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Point of Care Urinalysis Dipstick Testing Using Siemens Multistix® 10 SG

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. To describe how to perform urinalysis dipstick testing using the Siemens Multistix® 10 SG strips and to provide quality control (QC) and troubleshooting instructions for non-laboratory personnel.

B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

II. PRINCIPLE AND CLINICAL SIGNIFICANCE:

A. UA strips are for *in vitro* diagnostic use at the point of care (POC). The strips are intended for use in at-risk patient populations and to assist diagnosis in the following areas:

1. kidney function,
2. urinary tract infections,
3. carbohydrate metabolism (e.g. diabetes mellitus), and
4. liver function.

B. The strips also measure physical characteristics, including acid-base balance and urine concentration. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis and/or bacterial culture needs to be ordered.

C. Multistix® 10 SG strips include test pads for:

1. Protein: Protein in urine can be the result of urological and nephrological disorders.
2. Blood: Occult blood is present in urine as intact erythrocytes and hemoglobin, which can occur during urological, nephrological, and bleeding disorders.
3. Leukocytes: An increase in leukocytes (≥10 leukocytes/µL) is an indication of pyuria and is found in nearly all diseases of the kidney and urinary tract. However, pyuria may be present in non-infective condition.
4. Nitrite: Positive results are indicative of an enteric gram-negative bacterial infection.
5. Glucose: If too much glucose gets into the blood, the extra glucose will be eliminated through urine. This may be a sign of diabetes.
6. Ketones: In ketoacidosis, starvation, or other abnormalities of carbohydrate or lipid metabolism, ketones may appear in urine at levels of 10 mg/dL or higher before serum ketone levels are elevated.

D. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed by the main laboratory.

E. Users must have a record of color discrimination or functional assessment of test interpretation on file in order to perform testing.

III. SPECIMEN COLLECTION AND HANDLING:

Always follow established procedures for Standard Precautions/Hand Hygiene when collecting and handling a urine specimen. Hands must be washed or disinfected with antiseptic soap or an alcohol-based hand rub as outlined in the Laboratory Infection Control policy before and after gloves are used. Gloves must be worn when performing patient testing and changed between patients.

A. Patient Preparation
    1. A first-morning specimen is preferred but random collections are acceptable.
    2. Confirm the patient has not recently used skin cleansers containing chlorhexidine. Contamination may affect protein test results.

B. Patient Identification
    1. Patients must be identified at the bedside using two identifiers (Joint Commission).

C. Specimen Labeling
    1. Testing should be performed at the patient's bedside, when possible. If the specimen is taken to another location for patient testing, the specimen must be labeled with the patient name and identification (ID) number (Joint Commission).

D. Specimen Types
    1. Urine in clean container without preservatives.

E. Specimen Collection, Handling, Storage, and Disposal
    1. Confirm that the work areas and specimen container is free of detergents and other contaminants. Some substances can interfere with patient test results.

2. Verify that the specimen cup is not expired.
3. Collect a freshly-voided urine in a clean container. The container should allow for complete dipping of all reagent strip pads.
    a. First-morning specimens are preferred, but random collections are acceptable.
4. Test the urine sample within 2 hours of specimen collection.
    a. If the urine cannot be tested within 2 hours of collection, refrigerate the specimen immediately at 2-8°C / 36-46°F. Allow the sample to return to room temperature (15-30°C / 59-86°F) prior to testing.
5. Dispose of the urine specimen in an approved toilet or sink. Patient information on the specimen cup must be obliterated before disposing in a trash container.

F. Specimen Acceptability Criteria
    1. Specimen collected in a clean cup without preservatives that is tested within 2 hours of collection

G. Specimen Rejection Criteria
    1. The use of urine preservatives is not recommended.
    2. Specimens contaminated with skin cleansers containing chlorhexidine should not be tested, as protein test results may be affected.
    3. Specimens that are highly colored, bloody, or very cloudy may interfere with dipstick reading. A specimen should be sent to the main laboratory for analysis.

IV. REAGENTS:

A. Multistix 10 SG (100 Strip Bottles)
    1. Availability
        a. Dearborn and Trenton: Ordered and stored in testing areas.
    2. Ingredients
        a. Each test pad on the strip is composed of different ingredients.
            i. Protein: 0.3% w/w tetrabromphenol blue, 97.3% w/w buffer, 2.4% w/w nonreactive ingredients
            ii. 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 nonreactive ingredients
            iii. 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 nonreactive ingredients
            iv. Nitrite: 1.4%w/w p-arsanilic acid, 1.3% w/w 1,2,3,4-tetrahydrobenzo(h)quinolin-3-ol, 10.8% w/w buffer, 86.5% w/w nonreactive ingredients

v. Glucose: 2.2% w/w glucose oxidase (microbial 1.3 IU), 1.0% w/w peroxidase (horseradish, 3300 IU), 8.1% w/w potassium iodide, 69.8% w/w buffer, 18.9% w/w nonreactive ingredients

vi. Ketone: 7.1% w/w sodium nitroprusside, 92.9% w/w buffer

vii. pH: 0.2% w/w methyl red, 2.8% w/w bromthymol blue, 97.0% w/w nonreactive ingredients

viii. Specific Gravity: 2.8% w/w bromthymol blue, 68.8% w/w poly (methyl vinyl ether/maleic anhydride), 28.4 w/w sodium hydroxide

ix. Bilirubin: 0.4% w/w 2,4-dichloroaniline diazonium salt, 37.3% w/w buffer, 62.3% w/w nonreactive ingredients

x. Urobilinogen: 0.2% w/w ρ-diethylaminobenzaldehyde, 98.8% w/w nonreactive ingredients

3. Storage and Handling
    a. Store at temperatures between 15-30°C (59-86°F).
    b. Store unused strips in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become unreactive.
    c. Do not store the bottle in direct sunlight.
    d. Do not remove the desiccant from the bottle.
4. Expiration
    a. Do not use beyond the manufacturer's expiration date printed on the packaging.
5. Warnings/Precautions
    a. For *in vitro* diagnostic use only.
    b. Protection against exposure to light, heat, and ambient moisture is mandatory to guard against altered reagent reactivity.

B. Quantimetrix Dropper Plus Point of Care Urinalysis Dipstick Control (Level 1 and 2 - 5 mL Bottles)
    1. Availability
        a. Dearborn: Testing area orders the QC. The QC is stored in the walk-in refrigerator in the main lab prior to use.
        b. Trenton: Ordered and stored in testing areas.
    2. Ingredients
        a. Contains a mixture of 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone, 1, 2-propylene glycol, 2, 4-pentanedione.
    3. Storage and Handling
        a. Store at temperatures between 2-8°C / 36-46°F when not in use. Do not

freeze.

b. Discard controls if the solution appears turbid or if there is any evidence of microbial contamination.

4. Expiration
    a. If stored at 2-8°C / 36-46°F between uses, the opened control bottles are stable until the expiration date listed on the bottle.
    b. After the initial use, the opened control bottles may be stored at room temperature (18-25°C / 64-77°F). Do not store above 30°C / 86°F. When stored at room temperature, the controls are stable for 1 month.
        i. The room temperature expiration date must be written on the bottle.
5. Warnings/Precautions
    a. For *in vitro* diagnostic use only.
    b. Control material contains human urine, human blood cells, and human Chorionic Gonadotropin (hCG). Handle the QC material in the same manner as a patient sample.
    c. Dispose of unused QC material in a biohazard receptacle.

V. EQUIPMENT AND SUPPLIES:

A. Specimen Collection Container
B. Timer or Clock (With a Second Hand)
C. Gloves
D. Gauze, Paper Towel, or Tissue (For Strip Blotting)
E. Disposable Pipettes (External QC Procedure Only-Optional)
F. Test Tubes (External QC Procedure Only-Optional)

VI. QUALITY CONTROL (QC):

A. Both levels of controls are tested
    1. with each new lot of strips,
    2. with each new lot of QC,
    3. with each shipment of strips,
    4. each time a new bottle is opened,
    5. if the cap is left off the bottle during storage, and
    6. if the reagent areas on the test strip are discolored or darkened.
    7. Strips are also tested monthly when strips are stored for more than 30 days.
    8. New users will perform QC as part of their training.

9. QC will be performed to confirm test performance when test results do not correlate with the patient's clinical presentation.

B. QC Procedure

1. If stored refrigerated, remove the controls at least 15 minutes prior to testing and allow to come to room temperature (18-25°C / 64-77°F).
2. Mix by gentle inversion. Avoid foaming.
3. Remove the cap and invert the bottle.
4. While holding the dipstick, gently squeeze the sides of the dropper bottle to expel one drop on each test pad. Do not aspirate excess control material back into the bottle. Verify each pad is thoroughly saturated.
    a. Alternately, the QC material may be expelled into a test tube and the strip may be dipped into the test tube or a disposable pipette may be used to apply sample to the test pads from the test tube.
5. Turn the dipstick on its side and drain excess control material onto absorbent material (gauze, paper towel, or tissue).
6. Read the pads at the appropriate intervals (see Procedure section below) and record the results.
7. Wipe off the dropper tips and recap the control bottles.
8. The bottles may be returned to the refrigerator or may be stored at room temperature.
    a. Upon initial opening, the new room temperature expiration date must be written on the bottles.

C. QC Failure Procedure

1. If one or more parameters is out of the acceptable range, appropriate corrective action must be taken and documented. Patient testing must be discontinued until the problem is resolved.
2. If unacceptable QC results appear, follow the steps below:
    a. Verify that the QC and strips are not past their expiration dates.
    b. Confirm proper temperature storage for QC and strips.
    c. Verify that the controls were allowed to warm to room temperature and that the controls were mixed well prior to testing.
    d. Confirm that the proper procedure and technique were followed.
    e. Repeat the test using new QC and/or new strips.

VII. PROCEDURE:

A. Collect a fresh urine specimen in a clean, dry container.

B. Mix well just before testing. Do not centrifuge.

C. Inspect the specimen for acceptability. Send highly colored or very cloudy samples to the main

laboratory for testing.

D. Confirm that the strips are not expired.

E. Remove one strip from the bottle and replace the cap.

    1. Do not touch the test pads on the strip with fingers or other items that may contaminate the strips.

F. Dip all the test pads on the strip into the urine specimen and immediately remove the strip.

G. Start a timer or note the time on a clock.

H. Drag the edge of the strip against the container rim to remove excess urine or blot the edge of the strip on a paper towel or tissue.

I. Compare each test pad to the corresponding row of color blocks on the bottle label. Read each pad at the time shown on the bottle label, starting with the shortest time.

    1. Hold the strip close to the color blocks to match the colors carefully.
    2. Read the pads in adequate lighting.
        a. Note: Ignore the first pad. This is the "ID Band" for automated analyzers. Read times are listed below for all analytes, even those not reported.

Test	Read Times
Glucose Bilirubin	30 Seconds
Ketones	40 Seconds
Specific Gravity	45 Seconds
Blood pH Protein Urobilinogen Nitrite	60 Seconds
Leukocytes	2 Minutes

Any result read after 2 minutes is of no diagnostic value.

J. Document the results for entry into the patient's chart.

K. Dispose of the urine specimen in an approved toilet or sink. Patient information on the specimen cup must be obliterated before disposing in a trash container.

VIII. RESULT REPORTING:

A. Document the results in the Epic chart notes. Include the date and time of specimen collection and testing, results, and the name of testing personnel.

    1. Dearborn only reports results for ketones, blood, protein, leukocytes, and nitrites.
    2. Trenton only reports results for glucose, ketones, and protein.

IX. EXPECTED VALUES AND INTERPRETATION OF RESULTS:

Analyte	Expected Values	Sensitivity	Interpretation
Protein	Negative	15-30 mg/dL albumin	In normal urine, less than 150 mg of total protein is excreted per day (24 hour period) (<15 mg/dL). Clinical proteinuria is indicated at greater than 500 mg of protein per day (strip result of ≥30 mg/dL). Positive results may indicate tubular or overflow proteinuria in the absence of any glomerular abnormality or proteins of renal origin that may be excreted during infection. Urinary protein excretions can be temporarily elevated in the absences of renal abnormality by strenuous exercise, orthostatic proteinuria, dehydration, urinary tract infections, and acute illness with fever. Clinical judgment is needed to evaluate the significance of "trace" results.
Blood	Negative	0.015-0.062 mg/dL hemoglobin	Normally, no hemoglobin is detectable in urine (<0.010 mg/dL or 3 RBC/µL). Small amounts of blood (0.030-0.065 mg/dL or a strip result of "small") are sufficiently abnormal to require further investigation. "Trace" reactions may very among patients, and clinical judgment is require for assessment. Blood is often, but not always, found in the urine of menstruating females.
Leukocytes	Negative	5-15 WBC/hpf	Normal urine specimens yield negative results. A result of "small" or greater is a useful indicator of infection. "Trace" results may be of questionable clinical significance. However, repeated "trace" results on the same patient may be clinically significant.
Nitrite	Negative	0.06-0.1 mg/dL	Many enteric gram-negative bacteria give positive results when their number is greater than 10^5/mL (0.075 mg/dL nitrite ion or greater). Pink spots or pink edges should not be interpreted as a positive result.
Glucose	Negative	76-125 mg/dL	Small amounts of glucose are (<30 mg/dL) are normally excreted by the kidney. These amounts are usually below the sensitivity level of this test but on occasion may produce a result between "negative" and 100 mg/dL that is interpreted as a positive result. Results at the lowest positive level may be significantly abnormal if found in the same patient consistently. If the color appears mottled at the higher glucose concentrations, match the darkest color to the color

			blocks.
Ketones	Negative	5-10 mg/dL acetoacetic acid	Normally, no ketones are detectable in urine (up to 2 mg/dL acetoacetic acid). Clinical judgment is needed to determine the significance of "trace" results, which may occur during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise.

X. REPORTABLE VALUES:

Test	Reportable Values						
Protein (mg/dL)	Negative	Trace	1+ 30	2+ 100	3+ 300	4+ 2000>	Not Done
Blood	Negative	Trace	1+ small	2+ mod	3+ large	Not Done	
Leukocytes	Negative	Trace	1+ small	2+ mod	3+ large	Not Done	
Nitrite	Negative	Positive	Not Done				
Glucose (mg/dL)	Negative	100	250	500	1000	2000 or >	Not Done
Ketones (mg/dL)	Negative	5 trace	15 small	40 mod	80 large	160 large	Not Done

XI. CRITICAL VALUES:

A. Ketone: >79 mg/dL "large"

B. Follow the institutional policy for critical result reporting and documentation.

C. Critical values may be confirmed by repeating the test or sending a sample to the main laboratory, per the testing personnel's discretion.

XII. RESULT REVIEW:

A. Review the results on the Point of Care Urinalysis Result Log.

XIII. SYSTEM DOWNTIME:

A. Continue to document results on the Point of Care Urinalysis Result Log. When Epic becomes available, enter the results in the Epic chart notes.

XIV. LIMITATIONS AND INTERFERING SUBSTANCES:

A. Protecting the strips from exposure to light, heat, and ambient moisture is mandatory to guard against altered reagent reactivity. Only remove the strip from the bottle immediately before use. Replace the cap immediately and tightly after removing the reagent strip.

B. Substances that cause abnormal urine color may affect the readability of test pads. These substances include visible levels of blood or bilirubin and drugs containing dyes (e.g. Pyridium, Azo Gantrisin, Azo Gantanol), nitrofurantoin (Macrodantin, Furadantin), or riboflavin.

C. Some detergents and other contaminants may interfere with patient results. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein test results (and to a lesser extent specific gravity and bilirubin).

D. It is important to use fresh urine to obtain optimal results with tests for bilirubin and urobilinogen, as these components are very unstable when exposed to room temperature and light.

E. Do not read any test pad after 2 minutes. Any color changes that occur after this time are of no diagnostic value.

F.

Analyte	Limitations and Notes
Protein	The protein test pad is not specific for a particular protein and proteins other than albumin can cause a positive reaction. The test is less sensitive to mucoproteins and globulins, which are generally detected at levels of 60 mg/dL or higher. A visibly bloody urine may cause falsely elevated results.
Blood	The appearance of green spots on the reacted test pad indicates the presence of intact erythrocytes, while green color across the entire test pad indicates free hemoglobin. The test is equally sensitive to myoglobin as to hemoglobin. Capoten (captopril) may reduce the sensitivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infections may cause a false positive reaction.
Leukocytes	Elevated glucose concentrations (≥3 g/dL) may cause decreased test results. The presence of cephalexin (Keflex), cephalothin, or high concentrations of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity and high levels fo the drug may cause a false negative reaction. Positive results may occasionally be due to contamination of the specimen by vaginal discharge.
Nitrite	Nitrite concentration during infection increases with the length of time the urine specimen is retained in the bladder prior to collection. A minimum of 4 hours of bladder incubation significantly increases the likelihood of obtaining a positive result. A negative result does not rule out significant bacteriuria. False negative results may occur with shortened bladder incubation of the urine, absence of dietary nitrate, or the presence of nonreductive pathological microbes.
Glucose	Ketone bodies reduce the sensitivity of the test. Moderately high ketone levels (40 mg/dL) may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dL) but the combination of such ketone levels and low glucose levels is metabolically improbable in screening.
Ketone	False "trace" results may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such

	as mesna (2-mercaptoethane sulfonic acid) that contain sulfhydryl groups may cause false positive results or an atypical color reaction.

XV. TROUBLESHOOTING:

A. Discoloration or darkening of the test pads may indicate deterioration. If this is evident, or if test results are inconsistent with expected findings, the following steps are recommended:
    1. Confirm that the strips are within the expiration date printed on the label.
    2. Review the procedure was followed correctly. Timing is critical for reliable test results.
    3. Check the performance against both levels of QC material.
    4. Retest with fresh strips.
    5. Urine specimens may be sent to the main laboratory fo analysis when the above steps have not resolved the problem or abnormal urine color interferes with the ability to accurately interpret the pads.

XVI. REFERENCES:

A. Point of Care Testing Approval Process
B. The Joint Commission. (2022) Standard NPSG.01.01.01 EP 1 in The Joint Commission. Comprehensive accreditation manual. Hospital edition. Oak Brook, IL: The Joint Commission.
C. Siemens Multistix® 10 SG Reagent Strips Package Insert, Siemens Healthcare Diagnostics Inc., 511 Benedict Ave Tarrytown, NY 10591-5097, Revision 11306391 Rev A 7/2017, www.siemens.com/poc
D. Quantimetrix® Dropper Plus Point-of-Care Urinalysis Dipstick Control Package Insert, Quantimetrix Corporation 2005 Manhattan Beach Blvd. Redondo Beach, CA 90278-1205, Revision E-MO4786A 7/2020, https://quantimetrix.com/

Attachments

POC Urinalysis New Lot Evaluation Log.pdf

POC Urinalysis Quality Control Log.pdf

POC Urinalysis Result Log.pdf

POC Urinalysis Training and Competency Assessment.pdf

POC Urinalysis Training Guide.pdf

Approval Signatures

Step Description	Approver	Date
	Jeremy Powers: Chief, Pathology	11/1/2023
	Muhammad Arshad: Chief, Pathology	10/31/2023
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Mgr, Division Laboratory	10/27/2023
	Ann Marie Blenc: System Med Dir, Hematopath	10/26/2023
	Caitlin Schein: Staff Physician	9/27/2023
	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	9/8/2023
POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	9/5/2023
	Jessica Czinder: Mgr, Division Laboratory	9/5/2023

Applicability

Dearborn, Trenton