POC URINE URISTIX (DIPSTICK) PROCEDURE

DATE PREPARED: 3/98

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DATE ACCEPTED: 3/98

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REPLACES: N/A

REVIEWED BY:
DATE MANAGER COMMENTS
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11/07 Procedure review / Website added ____________________

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I. **TITLE:** POC URINE URISTIX (DIPSTICK) PROCEDURE

II. **PRINCIPLE:**

Reagent strips contain separate test pads for determinations of protein, leukocytes, nitrite, and glucose in urine. The strips are intended for use in assisting diagnosis in the following areas: kidney function, urinary tract infections, carbohydrate metabolism (e.g. diabetes mellitus). Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

**Glucose:** Based on a double sequential enzyme reaction. Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Peroxidase catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown.

**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.

**Nitrite:** This test depends upon the conversion of nitrate (derived from the diet) 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.

**Leukocytes** Granulocytic leukocytes contain esterases that catalyze the hydrolysis of the 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.

III. **SPECIMEN REQUIREMENTS:**

Fresh urine specimen collected in a clean, dry container. Refer to “Urine Specimen Types and Collection Procedure” Policy 7.1 under Pathology on the LSUHSCS website. Testing should be performed immediately.

If testing is to be delayed for more than one hour, the specimen should be placed in the refrigerator (2-8 C). Prior to performing the test, the specimen must be allowed to return to room temperature (approximately 15 minutes).

NOTE:* Do not centrifuge the specimen prior to testing.
* Always mix thoroughly prior to testing.
* Do not use chemical preservatives.
* Refer to Procedural Notes for additional information.

IV. REAGENTS AND SUPPLIES:

1. Uristix 4 Reagent Strips - store at room temperature. **Do not** remove the desiccant from the bottles. **Keep tightly capped** at all times. Remove **only** the quantity of strips to be **immediately used** and replace cap immediately to prevent deterioration. **Do not** transfer strips to another container. Indicate date and initials of person opening container when first put into use (PIU). **Do not** touch the test area of the strips. **Do not** store bottle in direct sunlight. **Do not** use after expiration date printed on bottle label. Discoloration or darkening of test pads prior to testing may indicate deterioration.

   **Glucose** - 2.2% w/w glucose oxidase; 1.0% w/w peroxidase; 8.1% w/w potassium iodide; 69.8% w/w buffer; 18.9% w/w nonreactive ingredients.
   **Protein** - 0.3% w/w tetrabromphenol blue; 97.3% w/w buffer; 2.4% w/w nonreactive ingredients.
   **Nitrite** - 1.4% w/w ρ-arsanilic acid; 1.3% w/w1,2,3,4-tetrahydrobenzol(h)-quinolin-3-ol; 10.8% w/w buffer; 86.5% w/w nonreactive ingredients.
   **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.

   Siemens Reagent Strips are for in vitro diagnostic use. They have been determined to by nonhazardous under the guidelines issued by OSHA in 29 CFR 1910.1200(d).

2. Timer or watch capable of telling seconds.

3. Quantimetrix Dropper Plus Urine Controls - Level 1 and Level 2 - 5 mls per bottle. When stored at 2-8C, unopened controls are good until expiration date on bottle.
   If stored in the refrigerator, controls must be allowed to come to room temperature (@ 15-30 minutes) prior to use. **Date and initials must be written on controls when put into use**. Once opened, controls are **good for one month**. Discard controls if turbid or any evidence of microbial contamination is present.
V. **CALIBRATION:**
Not Applicable.

VI. **QUALITY CONTROL:**
Two levels of Quantimetrix Dropper Plus controls (one normal and one abnormal) are run as indicated below.

- **Control tests are performed and recorded in Quality Control Log...**
  - a. On each bottle of test strips every day of use
  - b. Each time a new bottle of test strips is opened
  - c. When a bottle of strips has been left opened to ensure reagent storage integrity
  - d. When the test strips have been exposed to extreme heat, humidity or cold
  - e. When test results contradict clinical symptoms

- All corrective action **must** be recorded in the comment area of the log.
- If a quality control test result falls within the acceptable control range, it is acceptable to proceed with patient testing.
- If a quality control test result falls outside of the acceptable control range, the following should be checked/performed:
  - a. ...repeat test. If results are within acceptable ranges, continue, if results are not within acceptable ranges, go to step b.
b. ...check expiration dates of strips and verify controls are not expired. If expired, replace and repeat test. If not expired, go to step c.

c. ...try a new vial of strips. If acceptable, discard old strips and continue. If unacceptable, go to step d.

d. ...try new controls. If acceptable, discard old controls and continue. If unacceptable, go to step e.

e. ...call the POC section of the Clinical Laboratory at ext. 57951 or 55572. If necessary, send specimen to laboratory for testing until quality control problem is resolved.

• In areas where dipsticks are not being used daily, quality control will be performed when patient testing/CAP proficiency testing is required.

• Internal proficiency testing to verify operator competency will be performed according to the institution’s policy.

• The POC coordinator or designee will review the quality control records for completion monthly, as well as note any trends that may indicate potential problems. These trends include: gradual drifting of values, sudden shifts in control values while using the same lot of strips, and operator performance.

VII. PROCEDURE:

A. Patient Testing – All INSTRUCTIONS MUST BE FOLLOWED EXACTLY!
Standard precautions should always be followed.
Always wear gloves when handling specimens or performing test! Follow appropriate institutional guidelines for gloves, handwashing, and specimen disposal. Work areas and specimen containers should always be free of detergents and other contaminating substances.

1. Collect a FRESH urine specimen in a clean, dry container. Mix well just before testing. Specimen identification must be placed on the container.
2. Remove one strip from the bottle and replace the cap immediately. Do not touch the test pads of the strip.
3. Completely immerse test pads of the strip into the specimen and then remove immediately. Allowing the strip to sit in the specimen will result in reagent deterioration.
4. While removing the strip from the specimen, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent test pads.

5. Compare the reagent test strip areas to the Color Chart on the side of the bottle. **Read time is critical for optimal results.** HOLD THE STRIP CLOSE TO COLOR BLOCKS WITHOUT ALLOWING THE STRIP TO TOUCH THE BOTTLE AND MATCH CAREFULLY THE FOLLOWING TEST AT THE TIMES INDICATED:

   From time dipped, after .....  
   30 Seconds - Glucose  
   60 Seconds - Protein, Nitrite  
   2 Minutes - Leukocytes  

6. Record results as specified by unit policy (log, patient chart, flowsheet, etc.).

**B. Quality Controls**

1. On initial use remove the control from the refrigerator and allow to come to room temperature (@15-30 minutes).

2. Label the controls with initials and put in use date. Controls will expire in 30 days. Label the controls with the new expiration date.

3. Remove cap and invert bottle. While holding dipstick, gently squeeze sides of the dropper bottle, and touch the tip of the bottle to the dipstick. Draw across the reagent pads, thoroughly saturating each pad. Do not aspirate excess control back into the bottle. Turn dipstick on its side and drain excess control onto absorbent material.

4. Read the urine dipstick visually.

5. Wipe off dropper tips and recap controls. Once put in use, controls can be stored at room temperature for 30 days.

**C. Proficiency (CAP) Testing**

Follow the same instructions as Patient Testing substituting the Proficiency Survey Sample for the specimen.

**VIII. CALCULATIONS:**

Not Applicable.
IX. REPORTING RESULTS:

Expected Results for typically “normal” healthy populations:

Glucose - Small amounts are normally excreted by the kidney. These amounts are generally below the sensitivity of the test. On occasion a color between the negative and the first block (100 mg/dL) may occur. Results at the first positive level may be significantly abnormal if found consistently.

Protein - Negative
Note: All results greater than trace indicate significant proteinuria. Urines with high specific gravities may most closely match the Trace color block even though only normal concentrations of protein are present.

Nitrite - Negative

Leukocytes - Negative

X. PROCEDURAL NOTES:

1. If testing is to be delayed for more than one hour, the specimen should be placed in the refrigerator (2-8°C). Prior to performing the test, the specimen must be allowed to return to room temperature (@15 minutes).
2. Do not centrifuge the specimen prior to testing.
3. Always mix thoroughly prior to testing.
4. Do not use chemical preservatives.
5. Nitrite test results are optimized by using first morning specimen or one that has incubated in the bladder for four hours or more.
6. Urine left at room temperature for prolonged periods of time can result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results for protein. Urines with glucose may decrease in pH as organisms metabolize the glucose. Bacterial growth from contaminating organisms may cause false positive blood reactions.
7. Random specimens on females, may give a positive result for leukocytes due to contamination by vaginal discharge.
8. Read time is critical for optimal results. Hold the strip close to color blocks without allowing the strip to touch the bottle and match carefully the reagent pads at the appropriate times.
9. Urines with high specific gravities may most closely match the Trace color block even though only normal concentrations of protein are present.

XI. LIMITATIONS OF PROCEDURE:
1. **Sensitivity** - General detectable levels are listed, however, lesser concentrations may be detected under certain conditions.

<table>
<thead>
<tr>
<th>Test</th>
<th>False Positive</th>
<th>False Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>Strongly, oxidizing cleansing agents</td>
<td>Ascorbic Acid, with glucose values &lt; 100mg/dL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High ketone bodies</td>
</tr>
<tr>
<td>Protein</td>
<td>Strongly basic urine (pH 9 or greater), Bloody urine</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>phenazopyridine, polyvinylpyrrolidine,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(blood substitutes), chlorohexidine</td>
<td></td>
</tr>
<tr>
<td>Nitrite</td>
<td>Medication color (phenazopyridine)</td>
<td>shortened bladder incubation of the urine, absence of</td>
</tr>
<tr>
<td></td>
<td></td>
<td>dietary nitrate, or presence of nonreductive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>pathological microbes</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>Contamination by Vaginal discharge</td>
<td>Tetracycline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cephalexin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Glucose conc &gt;3 gms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oxalic acid</td>
</tr>
</tbody>
</table>
XII. REFERENCES:

9. Quantimetrix Dropper Plus Urine Dipstick Control Package Insert, Quantimetrix 2005 Mannhattan Beach Blvd., Redondo Beach CA 90278-1205 USA MO44753A – 10/10
10. Siemens Uristix 4 Package Insert, Siemens Healthcare Diagnostics, Inc . Tarrytown, NY 10591-5097 USA

XIII. DISTRIBUTION:

This procedure is on file in the Point-of-Care section of the Clinical Laboratory and in the LSUHSC website under Point-of-Care procedures.