

**SUNY Downstate Medical Center -University Hospital
of Brooklyn Network
Department of Pathology Policy and Procedure**



Subject: Point of Care Urinalysis Visual Multistix LAB 23G

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**SUNY DOWNSTATE MEDICAL CENTER
UNIVERSITY HOSPITAL OF BROOKLYN
POLICY AND PROCEDURE**

<p>Subject: <u>POINT OF CARE – Urinalysis</u> <u>Visual Using Multistix 10G</u></p> <p>Prepared By: <u>Jeronimo Belgrave BS MT (ASCP)</u> <u>Sandra Alfaro BS MT (ASCP)</u></p> <p>Reviewed by: <u>Alix Laguerre, MS MT (ASCP)</u></p> <p>Approved by: <u>Alejandro Zuretti, M.D.</u> <u>Raavi Gupta, M.D.</u> <u>Margaret Jackson, MA, RN</u> <u>Stanley Fisher, M.D.</u></p> <p><u>Michael Lucchesi, M.D.</u></p>	<p style="text-align: right;">No. <u>LAB-23G</u></p> <p style="text-align: center;">Page <u>1</u> of <u>8</u></p> <p>Original Issue Date <u>10/03</u></p> <p>Supersedes: <u>01/09</u></p> <p>Effective Date: <u>12/14</u></p> <p>The JC Standards: <u>WT.01.01.01.</u> <u>WT.02.01.01 WT.03.01.01 WT.04.01.01</u> <u>WT.05.01.01</u></p> <p>Distribution: Suite B Satellite Clinics</p> <p>Issued by: Department of Laboratories</p>
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I. PURPOSE: The visual urinalysis using the Multistix 10G as a Point of Care test is used in the Satellites Facilities to aid in the screening of any abnormal reactions that can be detected by visual examination using a random urine sample.

II. PRINCIPLE:

Urine is an important fluid and its chemical changes can indicate early disease. The composition of urine (for the most part is water with urea and certain minerals in solution) varies widely because it is the principal route for soluble waste materials from body metabolism. Many constituents of the blood, such as glucose, have a renal threshold (they must reach a certain elevated level in the blood before they are excreted in the urine). Other compounds, such as Ketone bodies, are efficiently removed from the blood by the kidneys and do not appear in the blood in sufficient quantities until urine concentration is very high and the kidneys excreting capacity is exceeded.

CHEMICAL PRINCIPLES:

Glucose: 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 chromogen (potassium iodide) to change the color from green to brown.

Bilirubin: Bilirubin coupled with diazotized dichloroaniline in a strongly acid medium causes color reactions ranging through various shades of tan.

Ketone: Acetoacetic acid reacts with nitroprusside to develop a color from pink to purple.

Specific Gravity: Certain pretreated polyelectrolyte pKa changes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green through yellow-green corresponding to increase in ionic strength.

Blood: Hemoglobin catalyzes the reaction of disopropylbenzidine dihydroperoxide and 3,3', 5,5' - tetramethylbenzidine. The color changes from orange through green. Very high levels of blood may cause the color development to continue to blue.

pH: Double indicators give a broad range of colors (orange through yellow and green to blue) covering the range of urinary pH.

Protein: Reaction is based on the protein-error-of-indicators principle. At a constant pH any green color is related to protein in the urine. Colors range from yellow for "**Negative**" (Neg.) through yellow - green and green for "**Positive**" (Pos.) reactions.

Urobilinogen: p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color. (A modified Ehrlich reaction)

Nitrite: The conversion of nitrate (derived from the diet) to nitrite by the action of gram-negative bacteria in the urine. Nitrite in the urine (at the acid pH of the reagent area) reacts with p-arsanilic acid to form a diazonium compound. This compound in turn couples with 1,2,3,4, - tetrahydrobenzoquinolin-3-ol to produce a pink color.

Leukocyte: Granulocytic leukocytes contain esterase that catalyzes the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenol pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple color.

SPECIMEN COLLECTION:

Freshly voided urine specimens. (Preferably the first morning specimen) The urine must be collected in a clean container and should be tested as soon as possible after collection. Specimens should be free from fecal and vaginal contamination. It is of particular importance to use fresh urine to obtain the best results with the test for urine bilirubin because this compound is very unstable when exposed to room temperature and daylight. If testing cannot be performed within an hour after collection, the specimen should be refrigerated at 2-8°C immediately and returned to room temperature before testing. Mix thoroughly before use.

III. SPECIMEN ACCEPTABILITY:

1. Labeling
 - a. All samples must be properly labeled with a Cerner barcode label.
 - b. Unlabeled or mislabeled specimens are not to be run or returned to the doctor or nursing station of origin.
 - Request a new specimen.
 - For pediatric or anuric patients, the physician or charge nurse may sign an unlabeled/mislabeled specimen release form. The sample may then be run and a notation made in Cerner.
2. Do not run specimens, which are contaminated with fecal material.
 - The sample is to be discarded.
 - Request a new sample.
 - Document in Cerner
3. If specimen is not refrigerated, the specimen must be received in the laboratory within 1 hour of collection.
 - Do not run unrefrigerated specimens after this time. Do not return it to the doctor or the nursing station of origin.
 - Request a new sample.
 - Document in Cerner.

IV. REAGENTS:

Bayer Multistix 10SG Reagent Strips (#2300)

Strips must remain in the original bottle. **Do not remove desiccant from bottle.** Remove strip from the bottle immediately before use. Replace cap immediately and tightly after removing reagent strip.

Discoloration or darkening of reagent areas may indicate deterioration. Store at room temperature between 15°C - 30°C (59°-86°F).

Specimen Collection Container
Stop Watch

V. QUALITY CONTROL:

Quality control materials consists of two commercial materials, one normal (Kova Liquid-Trol Normal), and one abnormal level (Kova Liquid-Trol Abnormal)

1. Control Stability:
Store controls at 2-8°C. Do not freeze. Reconstituted lyophilized controls are stable for 5 days at 2-8°C. Liquid control is stable until expiration date.
2. Liquid Control Preparation:
Mix well and pour off aliquot for analysis

3. Test Performance:
 - a. Process and test the controls as routine specimens at the beginning of the day.
 - b. Compare the test results with the lot-specific assigned values and record in the Daily UA Quality Control logs.
 - c. If results are out of range - troubleshoot
 - Reagent strips (Check expiration date on vial. Repeat with new vial of strips)
 - Control material (re-constitute new controls)
 When cause is corrected, re-run the controls and fill out corrective action taken in the control result log. Notify Pont of Care staff for troubleshooting.

VI. PROCEDURE:

1. Appearance and Color:
 - a. Appearance - record as clear, slightly turbid, hazy, turbid, cloudy, slightly cloudy, bloody.
 - b. Color - may vary from colorless to dark amber. The most frequently encountered urine colors include straw, yellow, amber, red, orange and brown.
2. Chemical Examination:
 - a. Pour a 10-mL aliquot of well-mixed specimen into an Uri System Tube (Fisherbrand #14-375-201).
 - b. Remove one Multistix 10SG reagent strip from bottle and replace cap. Completely immerse reagent areas of the strip in the urine specimen and remove immediately to avoid dissolving out reagents.
 - c. While removing, run the edge of the strip against the rim of the urine tube to remove excess urine. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas.
 - d. Reading Results:
 - Visually - compare reagent areas to corresponding color chart on the bottle label at the time specified below.

Glucose and Bilirubin	30 seconds
Ketones	40 seconds
Specific Gravity	45 seconds
Blood	60 seconds
pH, Protein, Urobilinogen and Nitrite	60 seconds
Leukocytes	2 minutes

Hold strip close to color blocks and match carefully for manual readings

- e. To verify of Abnormal Values:

Send specimen to UHB laboratory for verification and microscopic analysis.

 - Protein - verify all positive protein values in alkaline urines.
 - Bilirubin - verify all suspect positive bilirubin values.
 - Ketones - verify all suspect positive ketone values.
 - Glucose - verify all negative glucose values in the presence of a positive ketone value.
- f. **Reducing Substances - Perform Clinitest tablet test for reducing substances on all pediatric patients < 6 months of age.**

ACTION VALUES:

>3+ glucose and \geq trace ketones.

Positive reducing substances in infants.

VII. REFERENCE RANGES AND EXPECTED VALUE:

1. Appearance and Color - Clear yellow.
2. Specific Gravity - 1.005 - 1.030.
3. Chemical Examination
 - a. **Glucose - "Negative"** (Neg.)
Small amounts of glucose are normally below the sensitivity of the test but on occasion may produce a color between the "Negative" (Neg.) and the 1000 mg/dl. color blocks results at the first positive level may be significantly abnormal if found consistently.
 - b. **Bilirubin - "Negative"** (Neg.)
Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation.
 - c. **Ketones - "Negative"** (Neg.)
Normal urines ordinarily yield negative results. Detectable levels of Ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise.
 - d. **Blood - "Negative"** (Neg.)
The significance of the Trace reaction may vary among patients, and clinical judgment is required for assessment in an individual case.
 - e. **pH 5.0 - 7.0.**
 - f. **Protein - "Negative"** (Neg.)
Normally no protein is detectable in urine, although the normal kidney excretes a minute amount. A color matching any block greater than Trace indicates significant proteinuria.
 - g. **Urobilinogen 0.2 - 1.0 mg/dl**
A result of 2.0 mg/dl. represents the transition from normal to abnormal and the patient should be evaluated further.
 - h. **Nitrites - "Negative"** (Neg.)
Normally no nitrite is detectable in urine. The preparation of positive nitrite tests in cases of significant infection depends on how long the urine specimens were retained in the bladder prior to collection.
 - i. **Leukocytes - "Negative"** (Neg.)
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 results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge.
 - j. Reducing Substances - negative

VIII. EMPLOYEE CERTIFICATION :

Personnel certification is completed upon in-servicing, and is required to be **renewed six months after first training and annually thereafter**. Documentation of certification is maintained in the employee's personnel folder.

Training and certification of personnel will be conducted by the Institute of Continuous Learning annually.

Participants must demonstrate competency in the use of the Urine Test. This according to the established validation criteria:

- a) Visual Observation of the operator performing the test and ensuring that written policy and procedures are consistently followed.
- b) Evaluation of a problem solving skills.
- c) Assessment of testing performance through an external proficiency testing (CAP).
- d) Monitoring the recording and reporting of test results.
- e) Review of intermediate test results (QC, PT results)

IX REPORTING RESULTS:

All patient results must be documented in a Patient Logbook containing the following information:

DATE, TIME, PATIENT'S NAME, PATIENT'S MR#, ORDERING PHYSICIAN, TEST RESULT, NURSE.

Upon completion, each patient's urine test result will be entered into Cerner LIS via one of the following methods:

a)

Order entry in Point of Care Test in Cerner:

- 1) Click Point of Care Result entry
- 2) In Encounter Search Enter Patient's Name or Medical Record number or financial Account
- 3) Test Site: POC Urine
- 4) Orderable Field : POC Urinalysis
- 5) Specimen Type: Urine
- 6) Performed Date/Time:
- 7) Performed ID:
- 8) Type in Result:
- 9) Click on Performed and submit.

X. PROFICIENCY TESTING

Semi annually, staff that is performing testing at any given time will be presented with a proficiency challenge. This test will be process as a patient. The result of this proficiency will be sent to CAP for evaluation and upon return, results will be given to the nursing supervisor where regular testing is performed.

XI. LIMITATIONS:

Glucose:

1. Sensitivity 75 - 125 mg/dl. glucose.
2. Ascorbic acid concentrations of 50 mg/dl. or greater may cause false negatives.
3. Ketone bodies reduce sensitivity. Positive ketone levels may cause false negatives.
4. Reactivity of the glucose test decreases as the specific gravity increases.
5. Reactivity may also vary with temperature.

Bilirubin:

1. Sensitivity 0.4 - 0.8 mg/dl. bilirubin.
2. Indican (indoxyl sulfate) can produce a yellow-orange to red color response, which may interfere with the interpretation of a negative or positive reading.
3. Ascorbic acid concentrations of 25 mg/dl. or greater may cause false negatives.

Ketones:

1. Sensitivity 5 - 10 mg/dl. acetoacetic acid.
2. False positive results may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites.
3. Compounds such as mesne (2- mercaptolthane sulfonic acid) that contain sulfhydryl groups may cause false positive results on atypical color reaction.

Specific Gravity:

1. Chemical nature of the Multistix test may cause slightly different results from those obtained with other specific gravity methods when elevated amounts of certain urine constituents are present.
2. High buffered alkaline urines may cause low readings relative to other methods.
3. Elevated specific gravity readings may be obtained in the presence of moderate quantities (100-750 mg/dl.) of protein.

Blood:

1. Sensitivity 0.015 - 0.062 mg/dl. hemoglobin.
2. Elevated specific gravity or elevated protein may reduce the reactivity of the blood test.
3. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results.
4. Microbial peroxidases associated with urinary tract infection may cause a false positive reaction.
5. Ascorbic acid concentrations normally found in urine do not interfere with this test.

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 onto the pH area, causing a false lowering in the pH result.

Protein:

1. Sensitivity 15 - 30 mg/dl. albumin.
2. False positive results maybe obtained with highly buffered or alkaline urines.
3. Contamination of the urine specimen with quaternary ammonium compounds or with skin cleansers containing chlorhexidine may also produce false positive result.

Urobilinogen:

1. The absence of urobilinogen cannot be determined with this test.
2. The test is not a reliable method for the detection of porphobilinogen.
3. Strip reactivity increases with temperature. The optimum temperature is 22°-26° C.
4. False negative results may be obtained if formation is present.

Nitrite:

1. Sensitivity 0.06 - 0.1 mg/dl. nitrite ion.
2. Pink spots or pink edges should not be interpreted as a positive result.
3. Any degree of uniform pink color development - should be interpreted as a positive nitrate test.
4. Color development is not proportional to the number of bacteria present.
5. A negative result does not in itself prove that there is no significant bacteriuria "**Negative**" (Neg.) results may occur when:
 - a. Urinary tract infections are caused by organisms, which do not contain reductase to convert nitrate to nitrite.
 - b. Urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to nitrite to occur.
 - c. Dietary nitrate is absent, even if organisms containing reductase are presence and bladder incubation is ample.
6. Sensitivity of the nitrite test is reduced for urines with high specific gravity.
7. Ascorbic acid concentrations of 25 mg/dl. or greater may cause false negative results with specimens containing small amounts of nitrite ion (0.06 mg/dl. or less).

Leukocytes:

1. Sensitivity 5 - 15 cells/hpf in clinical urine.
2. Elevated glucose concentrations (≥ 3 g/dl.) or high specific gravity may cause decreased test results.
3. The presence of cephalixin (Keflin) cephalothin (Keflin), or high concentrations of oxalic acid may cause decreased test results.
4. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction.

XII. REFERENCES:

1. Davidson and Henry; Clinical Diagnosis and Management by Laboratory Methods. Seventeen edition. W.B. Saunders Company, Philadelphia, PA. 1984.
2. Freeman and Beeler; Laboratory Medicine/Urinalysis and Medical Microscopy Second edition. Lea & Fibiger, Philadelphia, PA. 1983.
3. Miles Inc, Elkhart, Indiana Ames Multistix 10SG Reagent Strips #2320AD.

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