Multistix PRO

In Service Training

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Training Agenda

- Kidney Disease Statistics
- Multistix PRO® Test Strip Overview
- Getting Ready to Test
- Results Interpretation
- Ordering and Reimbursement Information
Statistics

Kidney Disease
Kidney Disease is an Under-Recognized Public Health Crisis

- **30 million** people are have chronic kidney disease
- 90% of those affected don't know it
- **1 out of 3** Americans at risk of developing kidney disease
- Diabetes and Hypertension account for **2/3 of cases**
- >$100 billion spent to treat kidney disease

1 National Kidney Disease 2016 Fact Sheet
Common Risk Factors May Impact Family and Friends

National Kidney Foundation (NKF) updated the risk factors to include persons with:
• Diabetes
• High blood pressure (hypertension)
• Age 60 or older
• Family history of kidney failure requiring dialysis or transplantation

Annual screening test recommended by NKF:
• Urinary albumin-to-creatinine test
• Blood tests for kidney function
• Glomerular filtration rate (GFR)

Overview

Multistix PRO Urine Test
What is Multistix Pro Urine Test?

• Semiquantitative urine test that provides results in minutes
• Includes test parameters for use in at-risk patient groups to assist diagnosis of:
  ✓ Kidney function
  ✓ Urinary tract infections
  ✓ Carbohydrate metabolism
• Includes a low protein pad, creatinine test pad
• Provides a protein-to-creatine (P:C) ratio which adjusts for varying urine concentration
What is the Value of Multistix PRO Urine Test?

1. A tool that measures clinical albuminuria:
   - Multistix PRO test strips measures low levels of protein in urine in the 8 to 15 mg/dL range (by definition, this is albuminuria)

2. A more robust test strip for protein assessment since creatinine is also measured and provides a protein-to-creatinine test result

3. Offers clinical, operational and financial benefits:
   - May reduce the false positive and false negative protein results
   - Reduces the number of samples for confirmatory testing
   - Identifies elevated, clinically significant proteinuria samples
Multistix PRO: Protein Pad Overview

- Multistix PRO test strip has two protein pads:
  - Protein low specifically detects very low levels of albumin (traditionally referred to as microalbumin)
  - Protein high measures protein other than albumin; however not specific for any particular protein
- Multistix PRO test strip has the sensitivity to detect low levels of albumin
- Results from both test pads are used, in conjunction with results from the creatinine pad to determine the protein-to-creatinine ratio (PCR)

Why is Creatinine Adjustment Important?

Two asymptomatic patients present with the same amount of protein in urine.

**Concentrated Urine**

- Patient A
  - (first morning void)

**Dilute Urine**

- Patient B
  - (after several glasses of water)

Urine Concentration Can Impact Protein and Cause False Positive or False Negative Results

- Creatinine is a normal waste product produced by muscle cells, *excreted at a constant rate*.
- It can be an indicator of patient hydration status.

**Source:** [www.niddk.nih.gov](http://www.niddk.nih.gov), [www.kidney.org](http://www.kidney.org)
Getting Ready to Test

Multistix PRO
Urine Test
What You Will Need to Perform Test

• Patient urine sample
• Multistix PRO test strip bottle
• Analyzer
• Color chart on bottle and result interpretation grid in Instructions for Use, if visually interpreting the results
• Quality control solution
• Paper towels
Sample Handling Recommendations

• Random collection is acceptable
• Urine container should allow for complete dipping of all reagent strip areas
• Urine must be tested within 2 hours after voiding
• If testing cannot be performed within 2 hours after voiding, immediately refrigerate
• Do not use urine preservatives
• Refrigerated specimens must be returned to room temperature before testing between 15 – 30°C (59 - 86°F)
• Collect specimen in a clean, dry container.
• Mix well just before testing, do not centrifuge
Test Strip Storage and Handling Recommendations

• Bottles must be stored at 15 - 30°C (59 - 86°F)
• Keep unused test strips in bottle with cap securely closed at all times
• Use test strips before the expiration date printed on bottle label
• Do not store bottles in direct sunlight
• Do not remove desiccant provided inside the bottle

Note: Protection against exposure to light, heat and ambient moisture is mandatory to guard against altered reagent reactivity
Proper Testing Technique for Patient Testing

• Do not touch the test pads on the test strip

• Dip all the test pads* into the urine and immediately remove the test strip

• For CLINITEK Status® Urine Chemistry Analyzer, follow the 4-step technique shown Only begin the dipping process after pressing the start button on the CLINITEK Status analyzer
  ✓ Dipping the test strip before pressing the START button may impact test results

• For CLINITEK Advantus® Urine Chemistry Analyzer, the same technique applies except there is no need to blot the strip prior to placing on the analyzer

Note: The ID band can be dipped into the urine and control specimens
Avoiding Errors

• Record the opening date on the bottle label when opening a new bottle
• Use a barcode reader to automatically record lot and expiration dating; analyzer will not allow expired strips to generate test result
• Remove test strip from the bottle and replace the bottle cap to minimize humidity exposure
  ✓ If using the CLINITEK Status family of analyzers or CLINITEK Advantus analyzers, Auto-Cheks® feature will check for humidity overexposure and prevent testing
• Do not test on visibly bloody urine (> 5 mg/dL) may cause falsely elevated results

Note: The ID band can be dipped into the urine and control specimens
Quality Control Recommendations

- Test negative and positive control when opening a new bottle.
- For CLIA-waived labs:
  - Test negative and positive controls with new lots, new shipments, when opening a new bottle and monthly for bottles stored more than 30 days
  - Run QC tests to train new users, confirm test performance and when patient’s clinical condition do not match test results
- If QC test results fail, do not test patient samples until problem is addressed
- Repeat QC tests until acceptable results are achieved

**Recommended QC Materials to Use:**

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Form Supplied</th>
<th>Shelf Life</th>
<th>Use Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantimetrix</td>
<td>Liquid Ready</td>
<td>Stable for 7-8 months at 2-8C, or until expiration date on bottle</td>
<td>Do not freeze. After initial use, each tube of control is stable for 3 months or 20 dipstick immersions, whichever occurs first.</td>
</tr>
<tr>
<td>Dipper Urine Dipstick Control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BIO-RAD quAntify Plus Control</td>
<td>Liquid Ready</td>
<td>Stable for 2 yrs at 2-8C</td>
<td>Opened bottle is stable for 31 days when stored tightly capped at 2-25C. Do not Freeze or store in direct light</td>
</tr>
<tr>
<td>BIO-RAD quAntify Control</td>
<td>Liquid Ready</td>
<td>Stable for 12-15 months at 2-8C, or until expiration date on bottle</td>
<td>Opened bottle is stable for 31 days when stored tightly capped at 2-25C. Do not freeze</td>
</tr>
</tbody>
</table>

Note: Do not use water as a negative control
Results Interpretation

Multistix PRO Urine Test
How to change paragraph levels

- All levels font Calibri 26 pt.
- Level 1 is subtitle, Bold, no bullet.
- Level 2 is bulleted: Regular, no indent.
- Level 3 is bulleted: Regular, indent 7.5 mm.
- Level 4 is bulleted: Regular, indent 15 mm.
- Level 5 is bulleted: Regular, indent 2.25 mm.

Switch between Text and bullet levels:
- click

### Protein-to-Creatinine Results Interpretation by CLINITEK Status Analyzers

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Units</th>
<th>Instrument Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>mg/dL</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>300</td>
</tr>
<tr>
<td>Creatinine</td>
<td>mg/dL</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>200</td>
</tr>
<tr>
<td></td>
<td></td>
<td>300</td>
</tr>
<tr>
<td>Protein-to-Creatinine Ratio</td>
<td>mg/g</td>
<td>Normal dilute</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Normal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>150 mg/g (Abnormal)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>300 mg/g (Abnormal)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;500 mg/g (Abnormal)</td>
</tr>
</tbody>
</table>

0 2 15 30 mg/dL

Normal Microalbuminuria | Albuminuria | Proteinuria
**Protein-to-Creatinine Result for Visual Interpretation***

<table>
<thead>
<tr>
<th>Reported Protein Result (mg/dL)</th>
<th>Dilute Urine</th>
<th>Creatinine Result (mg/dL)</th>
<th>Concentrated Urine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>Negative</td>
<td></td>
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<tr>
<td>15</td>
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<tr>
<td>100</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>300</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Not preferred since analyzer algorithms are more precise*
Ordering and Reimbursement Information

Multistix PRO Urine Test
# Multistix PRO – Ordering Information

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>10331147</td>
<td>Multistix PRO 10 LS Reagent Strips</td>
<td>1 bottle (100 test strips)</td>
</tr>
<tr>
<td>10332782</td>
<td>Multistix PRO 10 LS Reagent Strips</td>
<td>1 bottle (25 test strips)</td>
</tr>
<tr>
<td>10379675</td>
<td>CLINITEK Status+ Analyzer</td>
<td>1 each</td>
</tr>
<tr>
<td>10470849</td>
<td>CLINITEK Status Connect System</td>
<td>1 each</td>
</tr>
<tr>
<td>10636672</td>
<td>CLINITEK Advantus Analyzer</td>
<td>1 each</td>
</tr>
</tbody>
</table>
## Multistix PRO CPT Codes

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81000</td>
<td>Urinalysis, by dipstick or tablet reagent; non-automated, with microscopy</td>
</tr>
<tr>
<td>81001</td>
<td>Urinalysis, by dipstick or tablet reagent; automated, with microscopy</td>
</tr>
<tr>
<td>81002</td>
<td>Urinalysis, by dipstick or tablet reagent; non-automated, without microscopy</td>
</tr>
<tr>
<td>81003</td>
<td>Urinalysis, by dipstick or tablet reagent; automated, without microscopy</td>
</tr>
<tr>
<td>82570</td>
<td>Creatinine, other source</td>
</tr>
</tbody>
</table>

**CHOOSE 1 (81000, 81001, 81002 or 81003) plus 82570**

* Abridged CPT code descriptors
Thank you for your enthusiasm!

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