Multistix 9® and Uristix® Urinalysis

PURPOSE

Urinalysis can be used to screen for disorders or infections of the urinary tract, as well as metabolic disorders affecting the urinary excretion of certain substances. Multistix Reagent Strips are used to rapidly determine urine specific gravity, pH, protein, blood, glucose, ketones, bilirubin, nitrite and leukocyte esterase. Uristix Reagent strips are used to rapidly determine protein and glucose only.

SCOPE

Multistix/Uristix urinalysis is performed on patients in both the hospital and ambulatory setting. It is used for performing urinalysis on adult and pediatric patients. Common reasons for the test include, but are not limited to:

- to determine the presence of infection in patients with urinary symptoms, such as urinary urgency or dysuria
- to determine the presence of glycosuria and ketonuria in patients with known or suspected diabetes
- to determine the presence of proteinuria in patients with known or suspected nephrosis
- to determine hydration status in patients who have experienced fluid loss

PERSONNEL

Intended for use by clinical personnel who have received training and demonstrated competency in this procedure. In the hospital setting, this includes Clinical Laboratory Scientists, Registered Nurses, Nurse Practitioners, Physician Assistants, Respiratory Tech. In the ambulatory setting, this includes the aforementioned personnel as well as Medical Assistants, Licensed Vocational Nurses and other licensed Technologists. Physicians performing the test in either the hospital or ambulatory setting must be credentialed to do so. Personnel who have difficulties with color discrimination must demonstrate ability to read the test.

REAGENTS, EQUIPMENT, AND MATERIALS

- Specimen containers
- Multistix Reagent Strips
• Uristix Reagent Strips
  - Store at room temperature (15-30°C) sealed in the original container
  - Do not store the bottle in direct sunlight
• Gloves
• Paper toweling
• Safety glasses or goggles
• Disposable plastic pipettes
• Urine-tek plastic test tubes
• CHEK-STIX Positive & Negative controls
  - Use for performing QC when each new bottle of test strips is opened and every 30 days after opening.
  - Store at room temperature (15-30°C) tightly capped in the original container
• Distilled or Deionized water

SPECIMEN REQUIREMENTS

Volume

2 ml of freshly voided urine

Criteria for Acceptable specimens

Clean-voided urine for culture is collected in a clean, dry, plastic cup with a non-leaking lid (non-sterile containers are OK).

Criteria for Specimen Rejection

• specimens collected more than 1 hour prior to testing
• urine contaminated by skin cleansers, stool, or vaginal discharge
• use of medications that cause abnormal urine color (such as Pyridium, Azo Gantrisin, Azo Gantanol, nitrofurantoin, and riboflavin), which may affect the readability of the reagent areas on the strip. Highly Colored urine sample should be sent to the laboratory for testing.

QUALITY CONTROL

Control Strips

CHEK-STIX Control Strips are used in a urinalysis quality control program in order to:
1. Determine if Multistix or Uristix Reagent Strips are reacting properly
2. Confirm user’s ability to properly perform and reliably interpret the reagent strip tests.
3. Enhance demonstration and teaching process.

Control Solutions

CHEX-STIX Positive and Negative Control Strips are used to check Multistix and Uristix reagent strips. For best results, performance of reagent strips should be confirmed by testing
specimens with negative and positive controls whenever a new bottle of reagent strips is first opened and every 30 days after opening.

**Preparation of Control Solution**

1. Place 12ml of distilled or deionized water in an appropriately labeled URIN-TEK tube or a tube of similar size (approximately 16 X 100 mm). *Do not use tap water.*
2. Remove a CHEK-STIX Positive Control Strip from the bottle and replace the cap immediately and tightly. Place the strip in the tube labeled “Positive”. Cap tightly.
3. Repeat Steps 1 – 2, using a CHEK-STIX Negative Control Strip
4. Gently invert the tube back and forth for 2 minutes.
5. Allow the tube to stand for 30 minutes at room temperature.
6. Invert one more time, then remove and discard the strip.

**Quality Control Procedure**

NOTE: Test positive and negative controls when a new bottle of strips is first opened. Subsequently, QC strips monthly when in use and stored for more than 30 days.

1. Completely immerse a Multistix/Uristix reagent strip into the Negative Control Solution and remove immediately.
2. While removing strip from the control solution, run the edge of the entire length of the strip against the rim to remove excess solution.
3. Hold the strip in a horizontal position to prevent possible mixing of chemicals from the adjacent reagent areas.
4. Following directions for proper read time, compare reagent areas to corresponding color chart on bottle.
5. Record the results on the QC log.
6. Repeat step one with the Positive Control Solution.
7. If an unexpected result occurs with either the Negative or Positive Solutions, repeat the test. If the unexpected results continue to occur, the bottle of reagent strips should not be used for patient testing. Return the strips to Material Services for investigation.

Note: If excess solution is not removed from the strip, a phenomenon called “runover” may occur in which the acid buffer from the protein reagent will run onto the pH area causing a lowering of the pH result. If the color on the pH area is not uniform in color, read and compare the darkest area of the pad to the Color Chart.

**DOCUMENTING QUALITY CONTROL**

1. The results of the quality control tests performed using both Positive and Negative solutions must be recorded on the QC Log sheet each time QC is performed.
2. Test strips must be QC’d monthly when stored for more than 30 days and results documented on the QC log.
3. Write the date and your initials on the bottle each time QC has been performed.
STORAGE AND HANDLING

Product

To preserve result integrity, always use CHEK-STIX® Control Strips with this product and no other commercial control strips.

Storage

Test Reagent Strips and CHEK-STIX Control Strips must be stored in their original, tightly capped bottles at room temperature between 15° - 30° C (59° - 86° F). Do not remove desiccant from bottle. Do not store the bottle in direct sunlight. Do not use product after expiration date.

Control solution is prepared by reconstituting a CHEK-STIX® control strip with deionized or distilled water. Once prepared, control solution should be stored at temperatures under 30° C. The solution is stable for 8 hours after preparation except for bilirubin in the Positive Control, which is stable for 3 hours under normal conditions. Ketone reactivity in the Positive Control will increase with time due to continued hydrolysis of the reactive ingredient.

If using deionized water, it must meet the minimum quality specified in CLSI Guideline C03-A4 ‘Preparation and Testing of Reagent Water in the Clinical Laboratory.’

Handling

Do not remove the strip from the bottle until immediately before it is to be used for testing. Do not touch areas of the reagent strip. Replace cap immediately and tightly after removing reagent strip.

Sample for culture can be submitted to Microbiology after performing dipstick testing on the original urine cup.

Quality Control

Positive and negative controls must be run everytime a new bottle of Multistix or Uristix reagent strips is opened and every 30 days after opening. Initial and subsequent QC results must be recorded on the QC Log.

PROCEDURE

Specimen Collection

Using two patient identifiers, verify patient identification, and explain urine collection procedure to patient and/or family. If sample is not obtained from the patient by the person who will perform testing, and testing is not performed immediately, then the specimen container (not the lid) must be labeled with two forms of patient identification in the presence of the patient.
Females: While the labia are held apart, the vulva is thoroughly washed from front to back with two successive cleansing pads as supplied. Special attention should be paid to the urethral meatus - benzalkonium, chlorhexidine or hexachlorophene should not be used, as contamination of the collection with residual disinfectant can sterilize the urine sample. The patient should not halt and restart the urine stream for a “midstream” collection, but preferably should move the container into the path of the already voiding urine.

Males: The process is similar to that described above. The foreskin is retracted, and the glans penis is thoroughly washed with two successive cleansing pads as supplied, special attention being paid to the urethral meatus.

Analysis should be performed within 1 hour of collection or the specimen must be refrigerated. Specimen must return to room temperature before testing.

CAUTION: Ensure that work areas and specimen containers are always free of detergents and other contaminating substances. Some substances can interfere with patient results.

Testing Procedure

1. Put on gloves and protective eyewear.
2. Remove one reagent strip from bottle, and replace cap tightly.
3. Completely immerse reagent areas of strip in FRESH urine and remove immediately.
4. While removing strip from urine, run the edge of the entire length of strip against the rim to remove the excess urine.
5. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas.
6. Under good lighting conditions, (but not direct sunlight), compare test area to corresponding color chart on the bottle. Proper read time is critical for optimal results, so read reagent areas at the times specified on the bottle.
7. Hold strip close to color blocks and match carefully, making certain that the strip is oriented appropriately.
8. Avoid laying the strip directly on the color chart, as this will result in the urine soiling the chart.
9. Reading uristix: read protein immediately up to 2 minutes, and glucose after 30 seconds.
10. Reading multistix: read pH and protein immediately up to 2 minutes, glucose and bilirubin after 30 seconds, ketone 40 seconds, specific gravity 45 seconds, blood and nitrite at 60 seconds, and leukocytes at 2 minutes.

Note: If excess solution is not removed from the strip, a phenomenon called “runover” may occur in which the acid buffer from the protein reagent will run onto the pH area causing a lowering of the pH result. If the color on the pH area is not uniform in color, read and compare the darkest area of the pad to the Color Chart.
RESULTS AND REPORTING

Record results on the Multistix/Uristix Urinalysis Patient Results Log and/or in the patient’s medical record. The patient’s provider should be notified according to practice guidelines or MD order.

NOTE: Whenever a user identifies that an incorrect result has been reported, they are responsible for correcting/commenting the incorrect result (if possible), contacting the ordering provider, notifying them of the error, and documenting this notification, including the time and date, in the patient record.

INTERPRETATION

Interpretation of the test results will be made by the patient’s health care provider. General interpretation guidelines are provided below.

NORMAL VALUES:

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<th>Test</th>
<th>Value</th>
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<td>Glucose</td>
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<td>Bilirubin</td>
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<tr>
<td>Ketone</td>
<td>Negative</td>
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<tr>
<td>Specific Gravity</td>
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<tr>
<td>Blood</td>
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<tr>
<td>pH</td>
<td>4.6-8.0</td>
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<tr>
<td>Protein</td>
<td>Negative</td>
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<tr>
<td>Nitrite</td>
<td>Negative</td>
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<tr>
<td>Leukocytes</td>
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Glucose: Small amounts of glucose (<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 first positive level may be significantly abnormal if found consistently.

Bilirubin: Normal adult urine contains about 0.02 mg/dL of bilirubin, which is not detectable by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Since very small amounts of bilirubin (0.1 mg/dL or greater) may be found in the earliest phases of liver disease, the user must consider whether the sensitivity of Siemens Reagent Strips to bilirubin is sufficient for intended use.

Ketone: Normally, no ketone is detectable in urine (up to 2 mg/d: acetoacetic acid). In ketoacidosis, starvation or with other abnormalities of carbohydrate of lipid metabolism, ketones may appear in urine at levels of 10 mg/dL or higher before serum ketone levels are elevated. 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.

Specific Gravity: The normal SG of urine ranges from 1.001-1.035. If the specific gravity of random urine is 1.023 or greater, the concentrating ability of the kidney can be considered normal.
**Blood:** Normally, no hemoglobin is detectable in urine (<0.010mg/dL or 3RBC/µL). Occult blood occurs in urine as intact erythrocytes and hemoglobin, which can occur during urological, nephrological and bleeding disorders. Small amounts of blood (0.030-0.065 mg/dL or a strip result of Small) are sufficiently abnormal to require further investigation. The significance of the Trace reaction may vary among patients, and clinical judgment is required for assessment in an individual case. Blood is often, but not always, found in the urine of menstruating women.

**pH:** The normal pH or urine can range from 4.6 to 8.0. Certain dietary conditions can produce acid or alkaline urines, which can be useful in the treatment of some calculi.

**Protein:** Protein in urine can be the result of urological and nephrological disorders. 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 also indicate tubular or overflow proteinuria in the absence of any glomerular abnormality or proteins or renal origin that may be excreted during infection. Urinary protein excretion can be temporarily elevated in the absence 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.

**Nitrite:** Normally no nitrite is detectable in urine. Many enteric gram-negative organisms give positive results when their number is greater than $10^5$/mL (0.075 mg/dL nitrite ion or greater).

**Leukocytes:** Normal urine specimens generally yield negative results. 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 often be present in non-infective conditions. A strip result of Small or greater is a useful indicator of infection. Trace results may be of questionable clinical significance; however, Trace results observed repeatedly may be clinically significant.

**ALTERNATIVE TEST METHODS**

Freshly voided or refrigerated specimens may be sent to the Clinical Lab for testing.

**LIMITATIONS/INTERFERENCES**

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.

Substances that cause abnormal urine color may affect the readability of test pads on urinalysis reagent strips. 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. Highly colored urine samples should be sent to the laboratory for testing.

**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 a low glucose level is metabolically improbable in screening.
**Bilirubin:** Indican (indoxyl sulfate) can produce a yellow-orange to red color response that may interfere with the interpretation of a negative or positive reading. Metabolites of Lodine (etodolac) may cause false positive or atypical results. Atypical colors (colors that are unlike the negative or positive color blocks shown on the Color Chart) may indicate that bilirubin-derived bile pigments are present in the urine sample and may be masking the bilirubin reaction. These colors may indicate bile pigment abnormalities and the urine specimen should be tested further.

**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.

**Specific Gravity:** The Siemens SG test is dependent on ions in urine and results may differ from those obtained with other specific gravity methods when certain nonionic urine constituents, such as glucose, are present. Highly buffered alkaline urines may cause low readings, while the presence of moderated quantities of protein (100-750 mg/dL) may cause elevated readings.

**Blood:** Capoten (captoril) may reduce the sensitivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction.

**pH:** Bacterial growth by certain organisms in a specimen may cause a marked alkaline shift (pH >8.0), usually because of urea conversion to ammonia.

**Protein:** A visibly bloody urine may cause falsely elevated results.

**Leukocytes:** Elevated glucose concentrations (≥3 g/dL) may cause decreased test results. The presence of cephalaxin (Keflex), cephalothin (Keflin), or high concentration 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. Positive results may occasionally be due to contamination of the specimen by vaginal discharge.

**Nitrite:** Pink spots or pink edges should be interpreted as 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.

**DOCUMENTATION & RECORDS MAINTENANCE**

Retired Quality Control and Test Result Logs are kept in an accessible area for three years, as required by law. Patient Test Results are also documented in the patient’s medical record. Obsolete or revised procedures are removed to Discontinued Procedure binders for historical review when needed.
REFERENCES
Siemens Multistix® insert, rev. 06/10
Siemens Uristix® insert, rev. 08/08
Siemens Healthcare Diagnostics Inc. Tarrytown, NY 10591-5097 USA
Siemens Chek-Stix® insert, rev. 09/08
UCSF Medical Center Laboratory Manual On-Line, 2011
PROCEDURE REVIEW COVER SHEET

Procedure Title: MULTISTIX AND URISTIX URINALYSIS

Author: Department of Nursing

Director: Tim Hamill, M.D.

In Use Date: July 30, 2002

Discontinued Date________________

ACTION: Reviewed or Revised/Approved

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### Signature Manifest

**Document Number:** SOP-0053  
**Title:** MultiUR1stix Procedure

All dates and times are in Pacific Standard Time.

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### Multistix 9SG Procedure

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**SR Sup Review**

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**Med Dir Apprvl**

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