobin or myoglobin (>5 mg/dl) or a visibly bloody urine) may cause falsely elevated results with both the albumin and creatinine tests. Contamination of the urine specimen with soaps, detergents, antiseptics, or skin cleansers, or the use of urine preservatives other than boric acid (1.0 g/L) may also affect test results. The presence of cimetidine (Tagamet) may cause falsely elevated results with the creatinine test.

B. Any substances that cause abnormal urine color may affect the readability of the reagent areas on the strips. The color development on the reagent pad may be masked, or a color reaction may be produced on the pad that could be interpreted as a false positive.

VIII. **TESTING PROCEDURE:**

All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become unreactive. Remove each strip from the bottle immediately before it is to be used for testing. Replace cap immediately and tightly after removing reagent strip. Do not touch test areas of the reagent strip. Work areas and specimen containers should be free of detergents and other contaminating substances.

A. Collect a fresh urine specimen in a clean dry container.
B. Remove one strip from bottle and replace the cap tightly.
C. Dip the test pads into the urine, making sure both pads are wetted. Do not dip the colored bands near the handle.
D. Immediately remove the strip, dragging the edge of the strip against the rim of the urine container to remove excess urine.
E. Press the START key on the CLINITEK 50 at the same time as the strip is removed from the urine.
F. Blot the strip by touching the edge only to a paper towel.
G. Place the reagent strip, with the reagent pads facing up, onto the instrument’s test/feed table. Slide the strip along the table until it touches the end of the table.
H. The table is automatically pulled into the instrument, where the strip is identified and read. Results are displayed or printed as soon as they are available.
I. Record the results you obtain, then discard the strip into a suitable trash container.
J. Wipe the test table with a damp, lint-free tissue as often as needed to prevent urine from building up.

IX. REPORTING OF RESULTS:

A. Record results on patient result form.
B. Staple the printout to patient result form.

X. REFERENCE RANGES:

A. **Albumin**: Albumin is normally present in urine at concentrations of less than 20 mg/mL. Microalbuminuria is indicated with results of 20-200 mg/mL. Results of >200 mg/mL indicate clinical albuminuria. These levels have been found to be predictive of albumin excretion rates of 30-300 mg/24 hours, respectively. Urinary albumin excretions can be temporarily elevated by exercise, urinary tract infections and acute illness with fever.

B. **Creatinine**: Creatinine is normally present in urine at concentrations of 10-300 mg/dL (0.9-26.5 mmol/L).

C. **Albumin-to-Creatinine Ratio**: Albumin is normally present in urine at concentrations of less than 30 mg albumin/g creatinine (3.4 mg albumin/mmol creatinine). Microalbuminuria is indicated at a ratio result of 30-300 mg/g (3.4-33.9 mg/mmol = abnormal) and clinical albuminuria at a ratio result of >300 mg/g (>33.9 mg/mmol – high abnormal).

XI. CRITICAL VALUE CRITERIA

All laboratory tests are subject to random error. If the test result is questionable or if clinical signs and symptoms appear inconsistent with test results, re-assay the sample or confirm the results with another method. Send to UMC Clinical Laboratory for confirmation on all questionable results as well as those outside the linear range of the analyzer. Notify physician of any confirmed critical value.

XII. SAFETY

All products or objects that come into contact with human blood, even after cleaning, should be handled as if capable of transmitting viral/bacterial diseases. The user should follow the recommendations for prevention of blood-borne transmissible diseases in healthcare settings, as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XIII. STORAGE AND HANDLING:

A. Store at room temperature between 15-30 degrees Celsius (59-86 degrees). Do not use product after expiration date. Do not store the bottle in direct sunlight.
B. All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become unreactive. Do not remove desiccant packet from bottle. Remove each strip from bottle immediately before it is to be used for testing. Replace cap immediately and tightly after removing reagent strip. Do not touch
the area of the reagent strip. Work areas and specimen containers should be free of detergents and any other contaminating substances. Dip test areas in urine completely, but briefly, to avoid dissolving out the reagents.

C. IMPORTANT: PROTECTION AGAINST AMBIENT MOISTURE, LIGHT AND HEAT IS ESSENTIAL TO GUARD AGAINST ALTERED REAGENT REACTIVITY. Discoloration or darkening of reagent areas may indicate deterioration. If this is evident or if test results are questionable or inconsistent with expected findings, the following steps are recommended
   1. Confirm that the product is within the expiration date shown on the label
   2. Check performance against known positive and negative control materials
   3. Retest with fresh product.
   4. If proper results are not obtained, consult Bayer Customer Service.

XIII. PERFORMANCE IMPROVEMENT

A. Technical Supervisor/Director of Nursing or designee will review the QC and maintenance records on a regular basis, checking for completion of records and QC trends.

B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Head Nurse.

XIV. TRAINING/COMPETENCY EVALUATIONS:

A. Each testing personnel will be trained prior to reporting patient results. An initial competency exam of “return demonstration” will be given and repeated annually thereafter. The Nurse Manager of each clinical department will maintain documentation.

XV. REFERENCES:

A. CLINITEK Microalbumin Package Insert, Bayer Corporation, Elkhart, IN, Revised 1997.
Coaguchek PT-INR Test

Date prepared: 7/16/03

Author: Karen Spees BSMT, M(ASCP, LVN)

Date Effective: 07/02/08

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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Revised: 

Distribution:

07/02/08 Electronic

Risk Assessment: HIGH

Complexity Level: WAIVED
Coaguchek PT-INR Test

I. TITLE: Coaguchek PT-INT

II. PURPOSE:
The CoaguChek XS Plus System is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The CoaguChek XS Plus System uses fresh capillary or nonanticoagulated venous whole blood.

III. PRINCIPLE:
The CoaguChek XS Plus System, used as directed will provide an electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin. In simple terms, the blood works with the chemicals in the test strip that measures blood-clotting time.

IV. SPECIMEN PREPARATION:
The specimen requirements are collection a blood sample from a fingerstick. Optionally, you may use a plastic capillary tube to collect the fingerstick blood sample. You may also use the Coaguchek XS Plus System to test more venous blood. When collection any type of sample, follow universal blood collection precautions and guidelines.

V. MATERIALS AND REAGENTS:
A. Supplies
   1. CoaguChek XS Plus Meter
   2. CoaguChek XS PT Test Strip
   3. Test Strip Code Chip
   4. CoaguChek Lancet
B. If you are using test strips from a new unopened container, you will need to change the Test Strip Code Chip. The three-number code on the test strip container must match the three-number code on the code chip.

VI. QUALITY CONTROL:
The CoaguChek XS Plus System has quality control functions integrated control functions integrated into the meter and test strips, so you do not have to run quality control tests with liquid quality controls. The meter automatically runs its own quality control tests as part of every blood test.
VII. PROCEDURE:
A. Blood Collection: Increasing the blood flow in the finger will help you get a good drop of blood. Before you lance the finger, try the following techniques and you see that the fingertip has increased color.
   1. Warm the hand by having the patient hold it under his or her arm, use a hand warmer and/or wash the hand with warm water.
   2. Have the patient hold his or her arm down to the side, so that the hand is below the waist.
   3. Massage the finer from its base
   4. If needed, immediately after lancing, gently squeeze the finger from its base to encourage blood flow.
B. Performing the Test:
   1. Wash the patient’s hands with warm, soapy water or wipe the finger with alcohol. Dry the patient’s hands completely. Make sure you hands and gloves are dry before proceeding.
   2. When you are ready to test, remove 1 strip from the container and **immediately close the container. Make sure it seals tightly**. Do not open a container of test strips or touch a test strip with wet hands or gloves. This may damage test strips.
   3. Insert a test strip as far as you can into the meter. This turns the meter ON.
   4. Press PATIENT TEST. The meter warms the test strip for about 20 seconds. Then the meter begins a countdown. You have 120 seconds to apply a blood sample to the test strip.
   5. The meter automatically checks to see if you have the right Test Strip Code Chip. The three-digit code on the test strip container must match the number on the Test Strip Code Chip before the test can be run. If you are using test strips from a new, unopened container, you will need to change the Test Strip Code Chip.
   6. Use a CoaguChek lancet to perform a fingerstick.
   7. Hold the finger very close to the target area (clear area of the test strip). Apply 1 drop of blood to the top or side of the target area and wait until you hear the beep. You must apply blood to the test strip within 15 seconds of lancing the finger.
   8. Do not add more blood. Do not touch or remove the test strip while the test is in progress. The flashing blood drop symbol changes to an hourglass symbol when the meter detects sufficient sample. If the meter’s beeper is turned on, a beep sounds as well.
   9. The result appears in approximately one minute. Record the result.
10. Properly dispose of the used lancet and test strip.
11. Turn the meter OFF
12. If you need to redo a test, use a new test strip and lancet, and a different finger.
C. Reporting: The CoaguChek XS Plus meter displays test results in units equivalent to laboratory plasma measurements. The physician must determine the best INR level depending on the reason for anticoagulant treatment and how each individual responds to treatment based on Prothrombin Time. Each physician should establish expected values for his or her patient population or individual patients.

VIII. STORAGE AND HANDLING:
A. Meter – Place the meter on a flat surface (like a table or countertop) or hold it roughly horizontal so that it will not vibrate or move during testing. Vibrations or other movement can result in an error message.
B. Test Strips – Store the test strips in their container, with the cap closed. You can store the test strips at room temperature or in the refrigerator (2 – 30 degrees C or 36 – 80 degrees F). When stored properly, the test strips can be used until the expiration date
printed on the test strip container. Throw the test strips away if they are past their “Use By” date.

IX. LIMITATIONS:
A. The CoaguChek XS Plus System should not be used for patients being treated with Hirudin.
B. The CoaguChek XS PT Test uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or serum cannot be used.
C. Use only plastic syringes without anticoagulants or additives. Glass tubes or syringes must not be used.
D. The blood drop must be a minimum of 10 uL in volume. Low sample volume will cause an error message.
E. Never add more blood to the test strip after the test has begun or perform another test using the same fingerstick.
F. When a patient is on intravenous infusion therapy, do not collect the sample from the arm receiving the infusion line.
G. Hematocrit ranges between 25 – 55% do not significantly affect test results.
H. Testing performed with the following in vitro spiked samples or native blood samples (triglycerides) indicated no significant effect on test results.
   1. Bilirubin up to 39 mg/dL
   2. Hemolysis up to 1000 mg/dL
   3. Lipemic samples containing up to 500 mg/dL of Triglycerides
   4. The results are unaffected by heparin concentrations up to 0.8 U/mL.
   5. The CoaguChek XS PT Test is insensitive to low molecular weight heparins.
   6. Clopidogrel up to 20 mg/dL
   7. Fondaparinux up to 5 mg/
I. The presence of anti-phospholipid antibodies such as Lupus antibodies can potentially lead to prolonged clotting times, i.e., elevated INR values. A comparison to an APA-insensitivelaboratory method is recommended if the presence of APAs is know or suspected.
J. In rare cases, patients with long clotting times (>8 INR) may receive an “ERROR 7” message on the meter display. If this error message appears again when the test is repeated, the result must be checked using another method.

X. SAFETY:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XI. PERFORMANCE IMPROVEMENT:
A. The Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

XII. REFERENCES:
Texas Tech Physicians of Lubbock
Lubbock, Texas

Point of Care Manual

i-STAT Procedure for Glucose

Date Prepared: 05/18/2011

Author: Karen Spees MT, M(ASCP), LVN

Date Effective: 05/18/2011

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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Revised:

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Risk Assessment: High

Complexity Level: Waived
I. Title: i-STAT Test

II. Purpose:
The i-STAT 1 Analyzer is intended for use with the i-STAT cartridges for *in vitro* quantification of glucose in whole blood. Analyzers, cartridges and test strips should be used by healthcare professionals trained and certified to use the system and should be used according to the facility’s policies and procedures.

III. Principle:
The i-STAT System incorporates a comprehensive group of components needed to perform blood analysis at the point of care. A portable handheld analyzer, a cartridge with the required tests, and 2-3 drops of blood will allow the caregiver to view quantitative test results for whole blood glucose.

IV. Specimen Requirements:
Only fresh whole blood samples are recommended for use with the i-STAT System. Collect the venous blood sample in a collection tube containing sodium heparin, lithium heparin or EDTA ensuring that the tube is completely filled. Invert the tube with the sample several times immediately before removing the sample. Use a disposable transfer pipette to obtain a sample from the center of the collection tube.

V. Materials and Reagents:
A. i-STAT Analyzer
B. Two 9-volt lithium batteries (or nickel metal hydride rechargeable battery)
C. Software to store calibration information for the glucose test
D. Glucose testing cartridges
E. Transfer pipette or 1cc syringe

VI. Quality Control:
A. Calibration information for the glucose cartridge is included in the barcode on the foil packet in which each cartridge is packaged. The analyzer requires that this information be scanned or entered via the keypad before the test strip can be inserted into the analyzer.
B. Verify that cartridges stored in refrigerator are within the expiration date printed on the boxes, and have not been at room temperature for more than two weeks.
C. Verify that the storage refrigerator did not exceed 2-8 degrees C.
D. Verify that the performance of the thermal control system in each analyzer by using the Electronic Simulator.
E. I-STAT Level 1, 2 and 3 Controls are formulated at three clinically relevant levels and known concentrations of glucose and should be run and should be performed and documented with each new lot# of cartridges received.

VII. Procedure:
A. The glucose cartridges for the i-STAT analyzer are stored in the refrigerator. The cartridge should not be removed from its protective pouch until it is at room temperature (18-30 degrees C or 64-86 degrees F). Allow a single cartridge to stand for 5 minutes and a box of cartridges for 1 hour at room temperature before use. Use a cartridge immediately after removing it from its protective pouch. Prolonged exposure may cause a cartridge to fail a Quality Check.
B. Do not contaminate the contact pads with fingerprints or talc from gloves as the analyzer may not be able to make proper contact with the cartridge.
C. Do not apply pressure to the central area of the label as the calibrant pack inside could burst prematurely.
D. Do not block the air vent as the sample will not flow to the fill mark and the calibrant solution will not flow to the sensors.
E. Avoid contamination – do not use a cartridge on a surface in which blood or any other liquid has spilled. Avoid filling cartridges on surfaces that may cause the cartridge to pick up fibers, fluid or debris that may lodge in the analyzer.
F. Testing procedure:
   1. Place the cartridge on a flat surface or hold it in a horizontal position.
   2. Observe standard precautions.
   3. Direct the tip of the syringe, capillary tube or dispenser into the sample well.
   4. Dispense sample slowly and steadily until it reaches the fill mark indicated on the cartridge label. Leave some sample in the sample well.
   5. Fold the snap closure over the sample well.
   6. Press the rounded end of the closure until it snaps into place.
   7. Align the cartridge with the contact pads facing up and toward the cartridge port.
   8. Push the cartridge slowly and smoothly into the cartridge port until it clicks into place.
   9. Do not attempt to remove the cartridge while the message “Cartridge Locked” remains on the screen.
   10. When results are displayed, pull the cartridge straight out of the analyzer. Dispose of the cartridge in a container for biohazards.

VIII. Reporting of Results:
A. Document glucose results in POC section of patient’s EMR.
B. Notify physician of any critical value.
C. Normal results are as follows:
   1. Fasting Glucose < 95
   2. One Hour Glucose <180
   3. Two Hour Glucose <155
   4. Three Hour Glucose <140
   5. One Hour Glucola <140

IX. Storage and Handling:
A. Analyzer – Store at room temperature on a clean dry surface.
B. Cartridges – the main supply of cartridges should be stored at 2-8 degrees C (35-46 degrees F). Cartridges must be at room temperature before removing them from their pouches. Allow 5 minutes for an individual cartridge and one hour for a box of 25 cartridges to come to room temperature. Cartridges in use may be stored at room temperature 18-30 degrees C or 64-96 degrees F for two weeks. The calendar on the box should be used to indicate the two week room temperature expiration date.

X. Limitations:
A. Overfilling or under filling cartridge will cause error/inaccurate results.
B. Do not use cartridges stored at room temperature for more than 2 weeks.
C. Troubleshooting the analyzer – refer to i-STAT manual or notify i-STAT support services at number listed in the Troubleshooting section of the manual.

XI. Safety:
All products or objects that come in contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XII. Performance Improvement:
A. The Director of Nursing or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not performed, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager for review.

XIII: Training/Competency Evaluation:
Each testing personnel will be trained prior to reporting patient results. An initial competency exam of “return demonstration” will be given and repeated annually thereafter. The Nurse Manager of each clinical department will maintain documentation.

XIII. References:
Texas Tech Medical Center
Lubbock, Texas

Point-of Care Manual

BD Veritor System for Rapid Detection of RSV

Date Prepared:    02/06/2014
Author:       Karen Spees BSMT, M(ASCP), LVN
Date Effective:   02/06/2014
Approved by:    Dale M. Dunn MD, MBA
Chief Medical Officer

Date                 Signature/Title
Review:    02/06/2014   Dale M. Dunn MD, MBA
06/19/14   Dale M. Dunn MD, MBA

Date                 Signature/Title
Revised:  ____________      _____________________________

Distribution:        02/06/2014          Electronic
Risk Assessment:    High
Complexity Level:    Waived
I. TITLE: BD Veritor System

II. PURPOSE:
The BD Veritor System for Rapid Detection of RSV is a chromatographic immunoassay with an instrumented read for the direct and qualitative detection of RSV fusion protein from nasopharyngeal wash, aspirate and swab in transport media samples from patients suspected of having a viral respiratory infection. This test is intended for in vitro diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 20 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method.

III. PRINCIPLE:
The BD Veritor System for Rapid Detection of RSV is a chromatographic immunoassay to detect the RSV fusion protein in a respiratory specimen. When specimens are processed and added to the test device, RSV antigen binds to anti-RSV antibodies conjugated to detector particles in the RSV test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by the line of RSV antibody on the membrane. A positive result for the RSV is determined by the BD Veritor system reader when antigen-conjugate is deposited at the test “T” position and the control “C” position on the BD Veritor system RSV assay device.

IV. SPECIMEN REQUIREMENTS:
Acceptable specimens for testing with the BD Veritor system for rapid detection of RSV include nasopharyngeal washes, aspirates and swab specimens in transport media. It is essential that correct specimen collection and preparation methods be followed. Specimens obtained early in the course of the illness will contain the highest viral titers. Inadequate specimen collection, improper specimen handling and/or transport may yield a false negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

Specimen Transport Media: the following transport media have been tested and found to be compatible using moderate positive samples with the BD Veritor system for rapid detection of RSV: Amies, Bartel Viratrans, BD Universal Transport, Earle’s Minimal Essential, Hanks’s Balanced Salt solution, M4, M4-RT, M5, M6, Normal Saline, Phosphate Buffered Saline. Freshly collected specimens should be processed and tested immediately. However, samples in these transport media can be stored 2-8 degrees C for up to 72 hours. It is essential that correct specimen collection and preparation methods be followed. Do not centrifuge specimens prior to use as the removal of cellular material may adversely affect test sensitivity.
V. MATERIALS and REAGENTS:
BD Veritor System Reader
Vortex Mixer
Transport Media, Distilled or Deionized Water,
Tube rack for specimen testing
BD Veritor System RSV Devices (30 pouches available per kit)
RV Reagent C (30 tubes available per kit)
300 uL pipette
RSV Positive Controls Swab
RSV Negative Control Swab

VI. QUALITY CONTROL:
A. Quality control requirements must be performed in accordance with local, state and/or federal regulations or accreditation requirements and your laboratory’s standard Quality Control procedures. Each BD Veritor system RSV device contains both positive and negative internal/procedural controls.
B. The internal positive control validates the immunological integrity of the device, proper reagent function, and assures that the correct test procedure was followed. The membrane area surrounding test lines functions as a background check on the assay device.
C. These positive and negative internal/procedural controls are evaluated by the BD Veritor system reader after insertion of the BD Veritor system test device. The BD Veritor system reader will prompt the operator should a quality issue occur. Failure of the internal/procedural controls will generate an invalid test result
D. External Positive and Negative Controls: Swab controls (RSV positive and RSV negative) are supplied with each kit. These controls provide additional quality control material to demonstrate positive or negative assay results using the BD Veritor system reader and the BD Veritor system test device. BD recommends that positive and negative controls be run once for:

1. Each new kit lot
2. Each new shipment of test kits
3. Each new operator

As required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.
If the kit controls do not perform as expected, do not test patient specimens. Contact BD Technical Services at 1-800-638-8663

VII. PROCEDURE:
A. Reagents, specimens and devices must be at room temperature (15-30 degrees C) for testing. Thoroughly mix all specimens prior to removal of an aliquot for processing. Do not centrifuge specimens.
1. For each patient specimen and control swab, remove one RV Reagen C tube/tip and one BD Veritor system RSV device from its foil pouch immediately before testing.
2. Label one BD Veritor system device and one RV Reagent C tube for each specimen and control to be tested.
3. Place the labeled RV Reagent C tube(s) in the designated area of the tube rack
4. Process the specimen or control as directed below
   a. For NP washes, aspirates and swab specimen w/transport media:
      1. Vortex or thoroughly mix specimen. Do not centrifuge.
      2. Remove and discard the cap from the RV Reagent C tube corresponding to the sample to be tested.
3. Using the transfer pipette, transfer 300 uL of specimen into the RV reagent C tube. Discard pipette after use.

b. For Kit Swab Controls:
   1. Remove and discard the cap from the RV Reagent C tube corresponding to the sample to be tested
   2. Using the transfer pipette add 300 uL of distilled or deionized water to the RB Reagent C tube.
   3. Insert the control swab into the tube and vigorously plunge the swab up and down in the fluid for a minimum of 15 seconds
   4. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
   5. Press the attached tip firmly onto the RV Reagent C tube containing the processed specimen or control.
   6. Vortex or mix thoroughly.
   7. Invert the RV Reagent C tube and hold tube vertically (approximately one inch above the BD Veritor system RSV device sample well). Holding the tube at the ridged area, squeeze gently allowing three (3) drops of the processed sample to be dispensed into the sample well of the appropriately labeled BD Veritor System RSV device.

   Note: squeezing the tube too close to the tip may cause leakage.

8. After adding the sample, allow the test to run for 10 minutes before inserting into the reader.

9. When the test is ready, insert the BD Veritor System RSV device into the BD Veritor System Reader. The BD Veritor System reader should be powered-on prior to use and will indicate when it is ready for insertion of the BD Veritor System device.

10. Follow the reader on-screen prompts to complete the procedure and obtain test results

B. Interpretation of results:
    The BD Veritor System Reader instrument must be used for all interpretation of test results. Operators should not attempt to interpret assay results directly from the test strip contained within the BD Veritor System RSV assay device.

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<td>Positive Test for RSV (RSV antigen present)</td>
</tr>
<tr>
<td>RSV: =</td>
<td>Negative Test for RSV (no RSV antigen detected)</td>
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<tr>
<td>Control Invalid</td>
<td>Control line error</td>
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Invalid Test – if the test is invalid, the BD Veritor System Reader will display a “Control Invalid” result and the test or control must then be repeated.
C. Reporting of Results:
   1. Positive Test – Positive for the presence of RSV antigen. A positive result may occur in the absence of a viable virus
   2. Negative Test – Negative for the presence of RSV antigen. Infection due to RSV cannot be ruled-out because the antigen present in the sample may be below the detection limit of the test. A negative test is presumptive and it is recommended that these results be confirmed by viral cell culture or an FDA approved RSV molecular assay
   3. Control invalid – do not report results. Repeat the test

VIII: STORAGE AND HANDLING
The kit can be refrigerated (2-30°C). Do not freeze reagents and devices must be at room temperature (15-30°C) when used for testing. Do not use beyond the expiration date.

IX. LIMITATIONS:
A. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
B. The content of this kit are to be used for the qualitative detection of RSV antigens from nasopharyngeal wash, aspirate and swab in transport media specimens
C. The BD Veritor system for rapid detection of RSV is capable of detecting both viable and non-viable RSV particles. The performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
D. Results from the BD Veritor system should be correlated with the clinical history, epidemiological data and other date available to the clinician evaluation the patient.
E. A false-negative result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of RSV infection, and should be confirmed by viral cell culture or an FDA-cleared RSV molecular assay.
F. Positive test results do not rule out co-infections with other pathogens.
G. Negative test results are not intended to rule in other non-RSV viral or bacterial infections.
H. Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no RSV activity when disease prevalence is low. False negative test results are more likely during peak RSV activity when prevalence of disease is high.
I. This device has been evaluated for use with human specimen material only.
J. Monoclonal antibodies may fail to detect, or detect with less sensitivity, RSV viruses that have undergone minor amino acid changes in the target epitope region.
K. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
L. The validity of the BD Veritor system has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.
M. Therapeutic anti-RSV monoclonal antibodies may interfere with the BD Veritor system.
N. Performance characteristics have not been established for use with patients older than 20 years of age and for immunocompromised patients.
X. SAFETY:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precaution (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood and body fluids. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XIV. PERFORMANCE IMPROVEMENT:
F. A Technical Supervisor/Director of Nursing or designee will review the QC and maintenance records on a regular basis, checking for completion of records and QC trends.
G. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

XV. TRAINING/COMPETENCY EVALUATION:
Each testing personnel will be trained prior to reporting patient results. An initial competency exam of “return demonstration” will be given and repeated annually thereafter. The Nurse Manager of each clinical department will maintain documentation.

XVI. REFERENCES:
Point-of-Care Manual

Polymedco OC-Light FOB

Date Prepared: 02/06/2014

Author: Karen Spees BSMT, M(ASCP), LVN

Date Effective: 02/06/2014

Approved by: Dale M. Dunn MD, MBA
Chief Medical Officer

Review: 02/02/2015 Dale M. Dunn MD, MBA

Revised: 

Distribution: 02/06/2014 Electronic

Risk Assessment: High

Complexity Level: Waived
I. TITLE: Polymedco OC-Light FOB

II. PURPOSE:
The Polymedco OC-Light FOB test is an immunological test intended for the detection of fecal occult blood in feces by professional laboratories and physician office labs. The test is useful for the determination of gastrointestinal (GI) bleeding, found in a number of gastrointestinal (GI) disorders such as diverticulitis, colitis, polyps, and colorectal cancer. The OC Light test is recommended for use in routine physical examinations for monitoring bleeding in patients and screening for colorectal cancer or gastrointestinal bleeding. Early diagnosis and treatment has been shown to significantly reduce mortality from colorectal cancer. Immunological tests developed to detect human hemoglobin are more accurate and do not require special dietary restrictions on patients.

III. PRINCIPLE:
The Polymedco OC-Light FOB is an immunoassay utilizing a blend of a polyclonal and monoclonal antibodies to specifically detect the presence of Hb in feces. The sample end of the test strip is dipped in the feces extract. The liquid feces wicks through a series of absorbent materials and contacts latex particles conjugated to an antibody specific to Hb. The sample and latex conjugate then wick through a membrane that contains zones of immobilized antibodies – a patient test zone of anti-Hb capture antibody and a control zone of anti-mouse antibody. If Hb is present in the sample it serves to link the latex conjugate to the capture antibody in the patient test zone. The control zone antibody binds the monoclonal antibody on the latex. The buildup of latex particles in the zones leads to the development of visible blue bands.

IV. SPECIMEN COLLECTION AND HANDLING
Feces must be collected from a collection paper or from specimen caught in a clean cup. Contamination from toilet water should be avoided.

1. Fill in all required information on the sampling bottle.
2. Open green cap by turning to the left and pulling upwards.
3. Scrape the surface of the fecal sample with the sample probe.
4. Cover the grooved portion of the sample probe completely with stool sample.
5. Close sampling bottle by inserting the sample probe and screwing cap on tightly to the right. Do not reopen.
6. Extracted feces may be stored at room temperature for up to 15 days or can be refrigerated at 2-8°C for up to 30 days.
7. Bring extractions to room temperature prior to assaying and mix well before sampling.
V. MATERIALS and REAGENTS:
A. Reagents and materials supplied by OC-Light iFOBT Test Kit
   1. Test Strips
   2. Sampling bottle
   3. Collection Papers
B. Materials required but not provided
   1. Timing Device
   2. External Controls (FBT-POC Recommended)
   3. Rack (FOB-Rack)

VI. QUALITY CONTROL:
A. Good laboratory practices recommend the use of appropriate controls. There are two
types of controls for the OC-Light iFOBT, the internal procedural control and the
external controls
B. Procedural control – the Procedural Control is found in the Procedural Control Region
of the test strip. This control assures the operator that 1) sample addition and migration
through the test strip has occurred and that 2) the control anti-mouse antibody and the
reported MAb are intact and functional. This control does not ensure that the capture
antibody is accurately detecting the presence or absence of Hb in the sample.
C. External Control – External controls are used to assure the operator that the capture and
conjugated antibodies are present and reactive. External controls will not detect an
error in performing the patient test procedure. Controls should be assayed once per kit.
To use, unscrew the white cap on the sample bottle. Add four drops of the control.
Replace the white cap and shake vigorously. Follow step three of the patient test
procedure. If controls do not perform as expected, do not use the test result. Repeat the
test or call Polymedco Technical Services at 800-431-2123.

VII: PROCEDURE:
A. Bring the test materials and patient fecal extract to room temperature (20- 30°C). Shake
fecal extract vigorously.
B. Remove an OC-Light iFOBT strip from the canister. Minimize the amount of time that
the canister is left open and assure that the canister is securely closed after opening.
C. Remove the white cap on the extraction vial. Drop the sample end of the dipstick into
the extraction vial.
D. Start the timer.
E. When the timer reaches 5 minutes, read results. Specimens with high concentrations of
Hb may produce positive results in as little as 1 minute. Confirm negative results at 5
minutes. Do not read after allotted time. Read results as follows.
   1. Positive – carefully look for the appearance of a test line in the Test Region. ANY
      blue colored line, NO MATTER HOW FAINT, in the test region with a colored
      line in the Control Region is a positive result. Neither the intensity nor the color
      should be compared to that of the Procedural Control line
   2. Negative – if no blue line appears in the Test Region and one line in the Procedural
      control Region the result is Negative.
   3. Invalid – if no line appears in the Procedural Control Region, the test is invalid and
      must be repeated with a new strip.

VIII: STORAGE AND HANDLING
Store the OC-Light iFOBT kit at 1-30°C in the original canister. Do not freeze. Test strips
are stable when stored at these temperatures until the expiration date printed on the label.
IX. LIMITATIONS:

F. The OC Light iFOBT Test is intended only for the detection of hemoglobin in feces. It is not advised for use in patients suspected of upper GI bleeding.

G. Patients with the following conditions should not be considered for testing as these conditions may interfere with the test results.
   1. Bleeding hemorrhoids
   2. Constipation bleeding
   3. Urinary bleeding

H. Certain Medications such as aspirin and NSAID may cause gastrointestinal irritation and subsequent bleeding in some patients and cause positive results

I. As with any occult blood test, results obtained with the OC-Light iFOB Test should not be considered conclusive evidence of the presence of or absence of GI bleeding or pathology the test kit is designed for preliminary screening only and is not intended to replace other diagnostic procedures.

J. Because GI lesions may bleed intermittently and blood in feces is not distributed uniformly, a negative test result does not assure absence of a lesion.

K. Urine and excessive dilution of samples with water from the toilet bowl may cause erroneous test results. For best results, use the collection paper in the collection kit.

L. This test is not for use in testing urine, gastric specimens or other body fluids.

X. SAFETY:

All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precaution (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood and body fluids. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

XVII. PERFORMANCE IMPROVEMENT:

H. A Technical Supervisor/Director of Nursing or designee will review the QC and maintenance records on a regular basis, checking for completion of records and QC trends.

I. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

XVIII. TRAINING/COMPETENCY EVALUATION:

Each testing personnel will be trained prior to reporting patient results. An initial competency exam of “return demonstration” will be given and repeated annually thereafter. The Nurse Manager of each clinical department will maintain documentation.

XIX. REFERENCES:

POLYMEDCO OC-Light FOB Test Kit Package Insert, April 2012
CLIA Provider-Performed Microscopy (PPM)
General Policy

Date Prepared: 02/04/02

Author: Tina Anderson, MT (ASCP)

Date Effective: 03/01/02

Approved By: Dale M. Dunn MD
Chief Medical Officer

Annual Review:

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Revised:


Risk Assessment: High

Complexity Level: PPM
I. **Title:** CLIA Provider-Performed Microscopy (PPM) General Policy

II. **Statement of Purpose:**
To establish guidelines for Point-of-Care Testing for Provider-Performed Microscopy (PPM).

III. **Statement of Policy:**
The PPM General Policy outlines the requirements to be routinely followed by PPM Providers.

IV. **Policy:**
A. To be categorized as a PPM procedure, the procedure must meet the criteria specified in paragraph (b) of this policy.
B. The examination must be personally performed by one of the following Practitioners:
   1. A physician during the patient’s visit on a specimen obtained from his/her own patient or from a patient of a group medical practice of which the physician is a member or an employee.
   2. A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.
   3. A dentist during the patient’s visit on a specimen obtained from his/her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.
C. The procedure must be categorized as moderately complex.
D. The primary instrument for performing the test is the microscope, limited to bright-field or phase contrast microscopy.
E. The specimen is labile or delays in performing the test could compromise the accuracy of the test result.
F. Control materials are not available to monitor the entire testing process.
G. Limited specimen handling or processing is required.
H. A laboratory may qualify to perform tests under this section if:
   1. It restricts PPM examinations to one or more or the following procedures (or additional procedures added to this list as provided below) waived tests and no others.
a. All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites and human cellular elements
b. All potassium hydroxide (KOH) preparations
c. Pinworm examinations
d. Fern Tests
e. Post-coital direct, qualitative examinations of vaginal or cervical mucous
f. Urine sediment examinations
g. Nasal smears for granulocytes
h. Fecal leukocyte examinations
i. Qualitative semen analysis (limited to the presence or absence of motility)

V. Safety:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

VI. Performance Improvement:
A. A Technical Supervisor/Director of Nursing or Point of Care Coordinator or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

References:
Federal Regulations: 42, Volume 3, Parts 430 to End.
Point-of-Care Manual

Proficiency Testing

Date Prepared: 02/04/02

Author: Tina Anderson, MT (ASCP)

Date Effective: 03/01/02

Approved By: Dale M. Dunn MD
Chief Medical Officer

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Revised:

Risk Assessment: High

Complexity Level: N/A
I. **Title:** Proficiency Testing

II. **Statement of Purpose:**
To evaluate analytes or tests for which proficiency surveys exist and for those which proficiency surveys do not exist.

III. **List of Tests:**
The following is a list of tests performed within Texas Tech Physicians of Lubbock. If proficiency surveys are required and are not available, and then blind samples will be provided to assess competency.

<table>
<thead>
<tr>
<th>Test</th>
<th>Complexity</th>
<th>Proficiency Required</th>
<th>Proficiency Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinalysis Dipstick</td>
<td>Waived</td>
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<td>N/A</td>
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<tr>
<td>Urine Pregnancy</td>
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<td>N/A</td>
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<tr>
<td>Whole Blood Glucose</td>
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<td>N/A</td>
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<tr>
<td>Wet Mount</td>
<td>PPM</td>
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<td>N/A</td>
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<tr>
<td>Fern Test</td>
<td>PPM</td>
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<td>N/A</td>
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<tr>
<td>KOH</td>
<td>PPM</td>
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<tr>
<td>Cholestech LDX, GDX</td>
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<tr>
<td>Whole Blood HA1C</td>
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<td>N/A</td>
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<tr>
<td>Rapid Strep</td>
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<tr>
<td>Urine Microscopic</td>
<td>PPM</td>
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<td>Rapid RSV</td>
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<tr>
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<tr>
<td>Coaguchek PT-INR</td>
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<td>Occult Blood</td>
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<td>Urine Dipstick</td>
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<td>Urine GP</td>
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<tr>
<td>i-STAT</td>
<td>Waived</td>
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IV. **Evaluation:**
A. Evaluation will be made by the Director of Nursing, Technical Supervisor or Point of Care Coordinator or designee. The Nurse Manager of any clinic with unacceptable results will be notified and the testing personnel will be retested.
B. Records will be maintained for two years.
V. **Safety:**
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

**References:**
A. College of American Pathology Inspection Checklist.
KOH Preparation for Fungus

Date Prepared: 02/04/02

Author: Tina Anderson, MT (ASCP)

Date Effective: 03/01/02

Approved By: Dale M. Dunn MD
Chief Medical Officer

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Revised:

Risk Assessment: High

Complexity Level: PPM
KOH Preparation for Fungus

I. TITLE: KOH Preparation for Fungus

II. Purpose:
KOH is a useful test to perform when examining specimens for fungal elements in which the specimen contains skin scales, nail scrapings, hair, epithelial cells or other materials that are thick in consistency or opaque. KOH acts by dissolving keratin and intensifying the contrast of fungal structures with other materials on the mount.

III. Specimen Required:
Fragments of hair, skin scrapings, nail clippings or exudates for direct microscopic examination of fungus.

IV. Transport:
Specimen should be transported promptly to the laboratory in a sealed, sterile container enclosed in a plastic Ziploc bag to prevent contamination in case of leakage.

V. Processing Procedure:
A. Specimen preparation
   Using sterile razor blade, and wearing appropriate protective clothing, cut specimen into workable size pieces (if applicable). Reserve some specimen for fungus culture if ordered. Liquid specimens need no preparation.
B. Smear preparations
   1. Place one drop of KOH onto a clean, unused microscope slide.
   2. Place specimen into the drop of KOH.
   3. Place clean coverslip over specimen and KOH mixture. Press coverslip gently to make a thin mount.
C. Incubation
   Allow mount to gently warm 2-5 minutes on top of the 56 water bath incubator to enhance clearing before examining.

VI. Examination:
The slide mount must be carefully examined microscopically to detect hyphal segments, spores, yeast, spherules, or sclerotic bodies. Scan mount under low power with reduced light, then examine at high power to check the presence and characteristics of suspected fungal elements.
VII. Special Procedures: N/A

VIII. Normal Flora/Common Pathogens:
Yeast is commonly found in KOH preparations and may exist as normal flora or a potential pathogen. Some common yeast include Candida Albicans, Candida Tropicalis and Candida Glabrata.

IX. Recording/Reporting:
A. No fungal elements seen on KOH
B. (Quantitation) (Fungal Structures) see KOH
   Example - Few budding yeast seen on KOH

<table>
<thead>
<tr>
<th>Quantitation</th>
<th>Rare</th>
<th>Few</th>
<th>Moderate</th>
<th>Many</th>
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<tr>
<td></td>
<td>0-1 per HPF</td>
<td>1-5 per HPF</td>
<td>5-30 per HPF</td>
<td>More than 30 per HPF</td>
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Fungal structures:
1. Yeast
2. Budding yeast
3. Hyphal-like elements
4. Hyphae
5. Septate

X. Quality Control: N/A

XI. Clinical Significance:
This test is a rapid test to detect presence of fungal or yeast infection and can aid the physician with a presumptive diagnosis.

XII. Sources of Error:
A. Cotton swabs should not be used in preparing these slide mounts, as the cotton fibers may resemble hyphae.
B. KOH mount should be examined as soon as possible after the material is cleared because the KOH preparations are not permanent mounts. They can dehydrate and also the KOH will eventually destroy the fungi.

XIII. Biohazard:
KOH is extremely caustic. Avoid contact with the eyes and skin, as it may cause burns. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes.

XIV. Safety:
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.
XV. **Performance Improvement:**
   A. A Technical Supervisor/Director of Nursing or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.
   B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

**References:**
Vaginal Wet Preparation, KOH Preparation and Wet Preparation for Food Fibers

Date Prepared: 02/04/02

Author: Tina Anderson, MT (ASCP)

Date Effective: 03/01/02

Approved By: Dale M. Dunn MD
Chief Medical Officer

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Risk Assessment: High

Complexity Level: PPM
I. **Title:** Vaginal Wet Preparation, KOH Preparation and Wet Preparation for Food Fibers

II. **Purpose:**
Direct microscopic examination of a wet preparation of vaginal discharge provides the simplest rapid diagnostic test for *Trichomonas vaginalis*, vaginal candidiasis, and bacterial vaginosis. Motile trophozoites of *Trichomonas* can be visualized in a wet preparation in two thirds of cases, and budding cells also can be easily identified. The addition often (10%) potassium hydroxide (KOH) to a drop of the preparation serves two functions: by dissolving host cell protein, it enhances the visibility of fungal elements and by causing the discharge to become alkaline it elicits the fishy aminelike odor associate with bacterial vaginosis. Bacterial vaginosis, characterized by foul-smelling discharge, can be diagnosed microscopically or clinically. The discharge is primarily sloughed epithelial cell, many of which are completely covered by tiny, gram-variable rods and coccobacilli. These cells are called “clue cells”. The absence of predominance of lactobacilli on Gram Stain, present in the normal vagina, is another sign of bacterial vaginosis.

III. **Specimen Required:**
Using a cotton tipped or calcium alginate swab, vaginal or urethral discharge is collected and placed in a vacutainer tube containing approximately 0.5 ml of physiological saline. The wooden shaft of the swab is broken off far enough to allow the vacutainer stopper to be placed back in the tube.

IV. **Transport:**
The specimen is delivered to the laboratory as soon after collection as possible to ensure viability of *Trichomonas*.

V. **Processing Procedure:**
A. **Specimen preparations:** Physiological saline may need to be added to the tube if the cotton end of the swab is not covered in Saline. This tube is gently mixed by shaking a few times.
B. **Smear preparations:** A drop of the saline/discharge mixture is placed on a microscope slide and cover slipped. This preparation is examined under high dry magnification (40x) using a light microscope.
C. **Inoculation media:** N/A
D. **Incubation:** N/A
VI. **Examination:**

A. Examine under high dry (40x) using reduced light. Examine 8-10 fields.

B. Quantitate as follows:
   1. Less than 1 organism and/or cell per hpf:  **RARE**
   2. 1-5 organisms and/or cells per hpf:  **FEW**
   3. 5-30 organisms and/or cells per hpf:  **MODERATE**
   4. Greater than 30 organisms and/or cells per hpf:  **MANY**

C. **Trichomonas Vaginalis**
   This parasite is a large flagellate, actively mobile, possessing four anterior whip like flagella and undulating membrane extending about two thirds of the length of the body.

D. **Yeast** may be seen as single cells, single cells with buds, pseudohyphae or blastocondia. *Candida Albicans* is the usual species of yeast seen in vaginal discharge.

E. **Clue Cells**
   As described above these consist of squamous epithelial cells covered with bacilli and coccobacilli when the fine course adjustment on the microscope is focused up and down, the cells seem to “glitter”.

F. **Bacteria**
   1. Quantity is reported.
   2. Specify types present as:
      a. Mixed morphotypes.
      b. Lactobacillus – long square ended bacilli that may form chains.
      c. Curved motile bacilli suggestive of Mobiluncus which must be confirmed by gram stain. Mobiluncus has a unique motility, which is best described as “spinning in all directions at once”. On Gram Stain it will appear as a curved gram variable bacillus.

G. **Other elements reported**
   1. White blood cells
   2. Red blood cells
   3. Epithelial cells

VII. **Special Procedures:**

A. Ten percent potassium hydroxide (KOH) prep
   1. Add 1 drop of KOH to 1 drop of saline/discharge mixture. Let set for 10-15 minutes at room temperature. Examine under high dry for yeast, pseudohyphae, etc. The KOH clears epithelial cells and other host cell protein, making it easier to see yeast and fungal elements. This technique can also be done on skin scrapings which are ordered when a dermatophyte infection is suspected.

B. **Wet prep for food fibers**
   This procedure is usually ordered “stat” on peritoneal fluid from a trauma victim when perforation of the bowel is suspected. A drop of uncentrifuged peritoneal fluid is placed on a microscope slide and cover slipped and examined under high dry. The presence or absence of food fibers is reported. Examples of food fibers are shown below.
VIII. **Recording/Reporting:**
A. Record all results on Wet Prep Screen in the computer.
B. Also record all results on a work card.

IX. **Quality Control:**
A. The physiological saline and the KOH should be sterile and clear in appearance. Do not use either if cloudiness is evident because this could indicate contamination.

X. **Clinical Significance:**
A. *Trichomonas Vaginalis*
   Typical symptoms usually associated with trichomoniasis in women include vaginal discharge, which may be copious, frothy, and malodorous; a “strawberry cervix”; and severe itching of the vulva and inner thighs. These symptoms may occur singly or in combination. Although most men are asymptomatic, some may complain of minor itching or penile discharge.

   *Trichomonas Vaginalis* has a cosmopolitan distribution and ranks as one of the most frequently occurring sexually transmitted diseases, yet data on incidence and prevalence are confusing.

   Prevalence in females is higher in the sexually active age groups, particularly among persons with multiple partners. Because epidemiologic studies have been conducted without standardized sampling and diagnostic techniques, the true prevalence of *T. Vaginalis* infections remains unclear. The difficulty in making the diagnosis in males makes estimates of true prevalence in men almost impossible.

B. **Yeast**
   An itching and burning sensation accompanied by pruritis typify vulvovaginitis, an often chronic disease and the most common Candida infection. The vulva is inflamed, and ulcerations may spread to the adjacent mucosa. The discharge may be thick and curdlike.

C. **Vaginosis**
   Women with bacterial vaginosis typically complain of excessive vaginal discharge and malodor, the latter often reported as more intense after intercourse. The discharge is this, homogeneous, gray and uniformly adherent to the vaginal wall. There are no signs of gross inflammation and, on colposcopy, no abnormally dilated vessels or increased density of vessels can be seen on the vaginal wall. The pH of the vaginal discharge is increased above 4.5 (usually 5.0 to 5.3)

   The pathogenesis and etiology of bacterial vaginosis are still controversial issues. Both *G. Vaginalis* and anaerobic bacteria have been isolated from the vagina of nearly all women with bacterial vaginosis, as compared with approximately 50% of women without this condition. In addition, the concentrations of *G. Vaginalis* and anaerobes are drastically increased (107 to 108 colony-forming unites per milliliter of vaginal fluid) in bacterial vaginosis. Anaerobes implicated in vaginosis include mainly *Bacteroids* ssp., peptococci, peptostroptococci, Mobiluncus Curtisii and *Mobiluncus mulieris*. *M. homonis* is also associated with bacterial vaginosis. This mixed bacterial flora replaces the normal vaginal flora, which is dominated by facultative lactobacilli.

XI. **Sources of Error:**
A. Most errors are caused by inexperience in looking at wet preps. Be certain to ask another Technologist for their opinion if any doubt. Also refer to reference books.
B. **Trichomonas Vaginalis** can become non-motile within an hour after it is collected, therefore it is important that wet preps be delivered to the laboratory as soon after collection as possible. Non-motile Trichomonas may look like white blood cells.

C. If many epithelia cells are seen, a KOH preparation should be done to be certain of the presence or absence of yeast.

**XII. Safety:**

All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.

**XIII. Performance Improvement:**

A. A Technical Supervisor/Director of Nursing or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.

B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

**References:**


Microscopic Examination of Urine Sediment Using Sedistain

Date Prepared: 02/04/02
Author: Tina Anderson, MT (ASCP)
Date Effective: 03/01/02
Approved By: Dale M. Dunn MD
Chief Medical Officer
Annual Review:

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Risk Assessment: High
Complexity Level: PPM
I. **Title:** Microscopic Examinations of Urine Sediment Using Sedistain

II. **Statement of Purpose:** To evaluate urinary sediment using a concentrated stain.

III. **Principle:** The chemical and physical properties of the various formed elements of urinary sediment cause the crystal violet and safranin to be taken up in varying proportions. The resultant distinctive staining permits rapid and accurate identification.

Of particular significance is the differential staining of normal leucocytes and Sternheimer-Malbin positive, or “glitter” cells. The glitter cells are polymorphonuclear leucocytes, which usually exhibit Brownian movement of their cytoplasmic granules. The Brownian movement can be influenced however, by altering the water content of the cell as the urine concentration is changed.

Under the same conditions, the cellular staining qualities remain unaffected. A normal poly takes up both crystal violet and safranin, staining a deep purple. The glitter cell takes up only crystal violet in variable amount, resulting in a colorless, pale blue or grey appearance. Because the staining quality, unlike the Brownian movement, is not altered by urine concentration, many workers prefer it as the more sensitive method for recognizing these cells. (6, 7)

IV. **Specimen Collection and Preparation:**

<table>
<thead>
<tr>
<th>WARNING:</th>
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<tbody>
<tr>
<td>Body fluids may contain infectious diseases. Handle specimens as potential hazards capable of transmitting disease. Always wear protective laboratory gloves when working with body fluids.</td>
</tr>
</tbody>
</table>

The urine specimen should be a freshly voided sample collected in a clean container, which is closed immediately and processed as soon as possible. There is no need for elaborate cleansing procedures for routine microscopic examination unless the specimen is contaminated by vaginal discharge or hemorrhage. (8) Specimens that cannot be examined immediately should be refrigerated, but must not be frozen. If examination is to be delayed beyond 4 hours, it is suggested that 1 drop of 40% formalin per 30 mL urine be added to prevent growth of microorganisms and preserve urinary sediments. (9)

Chloroform should not be used as a preservative since it settles to the bottom of the container and may interfere with microscopic examination.

*Caution should be exercised in selecting preservatives, which will not interfere with other tests to which the specimen may be subjected.*
V. **Quality Control:**
All individuals will perform urine microscopic controls to assess competency performing the test. Controls or proficiency material will be provided to all who perform the test.

VI. **Procedure:**
1. Use a freshly voided specimen collected in a clean container.
2. Mix the specimen thoroughly and pour into a centrifuge tube.
3. Centrifuge for 5 minutes at about 400 g’s (e.g. 1500 RPM, 6” radius).
4. Decant the supernatant without disturbing the sediment.
5. Add 1-2 drops of stain to the sediment in the tube. (Occasionally, a technician may prefer to use 3 drops of stain).
6. **Thoroughly mix** the contents of the tube by flicking the bottom of the tube sharply with the index finger several times.
7. Transfer 1 drop of the stained sediment onto a micro slide. A coverslip may be placed over the drop to facilitate handling and to provide a uniform layer.
8. As an alternative to steps 5, 6 and 7, transfer 1 drop of the unstained sediment from the centrifuge tube onto a micro slide and add up to one drop of stain directly to the sediment on the slide. Small quantities of stain may be transferred to the sediment by using a glass rod instead of the dropper.
9. Examine microscopically. Report average number of red blood cells and white blood cells per high power field. Report average number of cast and other formed elements per low power field, as examined under dimmed light.

VII. **Limitations:**
Microscopic examination of urinary sediment is a semi-quantitative procedure. In cases where exact counts of leucocytes, bacteria, casts, etc., are required, techniques employing a hemocytometer are preferred.

VIII. **Expected Values:**
Some erythrocytes, leucocytes and casts are excreted by normal individuals, but they are seen only occasionally in urinary sediments examined microscopically.

Two to three red blood cells, 4-5 leucocytes per high power field and occasional hyaline casts are accepted as normal.

IX. **Safety:**
All products or objects that come into contact with human blood or body fluids, even after cleaning, should be handled with universal precautions (capable of transmitting viral/bacterial diseases). The user should follow the recommendations for prevention of transmission of blood/body fluid diseases in the health care setting as recommended for potentially infectious human blood specimens. Gloves must be worn during collection and testing. All specimens and reagents must be disposed of in a biohazardous waste receptacle. Standard blood and body fluid precautions should be used in handling all specimens and biohazardous waste.
### Elements in Urinary Sediments

<table>
<thead>
<tr>
<th>Elements in Urinary Sediments</th>
<th>Usual Distinguishing Color of Stained Elements</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Blood Cells</td>
<td>Neutral – Pink to Purple</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acid – Pink (unstained)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alkaline – Purple</td>
<td></td>
</tr>
<tr>
<td>White Blood Cells – Dark Staining Cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glitter Cells (Sternheimer-Malbin positive cells)</td>
<td>Purple</td>
<td>Colorless or light blue</td>
</tr>
<tr>
<td>Renal Tubular Epithelial Cells</td>
<td>Dark shade of blue-purple</td>
<td>Light shade of blue-purple</td>
</tr>
<tr>
<td>Bladder tubular Epithelial Cells</td>
<td>Blue-purple</td>
<td>Light purple</td>
</tr>
<tr>
<td>Squamous Epithelial Cells</td>
<td>Dark Shade of orange-purple</td>
<td>Light purple or blue</td>
</tr>
</tbody>
</table>

### Inclusions & Matrix

<table>
<thead>
<tr>
<th>Inclusions &amp; Matrix</th>
<th>Usual Distinguishing Color of Stained Elements</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyaline Casts</td>
<td>Pale pink or pale purple</td>
<td>Very uniform color. Slightly darker than mucous threads.</td>
</tr>
<tr>
<td>Coarse Granules Inclusion Casts</td>
<td>Dark purple granules in purple matrix</td>
<td></td>
</tr>
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</table>

### Elements In Urinary Sediments

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<tr>
<td>Inclusions &amp; Matrix</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finely Granular Inclusion Casts</td>
<td>Fine dark purple granules in pale pink or pale purple matrix</td>
<td></td>
</tr>
<tr>
<td>Waxy Casts</td>
<td>Pale pink or pale purple</td>
<td>Darker than hyaline casts but of a pale even color. Distinct broken ends.</td>
</tr>
<tr>
<td>Fat Inclusion Cast</td>
<td>Fat globules unstained in a pink matrix</td>
<td>Rare. Presence is confirmed if examination under polarized light indicates double refraction.</td>
</tr>
<tr>
<td>Red Cell Inclusion Cast</td>
<td>Pink to orange-red</td>
<td>Intact cells can be seen in matrix.</td>
</tr>
<tr>
<td>Blood (Hemoglobin) Casts</td>
<td>Orange-red</td>
<td>No intact cells.</td>
</tr>
<tr>
<td>Bacteria</td>
<td>Motile: Don’t stain</td>
<td>Motility unimpaired in fresh specimens when recommended volumes of stain are used. Immobile organisms also identifiable.</td>
</tr>
<tr>
<td></td>
<td>Non-Motile: Stain Purple</td>
<td></td>
</tr>
<tr>
<td>Mucous</td>
<td>Pale pink or pale blue</td>
<td></td>
</tr>
<tr>
<td>Background</td>
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X. **Performance Improvement:**

A. A Technical Supervisor/Director of Nursing or designee will review the quality control (QC) and maintenance records on a regular basis, checking for completion of records and QC trends.

B. Any problems ascertained from the review of the QC records (maintenance not done, QC not within acceptable limits without corrective action, expired kits) will be submitted to the Nurse Manager.

**Bibliography:**

11. Kark, R.M., et al., op,cit, p.64

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Becton Dickinson and company
7 Loveton Circle
Sparks, MD 21152-0370

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Urinalysis Microscopic Exam

Date Prepared: 02/04/02

Author: Tina Anderson, MT (ASCP)

Date Effective: 03/01/02

Approved By: Dale M. Dunn MD
Chief Medical Officer

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Risk Assessment: High

Complexity Level: PPM
Urinalysis Microscopic Exam

I. Title: Urinalysis Microscopic Exam

II. Statement of Purpose: To provide a morphologic evaluation of formed elements in urine.

III. Materials Required:
1. Plastic conical tube
2. Plastic transfer pipets
3. Plain microscope slides
4. Microscope cover slips (22 x 22)
5. Centrifuge (2500 rpm’s)
6. Phase Microscope

IV. Procedure:
A. Pour off the supernatant and re-suspend the sediment.
B. Transfer one drop of well-mixed sediment to a microscope slide and cover with a cover slip.
C. Casts are reported as number per low power field (view at high power to make certain about cellular structures).
D. Crystal types are determined and are reported as present unless they are in very large numbers.
E. Epithelial cells, white cells and red cells are reported per high power field.
F. Make certain that the results of the microscopic examination are consistent with the chemical findings. Any discrepancies of results should be investigated. Make certain that there has been no mistaken identity and if warranted reanalyze the specimen.

G. KEY NOTES:
1. Casts are frequently accompanied by proteinuria, but casts can be seen in the absence of protein.
2. A-positive blood indicates presence of hematuria, free hemoglobin or myoglobin, therefore, carefully search for RBC’s, red cell casts, and ghost cells. Remember that elevated specific gravity may reduce the reactivity of the blood portion of the multistix. Also microbial peroxidase may cause a false positive.
3. A negative nitrite does not mean that there cannot be bacteria present since all pathogens do not form nitrite or the urine may not have been in the bladder long enough for nitrite formation. A positive nitrite though should indicate the presence of bacteria.
4. A positive leukocyte esterase should be correlated with the presence of WBC, but WBC’s are sometimes found in urines with negative esterase (glucose, high specific gravity, and some interfering medications cause false negatives). Also, occasionally no WBC’s are found in a urine with a positive esterase if the cells are disintegrated but the granules have released esterase. Any urine which is hazy or cloudy should be carefully searched for WBC’s.

V. Limitations:
1. Urine should be fresh or refrigerated until examination; at room temperature for more than 2 hours, bacteria may multiply, pH may increase and glucose may decrease. Cellular elements may lyse and casts may disappear.
2. False positive protein may be obtained on the multistix with alkaline, highly buffered urines. Contaminating quaternary ammonium compounds may also give false positive results.
3. Urine specimens containing bromosulphalein or large amounts of phenylketones or L-Dopa metabolites may give positive ketone reactions.
4. Highly pigmented urines may give unreliable results if tested on the Clinitek (reflectance interference) and must be tested by visual evaluation. If results are still doubtful, the statement “possible drug interference” must be added.
5. Rarely, the presence of RBC’s may interfere with testing of chemicals with the Clinitek and with the performance of microscopics. If the Multistix appears abnormally stained with blood, the Clinitek will perform much better if the urine is spun before tested. If the presence of RBC’s obscures viewing any other elements, use a drop of lysing reagent.

VI. Safety:
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