CLINITEK Microalbumin 2 Reagent Strips

In-service Training

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Training Agenda: CLINITEK® Microalbumin 2 Reagent Strips

• Diabetes and Kidney Disease Statistics
• Test Overview
• Getting Ready to Test
• Results Interpretation
• Ordering and Reimbursement Information
Statistics

Kidney Disease
Diabetes Is a Leading Chronic Disease, and Its Burden Continues to Grow

1. Number of people with chronic conditions increasing to **171 million** by 2030
2. 33.5 million people diagnosed with diabetes
3. 12 million adults with undiagnosed diabetes
4. 1 in 3 adults at increased risk of CKD or ESRD
5. 73 million adults
6. >$400 billion spent to treat diabetes

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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)
American Diabetes Association: Standards of Medical Care

• Recommendations for annual check with a urinary albumin test.

• Supports urinary albumin-to-creatinine ratio in a random spot urine collection.

• Measurement of a spot urine sample for albumin alone (whether by immunoassay or by using a sensitive dipstick test specific for albuminuria) without simultaneously measuring urine creatinine (Cr) is susceptible to false-negative and false-positive results.

• Two to three specimens collected in 3 to 6 months to confirm albuminuria with UACR.

http://care.diabetesjournals.org/content/suppl/2017/12/08/41.Supplement_1.DC1
Overview

CLINITEK® Microalbumin 2 Urine Test
What is the CLINITEK Microalbumin 2 Urine Test?

- Semiquantitative urine test that provide results in minutes.
- Provides results for albumin, creatinine, and albumin-to-creatinine (A:C) ratio.
- For screening samples for microalbuminuria; positive results should be confirmed with quantitative methods for albumin.
- For patients with diabetes and hypertension and at risk of developing kidney disease and preeclampsia.
- Test results may aid clinicians in the detection of patients at risk of developing kidney damage.
What Is the Value of the CLINITEK Microalbumin 2 Urine Test?

1. A tool that measures albuminuria as low as 10 mg/dL.
2. A more robust test strip for albumin assessment, since it measures creatinine and provides an albumin-to-creatinine ratio.
3. Offers clinical, operational, and financial benefits:
   - May reduce false-positive and false-negative results versus measuring albumin alone.
   - Identifies elevated, clinically significant albumin samples.
   - Affordable frontline test for early detection of kidney disease in at-risk patients.
What is Albuminuria?

- Albumin is a type of protein found in blood.
- Helps build muscle, repair tissue, and fight infection.
- Protein from damaged kidneys may leak into urine.
- Albumin is smaller in molecular weight than any of the other proteins.
- Low levels of albumin in the urine of patients with diabetes is clinically significant.
- Urine concentration can impact the albumin measurement.

### What Do Frontline Urine Dipstick Tests Measure?

<table>
<thead>
<tr>
<th>Substance</th>
<th>Description</th>
<th>Semiquantitative Units</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>Albumin is a type of protein and is one of the smallest by molecular weight</td>
<td>10–150 mg/L</td>
<td>Often indicates early kidney damage</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Normal waste product from dehydration of skeletal muscle</td>
<td>10–300 mg/dL</td>
<td>Excreted at a continuous rate into the urine</td>
</tr>
</tbody>
</table>
| Albumin-to-creatinine ratio (ACR) | Comparison of albumin and creatinine results obtained from individual urine tests | <30 mg/g (Normal)  
30-300 mg/g (Abnormal)  
>300 mg/g (High Abnormal) | Comparative test that allows a clinician to correct for varying urine concentration in patient samples |

Two patients present with the same amount of albumin in their urine.

Why is Creatinine Adjustment Important?

Urine Concentration Can Impact Albumin Results and Cause False-Positive or False-Negative Results

Normal ACR

Patient A
(concentrated urine)

Normal A:C ratio
Confirmed negative by microscopy
Clinically insignificant levels
May result in unnecessary follow up testing

Elevated ACR – Early Kidney Disease

Patient B
(dilute urine)

Abnormal A:C Ratio
Confirmed positive by microscopy
Clinically significant levels
Potentially miss clinically significant samples

Getting Ready to Test

CLINITEK Micoalbumin 2 Urine Test
What You Will Need to Perform the Test

• Patient urine sample
• CLINITEK Microalbumin 2 test strip bottle
• CLINITEK Status® analyzers
• Paper towels

Note: This test strip cannot be read visually and is not available on the CLINITEK Advantus® Urine Chemistry Analyzer.
Sample Handling Recommendations

• First morning specimens are recommended and random urine specimens are acceptable.

• Urine specimen should be tested as soon as possible.

• If testing cannot be performed within 2 hours after voiding, immediately refrigerate.

• Boric acid at concentration of 1.0 g/L is the only preservative that can be used.

• Specimens can be stored at 0–8°C for one week or at -20°C for one month.

• Refrigerated specimens must be returned to room temperature before testing: 15–30°C (59–86°F).

• Collect specimen in a clean, dry container.
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 included 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.
- Follow the 4-step technique shown.
- Do not begin the dipping process until after you press the Start button on the CLINITEK Status analyzer.
  ✔ Dipping the test strip before pressing the Start button may affect test results.

*The ID band can be dipped into the urine and control specimens.
Avoiding Errors

• Can only be read on CLINITEK Status analyzer.
• Record the opening date on the bottle label when opening a new bottle.
• Use a bar-code reader to automatically record lot and expiration dating; analyzer will not allow expired strips to generate test results.
• Remove test strip from the bottle and replace the bottle cap to minimize humidity exposure.
• Do not test on visibly bloody urine or in the presence of hemoglobin or myoglobin ≥5 mg/dL.
• For best results, do not test on patients with protein results above 30 mg/dL.
• Avoid urine contamination with soaps, detergents, antiseptics, or skin cleansers.
Potential Interferences

• The presence of cimetidine (TAGAMET) may cause falsely elevated results with the creatinine test.

• Substances that cause abnormal urine color, such as drugs containing azo dyes (e.g., PYRIDIUM, Azo GANTRISIN, Azo GANTANOL), nitrofurantoin (MACRODANTIN, FURADANTIN), and riboflavin, may affect the readability of the reagent areas on urinalysis reagent strips.

  ✓ The color development on the reagent pad may be masked, or a color reaction may be produced on the pad that could be interpreted as a false positive.
Quality-control Recommendations for ACR Testing

- Test negative and positive controls 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 the 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 Dipper Urine Dipstick Control</td>
<td>Liquid ready</td>
<td>Stable for 7–8 months at 2–8°C, 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>Bio-Rad QUANTIFY Plus Control</td>
<td>Liquid ready</td>
<td>Stable for 2 years at 2–8°C</td>
<td>Opened bottles is stable for 31 days when stored tightly capped at 2–25°C. 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 2–8°C, or until expiration date on bottle</td>
<td>Opened bottle is stable for 31 days when stored tightly capped at 2–25°C. Do not freeze.</td>
</tr>
</tbody>
</table>

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

CLINITEK Microalbumin 2 Urine Test
# Albumin-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>Albumin</td>
<td>mg/L</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80</td>
</tr>
<tr>
<td></td>
<td></td>
<td>150</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>Albumin-to-creatinine Ratio</td>
<td>mg/g</td>
<td>30 mg/g (normal)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30–300 mg/g (abnormal)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;300 mg/g (high abnormal)</td>
</tr>
</tbody>
</table>
Ordering and Reimbursement Information

CLINITEK Microalbumin 2 Urine Test
# CLINITEK Microalbumin 2 Test: Ordering Information

## CLINITEK Status® Analyzers and Accessories

<table>
<thead>
<tr>
<th>Part#</th>
<th>Legacy Part#</th>
<th>Description</th>
<th>Hazard/Refrig.</th>
<th>Packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>10379675</td>
<td>1780</td>
<td>CLINITEK Status+ Analyzer</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>10376323</td>
<td>1790</td>
<td>CLINITEK Status Connector</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>10484591</td>
<td>1782</td>
<td>CLINITEK Status Upgrade Kit (includes Status Connector and Bar-code Reader)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>10282579</td>
<td>6502880</td>
<td>Bar-code Scanner (CLINITEK Status Connect and DCA Vantage Analyzers)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>10470849</td>
<td>1797</td>
<td>CLINITEK Status Connect System (includes CLINITEK Status+ Analyzer, Status Connector, and Bar-code Reader)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>11046800</td>
<td>N/A</td>
<td>CLINITEK Status+ V2.62/2.4.2.0 SW UPG KIT U.S. USB (for instruments with connector base)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>11046802</td>
<td>N/A</td>
<td>CLINITEK Status+ V2.62/2.4.2.0 SW UPG KIT U.S. MMC (for instruments without connector base)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>10376825</td>
<td>1795</td>
<td>CLINITEK Status Wireless Adapter</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>10328736</td>
<td>5773</td>
<td>Thermal Printer Paper (CLINITEK Adventus, CLINITEK Status, and DCA Vantage Analyzers)</td>
<td>-</td>
<td>5/pk</td>
</tr>
<tr>
<td>10324219</td>
<td>1759</td>
<td>Label Printer Paper (CLINITEK Status and DCA Vantage Analyzers)</td>
<td>-</td>
<td>5/pk</td>
</tr>
</tbody>
</table>

## Urinalysis Tests and Accessories

<table>
<thead>
<tr>
<th>Part#</th>
<th>Legacy Part#</th>
<th>Description</th>
<th>Hazard/Refrig.</th>
<th>Packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>10317439</td>
<td>2083</td>
<td>CLINITEK® Microalbumin 2 Reagent Test Strips (test for semiquantitative determination of microalbumin and creatinine in urine)</td>
<td>-</td>
<td>25s = 1 PC</td>
</tr>
</tbody>
</table>
**CLINITEK Microalbumin 2 CPT Codes**

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description*</th>
</tr>
</thead>
<tbody>
<tr>
<td>82044</td>
<td>Albumin; urine, microalbumin, semi-quantitative (e.g., reagent strip assay)</td>
</tr>
<tr>
<td>82570</td>
<td>Creatinine, other source</td>
</tr>
</tbody>
</table>

*Code both: 82044 and 82570*
Why Use the CLINITEK Microalbumin 2 Test?

• Easy to use, CLIA-waived
• Albumin results in 1 minute
• Adjusted for urine concentration
• Meets annual kidney check requirement
• Instrument-read and recorded
• Interfaced to LIS/HIS/EMR
Thank You
for Your Enthusiasm!

Siemens Healthineers
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