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Applicability	Dearborn, Taylor, Trenton, Wayne

Laboratory Manual Urinalysis Dipstick Testing

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

To provide guidance on performing a manual urinalysis dipstick using Siemens Multistix® 10 SG Reagent Strips when automated testing methods are not available or for a quick confirmation of automated Urinalysis results.

II. CLINICAL SIGNIFICANCE:

Siemens Multistix® 10 SG Reagent Strips are intended for use in at-risk patient groups to assist in diagnosis in kidney function, urinary tract infections, carbohydrate metabolism (e.g. diabetes mellitus) and liver function.

III. SPECIMEN COLLECTION AND HANDLING:

A. Patient Preparation
No special preparation required for random urine sample

B. Specimen Type: Urine

1. Acceptable Containers

a. Vacutainer Urine Collection Kit should be used for clean catch midstream urines.

b. ~~BD Vacutainer Plus UA Preservative Tubes, conical bottom, 8 milliliter (mL).~~

c. Sterile urine container.

d. A separate, preserved specimen is required for Microbiology Culture and Sensitivity.

2. Volume
    a. Optimum volume for non Vacutainer specimens is 20 mL.
    b. A minimum of ~~5~~3 mL of urine is required for ~~automated~~manual dipstick urinalysis.
    c. ~~A minimum of 10 mL of urine is required for a manual microscopic examination only.~~
    d. ~~A minimum 3 mL of urine is required for automated microscopic examination.~~

3. Collection
    a. First morning clean catch midstream urine is preferred.
    b. Random urine specimens will be accepted.

4. Storage/Stability Instructions
    a. Specimen is stable for 2 hours at room temperature (20-26º C).
    b. Refrigerated (2 – 8ºC) urine samples are stable for 8 hours.
    c. Specimens must be brought to room temperature before analysis.
    d. Refrigerated specimens greater than 2 hours old may be reported with the following smart phrase comment: "**.2HO" (Sample greater than 2 hours old - may be loss of cell casts and other formed elements. Dipstick testing may yield inaccurate results.)**
    e. Specimens left at room temp for greater than 2 hours may be reported with the following smart phrase comment: "**.UA2H" (Sample >2 hours old and not refrigerated-may be loss of cell casts and other formed elements. Dipstick testing may yield inaccurate results.)**

5. Causes for rejection
    a. Improperly identified specimen.
    b. Insufficient quantity to perform the test (< 1 mL)
    c. Specimens greater than 24 hours old.
    d. Specimens that have been frozen.
    e. Specimen received in container with preservatives ~~present other than the BD Vacutainer preservative~~.

6. Specimen Identification
    a. All specimens should be labeled with patient's name, unique identification number, time, date of collection which is included on the Laboratory Information System (LIS) label.

7. Specimen Handling

a. Follow Universal Precautions due to the potential presence of pathogenic material. CAUTION: Gloves and a lab coat must be worn when handling open specimens.

IV. REAGENTS:

A. **Multistix 10 SG:** Protection from exposure to light, heat and ambient moisture is mandatory to guard against altered reagent activity. All unused strips must remain in the original bottle. Do not use strips past the expiration date on the bottle.

1. **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.
2. **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 the presence of protein. Colors range from yellow for “Negative” through yellow-green and green to green-blue for “Positive” reactions.
3. **Glucose**: This test is based on a double sequential enzyme reaction. One enzyme, 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.
4. **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.
5. **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.
6. **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.
7. **Nitrite:** This test depends upon the conversion of nitrate to nitrite by the action of 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 a diazonium compound. This diazonium compound in turn couples with 1,2,3,4 – tetrahydrobenzo (h)-quinolin-3-ol to produce a pink color.
8. **Leukocytes:** Granulocytic leukocytes contain esterases that catalyze the hydrolysis of 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.
9. **Urobilinogen:** This test is based on a 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.
10. **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.

V. EQUIPMENT:

A. Timing Device

B. 16 X 100 Plastic tube

VI. QUALITY CONTROL (QC):

A. KOVA-trol® I and KOVA-trol® III are run daily when patient testing is performed.

1. Quality Control Test Procedures

a. Controls are prepared weekly by reconstituting with clinical laboratory reagent water (deionized water) using a graduated cylinder. See package insert for more details based on the bottle size.

b. Gently rotate the bottle until completely dissolved (approximately 15 minutes).

c. Allow QC controls to come to room temperature before performing testing.

d. Gently mix the control material and transfer an aliquot to a clean 16 X 100 plastic tube

e. Remove a Reagent Strip from the bottle and replace cap.

f. Dip the Reagent Strip into the plastic tube containing the control material. Thoroughly saturate all of the reagent pads on the test strip. Excess control may be removed by slowly running the edge of the entire length of the strip against the side of the tube.

g. Immediately start timing.

h. Visually read the Reagent Strip. Read each pad at the time shown on the bottle label, starting with Glucose at 30 seconds.

i. Compare each test pad to the corresponding row of color blocks on the bottle label.

i. Hold the Reagent Strip close to the color blocks and match carefully.

ii. Read each pad at the time shown on the label.

iii. Read the pads in good light.

iv. Do not read any test pad after 2 minutes of being dipped in urine.

2. Record results on the Urine Dipstick QC/Patient Log.

VII. PROCEDURE:

A. Patient Testing

1. If samples have been refrigerated, allow patient samples to come to room

temperature before performing testing.

2. Gently mix the patient sample.
3. Remove a Reagent Strip from the bottle and replace cap.
4. Dip the Reagent Strip into the well mixed patient sample. Thoroughly saturate all of the reagent pads on the test strip. Excess control may be removed by slowly running the edge of the entire length of the strip against the side of the urine container.
5. Immediately start timing.
6. Visually read the Reagent Strip. Read each pad at the time shown on the bottle label, starting with Glucose at 30 seconds.
7. Compare each test pad to the corresponding row of color blocks on the bottle label.
    a. Hold the Reagent Strip close to the color blocks and match carefully
    b. Read each pad at the time shown on the label.
    c. Read the pads in good light.
    d. Do not read any test pad after 2 minutes of being dipped in urine.
8. Record results on the Urine Dipstick QC/Patient Log.
9. Evaluate the results for the requirements of a microscopic exam. Any positive macroscopic result (except urobilinogen) reflexes a microscopic exam. Please refer to Laboratory Examination of Urinary Sediment.

VIII. EXPECTED VALUES/REPORTABLE RANGES:

Parameter	Reference range	LIS Reportable Range
Urine pH	5.0-8.0	5-8.5, >9.0
Urine Specific Gravity	1.005-1.030	≤1.005-≥1.030
Urine Glucose	Negative	Neg, 100 (trace), 250 (1+), 500 (2+), >=1000 (3+) mg/dL
Urine Ketone	Negative	Neg, 5 (trace), 15 (1+), 40 (2+), >=80 (3+) mg/dL
Urine Bilirubin	Negative	Negative or Positive
Urine Blood	Negative	Neg,Trace (intact-lysed),1+, 2+, 3+
Urine Protein	Negative	Neg, 15 (trace), 30(1+), 100 (2+), >=300 (3+) mg/dL
Urine Urobilinogen	0.2-1.0 Ehrlich units/dL	Neg, 0.2, 2.0, 4.0, >=8.0
Urine NitrIte s	Negative	Negative or Positive
Urine Leukocyte	Negative	Neg, Trace, 1+, 2+, 3+
Color		Yellow, Amber, Red, Orange, Blue, Colorless, Other

Clarity		Clear, Cloudy, Turbid

IX. CRITICAL RESULTS:

Urine Ketones >=80 mg/dL

Note: Critical call notification is waived for patients in the Emergency Center (EC).

X. LIMITATIONS

A. Color Interference:
Abnormally colored or very dark urine may interfere with or obscure reagent strip test results. If such a specimen is submitted, all results (except color, clarity and Specific Gravity) should not be reported and should be resulted as COLOR INTERFERENCE in the LIS. Color and Clarity should be determined visually, and Specific Gravity testing should be performed on the refractometer and these results should be manually entered into the LIS. A microscopic exam should be performed.

B. Bloody Urine:

1. Enter the smart phrase comment "**.bldyua**" (**Bloody specimen. Urine chemistry testing was performed on the supernatant of a centrifuged specimen. Interpret results cautiously)** in the white comment box in the LIS.
2. ~~Spin the urine and process the chemistries manually using the supernatant.~~Spin the urine and process the chemistries manually using the supernatant.
    a. If the supernatant remains red, DO NOT perform the chemistry portion of the urinalysis.
        i. Manually result the color and clarity.
        ii. Perform and report the Specific Gravity by refractometer.
        iii. Report "color interference" for Glucose, Bilirubin, Ketone, Blood, pH, Urobilinogen, Nitrite, and Leukocytes.

XI. INTERFERING SUBSTANCES:

A. Substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium, Azo Ganstrisin, Azo Gantanol), nitrofurantoin (Macrodantin, Furadantin) and riboflavin, may affect the readability of reagent areas on urinalysis reagent 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 visually and/or instrumentally as a false positive. In these cases, results that are affected by the color (Pyridium dye) should not be reported and resulted as COLOR INTERFERENCE (see Limitations above).

B. pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as “run-over” may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing a false lowering in the pH result.

C. Protein: False positive results may be obtained with highly buffered or alkaline urines. Contamination of the urine specimen with quaternary ammonium compounds (e.g. from some

antiseptics and detergents) or with skin cleansers containing chlorhexidine may also produce false positive results.

D. Glucose: Ascorbic acid concentrations of 50 milligrams per deciliter (mg/dL) or greater may cause false negatives for specimens containing small amounts of glucose (100 mg/dL). 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 (100 mg/dL) but the combination of such ketone levels and low glucose levels is metabolically improbable in screening. The reactivity of the glucose test decreases as the specific gravity of the urine increases. Reactivity may also vary with temperature.

E. Ketone: False positive results (trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites.

F. Bilirubin: Indican (indoxyl sulfate) can produce a yellow-orange to red color response which may interfere with the interpretation of a negative or a positive bilirubin reading. Ascorbic acid concentrations of 25 mg/dL or greater may cause false negatives.

G. Blood: Elevated specific gravity or elevated protein may reduce the reactivity of the blood test. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction.

H. Nitrite: Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as positive. Color development is not proportional to the number of bacteria present. Sensitivity of the nitrite test is reduced for urines with a high specific gravity. Ascorbic acid concentrations of 25 mg/dL or greater may cause false negative results.

I. Leukocytes: Elevated glucose concentrations (> 3 mg/dL) or high specific gravity may cause decreased test results. The presence of cephalexin, cephalothin, or high concentrations of oxalic acid may cause decreased reactivity and high levels of the drug may cause a false negative reaction.

J. Urobilinogen: The test area will detect urobilinogen in concentrations as low as 0.2 mg/dL (approximately 0.2 Ehrlich Units per deciliter (EU/dL) in urine. The absence of urobilinogen in a specimens being tested cannot be determined.

K. Specific Gravity (SG): The specific gravity test permits determination of urine specific gravity between 1.000 and 1.030. In general, it correlates within 0.005 with values obtained with the refractive index method. Strips read instrumentally are automatically adjusted for pH by the instrument. The Siemens Diagnostics SG is not affected by certain nonionic urine constituents such as glucose or by the presence of radiopaque dye. All Specific Gravities ≥1.030 should be verified using a refractometer.

XII. NOTES:

A. Verification of unusual results is accomplished by comparing reagent strip to the color chart on the Multistix bottle and/or repeating the analysis from start to finish.

B. Nitrite test results are optimized by using a first morning urine specimen or one that has incubated in the bladder for 4 hours or more.

C. Bilirubin and urobilinogen must be done on fresh urine to achieve optimal results as these

substances are very unstable when exposed to room temperature and light.

D. Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation with a resultant change in pH. A shift to alkaline pH may cause false positives in the protein test area.

E. Bacterial growth from contaminating organisms may cause false positive blood reactions due to production of peroxidases.

XIII. REFERENCES:

1. Multistix® package insert, Siemens Healthcare Diagnostics, Tarrytown, NY 06/2010

Attachments

Manual Urinalysis Dipstick Testing Quality Control and Patient Log

UA Manual KOVA Level I QC - Dearborn

UA Manual KOVA Level II QC - Dearborn

UA Manual Refractometer QC - Dearborn

Approval Signatures

Step Description	Approver	Date
Medical Director	Muhammad Arshad: Chief, Pathology	9/27/2024
Medical Director	Jeremy Powers: Chief, Pathology	9/26/2024
Policy and Forms Steering Committee Approval (if needed)	Laura Bellon: Medical Technologist Lead	9/17/2024
	Christopher Ferguson: Dir, Lab Services	9/17/2024
	Ashley Beesley: Mgr, Laboratory	9/17/2024
	Helga Groat: Supv, Laboratory	9/12/2024
	Kristen DiCicco: Mgr, Laboratory	9/11/2024

Katherine Persinger: Mgr, Laboratory	9/10/2024
Laura Bellon: Medical Technologist Lead	9/10/2024

Applicability

Dearborn, Taylor, Trenton, Wayne