


Director's Approval \_\_\_\_\_ Date \_\_\_\_\_

 <p><b>UCSF</b> Medical Center <b>Clinical Laboratories</b></p>	<p><b>Point of Care Testing</b></p>
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## **Multistix® 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**

Multistix/Uristix is intended for use by clinical personnel who have demonstrated competency in this procedure. Personnel who have difficulties with color discrimination must demonstrate the ability to properly interpret color changes in the reagent areas. In the hospital setting, the test may be performed by Registered Nurses, Medical Technologists and Physicians. In the ambulatory setting, the test may be performed by Medical Assistants, Licensed Vocational Nurses, Registered Nurses, and Physicians.

## **REAGENTS, EQUIPMENT, AND MATERIALS**

- Specimen containers
- Multistix Reagent Strips
- Uristix Reagent Strips
  - Store at room temperature (15-30C) 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 to perform QC when opening each new bottle of test strips
  - Store at room temperature (15-30C) 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.

## **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

CHEK-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.

### **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 2-3, 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**

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 should be recorded on the QC Log.
2. Write the date and your initials on the bottle to denote that 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; however, the positive control for bilirubin may be affected over time.

### 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.

### Quality Control

Positive and negative controls should be run everytime a new bottle of Multistix or Uristix reagent strips is opened. 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.

## LIMITATIONS/INTERFERENCES

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

## INTERPRETATION

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

**Specific Gravity:** Reported as  $\leq 1.005$  to  $\geq 1.030$ ; the level found depends upon water intake; a fixed level around 1.010 which does not vary with the state of the patient's hydration suggests renal damage.

**pH:** Reported over the range of 5.0 to  $\geq 9.0$  and is diet-dependent; a level  $> 9.0$  suggests infection with a urea-splitting organism.

**Bilirubin:** False-positive results for bilirubin may occur due to the intrinsic coloration of urine. If concerns exist in this regard a sample should be sent to the clinical laboratory for confirmatory testing.

**Hemoglobin:** Dipstick testing does not distinguish between hemoglobin and myoglobin. To evaluate the possibility of myoglobinuria due to rhabdomyolysis send a serum sample to the clinical laboratory for Total CK, which will be markedly elevated in rhabdomyolysis.

**Nitrite:** A positive urinary nitrite test is highly suggestive of a urinary infection, but in a low risk population may detect as few as 50% of infections found on culture, particularly if urinary frequency is high, the diet is low in nitrate substrate or, of course, if the organisms are not nitrite-producers.

## ALTERNATIVE TEST METHODS

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

## 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

Bayer Chek-Stix® insert, revised 7/04

Siemens Multistix® insert, rev. 08/08

Siemens Uristix® insert, rev. 08/08

Siemens Healthcare Diagnostics Inc. Tarrytown, NY 10591-5097 USA

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