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URINE DIPSTICK, VISUAL POINT OF CARE TESTING	Supersedes: 9/29/14	**C-004**
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Departments Consulted:	Approved By:	Approved by:
Department of Nursing	(Signature on File) Laboratory Supervisor (Signature on File) Laboratory Director	(Signature on File) Health Services Administrator

PRINCIPLE

SIEMENS Multistix® 10 SG reagent strips for urinalysis are firm plastic sticks to which are affixed several separate reagent areas. Depending upon the product used, the strips provide tests for glucose, bilirubin, ketone (acetoacetic acid), specific gravity, blood, pH, protein, urobilinogen, nitrite, and leucocytes in urine. Test results may provide information regarding status of carbohydrate metabolism, kidney and liver function, acid-balance, and urinary tract infection. The reagent test areas on the strips are ready to use upon removal from the bottle, and the entire reagent strip is disposable. The strips are read visually, requiring no additional laboratory equipment for testing. The following tests may be done on each strip:

A. Glucose:
The test is based on a double sequential enzyme. One enzyme, glucose oxidase, 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:
This test is based on the coupling of bilirubin with diazotized dichloroaniline in a strongly acid medium. The color ranges through various shades of tan.

C. Ketone:
This test is based on the development of colors ranging from buff-pink, for a negative reading, to purple when acetoacetic acid reacts with nitroprusside.

D. Specific Gravity:
This test is based on the 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 urine samples 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:
This test is based on a double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.

G. Protein:
This test is based on the protein-error-of-indicators principle. At a constant pH, the development of any green color is due to presence of protein. Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reactions.

H. Urobilinogen:
This test is based on the modified Ehrlich reaction, in which p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with Urobilinogen in a strongly acid medium to produce a pink-red color.

I. Nitrite:
This test depends upon the conversion of nitrate (derived from. the diet) to nitrite by the action of the Gram-negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts with p-arsanilic acid to form adiazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h)quinolin-3-01 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-hydrox-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product.

REAGENTS, QUALITY CONTROLS, AND EQUIPMENT

A. Multistix Reagent Strips:

1. Source:
   Siemens Multistix 10 SG Reagent Strips for Urinalysis – Siemens Healthcare Diagnostics Inc.
2. Handling and Storage Requirements:
   a. Reagent strips should be stored at **room temperature (15º-30ºF).**
   b. Opened test strip bottle is stable until expiration date printed. When reagent strip bottle is first opened, write the open date and initials on the bottle. Do not use after manufacturer's expiration date.
   c. Do not store bottle in direct sunlight.
   d. Do not remove desiccant from the bottle, which prevents strip exposure to moisture.
   e. Do not remove strip from the bottle until immediately before it is to be used for testing.
   f. Replace cap immediately and tightly after removing reagent strip.

g. All unused strips must remain in the original bottle. Transferring strips to another container may cause reagent strips to deteriorate and become unreactive.
h. Do not use if strips are discolored as this can indicate deterioration of reagent.
i. Do not reuse strips.

NOTE: DO NOT USE IF TEST PADS ARE DISCOLORED OR DARKENED

B. Quality Controls:
BioSys Plus Liquid Urine Dipstick Control Level 1 Negative and Control Level 2 Positive

1. The control is specially designed and packaged to be stable in liquid state for two years at a refrigerated temperature of 2º-8ºC to react with commercial dipsticks to register listed responses on the color pads. The control should be used like a patient sample to assist in the assessment of the listed analytical procedures and routinely used for the day-to-day quality control of the assay system. The stable LIQUID CONTROL eliminates errors and discrepancies due to uneven lyophilization or improper mixing. URINE CONTROL contains certain chemical analogs of the constituents which stimulates the color reaction on the dipstick pads.

2. Product Stability:
   a. If the solutions will be used within 30 days, you may recap the control and leave it at ambient room temperature (15º-25ºC). An open tube can be tested for 20 dips at ambient temperature. If the bottle/vial will be used beyond 30 days, store the bottle at 2º-8ºC. Store unopened quality controls at refrigerator temperature (2-8 C.) before initial use. Do not freeze. Do not store above 30 ºC. At 2-8 ºC, they are stable until the manufacturer's expiration date.
   b. Liquid controls are stable for two years at a refrigerated temperature of 2-8 ºC and used as directed.
   c. Discard the controls if turbid or any evidence of microbial contamination is present or upon expiration.

C. Waste Disposal method:
The above product contains 0.10% sodium azide as a preservative. Best disposal method for biological material containing sodium azide is to wash it down the sewer with large excess of water. Disposal should be made in accordance with existing disposal practices.

D. **Biohazard:**

CAUTION: Human source material used in preparation has been found non-reactive for HBsAg when tested by RIA, and negative for HIV-1 antibody when tested with ELISA. However, no known test method can assure that a product derived from human source does notcontain hepatitis or HIV-1 viruses.

WARNING: **HANDLE AS IF CAPABLE OF TRANSMITTING HEPATITIS**
FOR IN VITRO DIAGNOSTIC USE ONLY
NOT FOR INTERNAL USE BY HUMANS OR ANIMALS

E. Equipment
- Clock with sweeping second hand.

QUALITY CONTROL

A. Description: The BioSys Plus Liquid Urine Control (QC) contains certain chemical analogs of the constituents which stimulates the color reaction on the dipstick pads. The listed values are method dependent and different laboratories may observe variations as a result of differences in techniques, the instrument and/or reagent variation, method modifications and other systemic and random errors. These differences may result in the values to fall outside the suggested ranges.

B. Testing Frequency and Handling:
1. Control expiration dates must be checked prior to QC testing.
2. Remove one reagent strip from the bottle and recap.
3. The QCs are run every 24 hours and when a new bottle of reagent strips is opened.
4. QC must be run in the same manner and by the same personnel as patient samples.

C. Procedure:
1. Bring controls to room temperature.
2. Start the timer and immediately saturate each test pad of the reagent strip with control material. and apply control material directly onto the dipstick by gently squeezing the bottle.
3. Remove excess control by tilting the dipstick on its edge on a paper towel.
4. To use drop control, remove dropper tip cap, invert and apply control material directly onto the dipstick by gently squeezing the bottle.
5. To use dip control, dip the urine test strip into the vial for less than one second, then remove excess control by tilting the dipstick on its edge on a paper towel.
6. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas.
7. Read the test pads in good light.
8. Visually compare each test pad to the corresponding row of color blocks and matched carefully.
9. Read Glucose (GLU) and Bilirubin (BIL) at 30 seconds.
10. Read Ketone (KET) at 40 seconds.
11. Read Specific Gravity (SG) at 45 seconds.
12. Read Blood (BLO), pH (pH), Protein (PRO), Urobilinogen (URO) and Nitrite (NIT) at 60 seconds.
13. Read the Leukocytes (LEU) at 2 minutes.
14. Record results on the Point of Care Quality Control Log. Verify that the results are within range.
15. If either control value is not within the expected limits, proceed to **QC Remedial Action**.
16. If either control value is not within the expected limits, **DO NOT** proceed with patient testing.

17. If the solution will be used within 30 days, you may recap the control and leave it at ambient room temperature (15º-25ºC).
18. On initial use, remove the controls from the refrigerator and allow to come to room Temperature (20-25 ◦C.), about 15-30 minutes.
19. An open tube can be tested for 20 dips at ambient temperature. If the bottle/vial will be used beyond 30 days, store the bottle at 2º-8ºC.
20. Read the urine dipsticks visually in accordance with the manufacturer's instructions. If QCs are within acceptable limits write a check mark in appropriate boxes for the date that they were ran on Urine Dipstick Quality Control Log along with initials. Be sure to record the lot number, level number, and expiration date of QC bottles, and lot number, expiration date of the strips and date the strips were opened.
21. Record the date when controls were first stored at room temperature and open expiration date which is 1 month from open date.
22. The results for the QCs must be within the assayed value ranges for each analyte to be acceptable so that the patient results can be reported.

D. QC Remedial Action:

a. Expected ranges for each lot of Level 1 and Level 2 are found on the QC Urine Dipstick Controls package insert and QC log.
b. If unexpected results are seen when running the controls, the control (s) test should be repeated using the same bottle of control and urine dipsticks. If the expected results are still not obtained, open new bottle control and repeat. If still out of range, open new bottle of reagent strips and repeat.
c. If the problem persists, discontinue the use of the test and immediately contact your Point of Care Representative at 323-226-8011, M-F, 7:30am-4:00pm.
d. Document any action taken (e.g., test repeated, etc.) on the log sheet.

E. Limitation of the Procedure:

The listed value and ranges were obtained using instruments, reagents and procedures available at the time the time of analysis. Any change in the reagents, methods or instrument methodology by the manufacturer may result in different values. Consult manufacturer's instructions for the procedures for further information. Laboratories employing methods other than those listed should establish their own mean values and ranges and determine if there is any interaction and/or interference from the system.

NOTE: DO NOT REPORT ANY PATIENT RESULTS UNTIL QCS ARE WITHIN ACCEPTABLE LIMITS.

SPECIMEN COLLECTION

A. Health and Safety Policy:

1. All patient samples should be treated as highly infectious, with universal precautions.
2. Proper care and technique should be taken by the operator when handling the samples so as not to contaminate themselves or create aerosols.
3. The employee performing the testing should wear gloves and eye wear when handling the samples.

4. All specimen splatters should be cleaned up immediately with Dakin's solution, 0.5 % hypochlorite solution.
5. All completed samples are to be disposed in the proper biohazard waste containers.

B. Specimen Collection and Labeling:
1. Printed specimen label is used to identify the specimen for testing.
2. Two identifiers, patient's last name and medical record number must be used to verify patient's identification.
3. Collect a minimum of 3 ml of fresh urine specimen in a clean, dry container and test as soon as possible. Mix well immediately before testing. Do not centrifuge.
4. [NOTE: First morning voided urine is the best specimen since it is fresh, concentrated and has an acid pH]
5. Determine if the specimen is acceptable. Specimen is unacceptable if it is:
    a. Less than 3 ml
    b. Stored at room temperature longer than 3 hours
    c. Grossly bloody
    d. Highly colored urine (e.g., dark straw, amber, red, orange, brown, blue-green, orother unusual color)
    e. Not a urine (e.g., gastric specimen)
6. Analyze the urine while fresh within 1 hour after voiding. If testing cannot be done within 3 hours after voiding, the specimen should be refrigerated and later allowed to return to room temperature before testing. [NOTE: Once the dipstick has been dipped in the urine the testing must be completed for the patient, the result should be sent electronically to interface in patient chart.]

RUNNING A PATIENT SAMPLE

A. Procedure:
1. Remove reagent strip from bottle and replace cap. Completely immerse reagent areas of the strip into a well-mixed urine sample and remove immediately to avoid dissolving out reagents.
2. While removing, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position to prevent possible mixing of the chemicals from adjacent areas.
3. Compare reagent areas to the corresponding color chart on the bottle label at the time specified. Hold strips close to color blocks and match carefully. Avoid laying the strip directly on the color chart, as this will result in the urine soiling the chart.
4. Proper read time is critical for optimal results. Some colors continue to become more intense for a short time and then fade. Read as follows:
    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 120 seconds

NOTES:

1. The pH and protein areas may also be read immediately or at any up to 60 seconds after dipping. After dipping the strip, check the pH area. If the color on the pad is not uniform, read the reagent area immediately, comparing the darkest color to the appropriate color chart.
2. Multistix may not be able to be interpreted if the urine is highly colored (e.g. dark straw, amber, red, orange, brown, green, or otherwise unusually colored)

REPORTING RESULTS

A. Procedure:

1. Enter the results onto the POC urinalysis power form or electronically send to the system for the result to interface in the patient's chart.
2. Record the patient's name and the accession number without a dash in the Clinitek machine.
3. Review the Patient Log with the electronic result in the patient chart and check the date of the QC run to ensure that mandatory quality control procedures are followed each day patient specimens are tested.

NOTE: In order to detect results which might be caused by incorrect testing or clerical errors in the transcription of results in a timely manner, the nurse taking responsibility for each patient does an assessment of each patient's condition and clinical plan at the beginning of each shift. The nurse who run the POC urinalysis should also initial the patient printed result after reviewing the results before pasting the result copy in patient's POCT log. For further details about this standard operating procedure, refer to the Nursing Quality Assurance Procedure.

B. Reporting Format

1. Glucose is reported in mg/dL, negative, trace (100), 250, 500, 1,000, 2,000 or more.
2. Bilirubin is reported as negative, small, moderate, large.
3. Urine Ketones are reported in mg/dL, negative, trace, 15, 40, 80, 160.
4. Specific gravity is reported as 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, and 1.030.
5. Blood is reported as negative, non-hemolyzed trace, non-hemolyzed moderate, hemolyzed trace, small, moderate, large.
6. PH is reported as 5.0, 6.0, 6.5, 7.0, 7.5, 8.0, or 8.5.
7. Protein is reported in mg/dL, negative, trace, 30, 100, 300, 2,000 or more.
8. Urobilinogen is reported in mg/dL (1 mg=approx. 1 EU), normal (0.2), normal (1), 2,4, or 8.
9. Nitrite is reported as negative or positive.
10. Leukocytes is reported as negative, trace, small, moderate, large.

C. Normal Values Visual

Test	Value	Units

Glucose	Negative	mg/dl
Bilirubin	Negative	
Urine Ketones	Negative	mg/dl
Specific Gravity	1.015-1.030	
Blood	Negative	
PH	5.0-8.0	
Protein	Negative/Trace	mg/dl
Urobilinogen	0.2	EU/dl
Nitrite	Negative	
Leukocytes Esterase	Negative	

PROFICIENCY TESTING

A. Description

Proficiency testing is performed to verify the accuracy of the dipstick testing within the Medical Center as well as to comply with current State and Federal laboratory testing regulations.

Proficiency testing specimens will be run every 6 months. The Point of Care Testing Laboratory Department will ask an employee who performs dipstick testing at each site to run two samples in the same manner as patient specimens and then record the results on a special form. The completed form with the results of the testing will be retained in the laboratory.

B. Results Reporting and Evaluation Review

The Point of Care Testing Laboratory Department will ensure that the values obtained on the proficiency specimens are reviewed and signed by appropriate individuals. If there are any deficiencies, the Point of Care Testing Laboratory will work with the ward to resolve the problem. Necessary repeat testing will be done by the same nurse who originally performed the testing. The nurse will first receive a brief in service and then asked to repeat the testing.

PERFORMANCE MONITORING

A. Monthly – the Point of Care Testing Technical Manager or designee will conduct the following performance checks:
   1. Review all quality control records to ensure that all quality control procedures are performed correctly and check for any problems or unusual situations in the quality control results.
   2. Generate a QA summary report and distribute the report to the nurse manager.

B. Semi-annually – proficiency testing results from different testing sites are compared to assure that results agree.

RECORD STORAGE

All records must be stored for three years.

QUALITY CONTROL MONITORING PROTOCOL FOR WAIVED TESTING PERFORMANCE STANDARDS

A. Criteria are based on compliance to quality assurance procedures, including maintenance of QC log, Patient Log, Quality Control samples, and Reagent Strips. See "POCT Multistix Monitoring codes". Each monitoring code is weighted equally. The maintenance of these logs helps assure that the results obtained are accurate, thereby, maintaining continued high-quality patient care. This protocol is one of the most important one the most important requirements of both Joint Commission of Accreditation of Hospital Organization (JCAHQ) and College of American Pathologists (CAP). Compliance is expressed as a percentage of acceptable documentation.

   1. Maintenance of QC and Patient Logs
      a. QC Log - Documentation deficiencies consist of failure to perform and/or document quality control as required by the testing procedure.
      b. Patient Log - Documentation deficiencies consist of failure to document all patients tested as required by the testing procedure.
   2. Maintenance of QC Samples and Reagent Strips
      a. Quality Control Samples and reagent strips –Documentation deficiencies consist of failure to perform quality control and maintenance procedures as required by the testing procedure.
   3. Compliance
      a. Monthly: Less than 90% - Non-compliant. Area subject to review and reagent strips and supplies removed. Equal to or greater than 90% - Compliant.
      b. Quarterly: Less than 90% - Non-compliant. Area subject to review and reagent strips and supplies removed. Equal to or greater than 90% - Compliant.
      c. Yearly: Less than 90% - Non-complaint. Area subject to review and reagent strips and supplies removed. Equal to or greater than 90% - Compliant.

B. Remediation is enforced once an area fails to comply with performance standards. The area will be required to perform the mandatory quality control procedures but will not be allowed to perform patient until the area can meet minimum performance criteria.

TRAINING POLICIES

A. Training may be provided by the manufacturer, Point of Care Testing Laboratory Department, Service Chief, Nurse Manager, or delegated employee previously trained and experienced in performing the test.

B. New employees will be trained and their competency assessed before they start Performing the test. Competency assessment will be done again in 6 months and yearly thereafter.

C. Before a new test can be started in a clinic, 80% of the operators must be initially trained and 100% within two months of starting, except for employees on extended leave. However, upon return, they must be trained before performing the test.

D. Any employee who is not trained and any employee whose competency assessment has not been validated six months after initial training, and yearly thereafter, cannot perform the test.

E. The Point of Care Testing Laboratory Department will coordinate yearly in servicing and competency assessment for all employees.

F. A record of the employees trained and authorized to perform the test are on file in the Service Chief or Nursing personnel training record and Technical Continuing Education notebook in the Point of Care Testing Laboratory Department.

POLICIES

A. Responsibility

In clinical departments, where the clinical staff will be performing urine dipstick testing, the Service Chief is responsible for the direction/supervision of the physician staff's compliance with the urine dipstick procedures, and the Nurse Manager is responsible for the direction/supervision of the nursing staff's compliance with the urine dipstick procedures.

B. Authorization

1. Employees of the physician staff are authorized to perform urine dipstick tests when the following quality assurance procedures have been completed:
    a. All quality control procedures have been completed.
    b. Employee performing the testing has successfully completed the in-servicing program and competency testing provided by the Point of Care Testing Laboratory Department, Service Chief, Nurse Manager or designee.

2. Employees of nursing staff are authorized to perform urine dipstick tests upon Written physician's order and when the following quality assurance procedures have been completed:
    a. All quality control procedures have been completed.
    b. Employee performing the testing has successfully completed in servicing program and competency testing provided by the point of Care Testing Laboratory Department, Service Chief, Nurse Manager, or designee.
    c. Demonstrates ongoing technical competency two times/year for first year of new employees and 1 time/year thereafter.

EQUIPMENT AVAILABILITY

Urine dipstick testing on specific clinical services is determined and approved by the point of Care testing Advisory Committee.

NURSING STAFF RESPONSIBILITIES

The daily running of the normal and positive controls and patient logs are the responsibility of the nursing staff.

REFERENCES

LAC-USC Medical Center Chemistry Laboratory Urinalysis Procedure Manual, 1995

Siemens Multistix® 10 SG Reagent Insert.

BIOSYS Laboratories, Inc. BIOSYS PLUS LIQUID URINE CONTROL Procedure, Reagent Insert. Reorder Numbers: C11, C12, C13, June 2021

REVISION DATES

March 8, 2021