INTENDED USE:
CLINITEK® Microalbumin 2 Reagent Strips are firm plastic strips that contain two reagent pads that test for albumin and creatinine in urine. An albumin-to-creatinine ratio is also determined, which allows for the use of single-void specimens in testing. The ratio is given in milligrams albumin per gram or millimole creatinine (mg/g or mmol/mmol). This product provides semi-quantitative results and can be used for screening samples for microalbuminuria; positive results should be confirmed with quantitative methods for albumin. Test results may aid clinicians in the detection of patients at risk of developing kidney damage.

SUMMARY AND EXPLANATION:
Microalbuminuria has been reported to be an early predictor of the development of glomerular damage in the absence of overt nephropathy.1-4 Patients with diabetes and hypertension are the primary risk groups. Patients who have been exposed to nephrotoxins or who suffer from immune disorders form the secondary risk groups; microalbuminuria has also been reported as an early predictor of the development of preeclampsia during pregnancy.4

The CLINITEK Microalbumin 2 Reagent Strips are ready to use upon removal from the bottle and the reagent strip is disposable. The strips are read instrumentally, using the CLINITEK Status® systems, CLINITEK 50, or CLINITEK 100 Urine Chemistry Analyzers and the appropriate software; contact your Siemens representative for further information. Siemens Reagent Strips with color ID bands near the handle of the strip provide Auto-Checks when read on select CLINITEK instruments. Auto-Checks include automatic strip identification. The reagent strips must be kept in the bottle with the cap tightly closed to maintain reagent reactivity. To obtain optimal results, testing should be done on FRESH urine.

INFORMATION REGARDING CLIA WAIVER (U.S. ONLY):
• The CLINITEK Status systems and CLINITEK 50 Analyzers are CLIA waived only when used with Siemens Healthcare Diagnostics Reagent Strips, manufactured by Siemens.
• CLINITEK Microalbumin 2 Strips are CLIA waived when run on the CLINITEK Status systems and CLINITEK 50 Analyzers. A certificate of CLIA waiver is required to perform these tests in a waived setting. To obtain a Certificate of Waiver, contact your state department of health or visit the CMS web site for an application, Form CMS-116.

WARNINGS AND PRECAUTIONS:
• Failure to adhere to the instructions for use, including instructions for limitations, intended use, and performance quality control testing, is off-label use, resulting in these tests being categorized as high complexity and subject to all CLIA regulations.

CHEMICAL PRINCIPLES OF PROCEDURES:
Albumin: This test is based on dye binding using a high affinity sulfonephthalein dye. At a constant pH, the development of any blue color is due to the presence of albumin. The resulting color ranges from pale green to aqua blue.
Creatinine: This test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange through green to blue.

REAGENTS: (based on dry weight at time of impregnation)
Albumin: 1.9% w/w bis (3,5’-diido-4,4’-dihydroxy-5,5’-dinitrophenyl)-3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange through green to blue.
Creatinine: 2.5% w/w copper sulfate; 4.5% w/w disopropylbenzene dihydroperoxide; 2.0% w/w 3,3',5,5'-tetramethylbenzidine; 56.4% w/w buffer; 34.6% w/w non-reactive ingredients.

QUALITY CONTROL:
CLIA-WAIVED LABORATORIES:
Test positive and negative quality controls with new lots, new shipments of reagents, and when you open a new bottle of reagent strips. Test reagents monthly that are stored for more than 30 days.

Run QC tests to ensure reagent strips integrity; train new users; confirm test performance; and when patients’ clinical conditions or symptoms do not match. Also, run QC tests per your laboratory procedures. Liquid ready-to-use controls are available. Do not use water as a negative control. For recommendations and technical questions, call Technical Support at 877-229-3711 or visit www.siemens.com/poc.

Compare QC results to the QC manufacturer’s acceptable results list. If the QC results are not acceptable, do not test the patient samples until you solve the problem. Repeat QC tests until you have acceptable results.

PROCEDURES FOR HANDLING CLINITEK MICROALBUMIN 2:
All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become unreactive. To obtain optimal results, testing should be done on FRESH urine.

PROCEDURES:
1. Collect a FRESH urine specimen in a clean, dry container.
2. Remove one strip from bottle and replace the cap tightly.
3. CLINITEK Status systems only: Touch the word “START.”
4. Dip the test pads into the urine, making sure both pads are wetted.
5. Immediately remove the strip, draining the edge of the strip against the rim of the urine container to remove excess urine.
6. CLINITEK 50 and CLINITEK 100 Analyzers only: Press the green key (START) at the same time as the strip is removed from the urine.
7. Blot the strip by touching the edge only to a paper towel.
8. Place the reagent strip, with the reagent pads facing up, onto the instrument’s test/feedback slide. Slide the strip along the table until it touches the end of the table.
9. The table is automatically pulled into the instrument, where the strip is identified and read. Results are displayed or printed as soon as they are available.
10. Record the results you obtain, then discard the strip into a suitable trash container.

NOTE: Wipe the test table with a damp, lint-free tissue as often as needed to prevent urine from building up.

LIMITATIONS OF PROCEDURES:
As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method. The presence of hemoglobin or myoglobin (≥ 5 mg/dl or a visibly bloody urine) may cause falsely elevated results with both the albumin and creatinine tests. Contamination of the urine specimen with soaps, detergents, antiseptics, or skin cleansers may affect test results. The color development on the reagent pad may be masked, or a color reaction may be
Albumin-to-Creatinine Ratio

10–300 mg/dL (0.9–26.5 mmol/L).

Microalbuminuria is defined as an albumin excretion rate of 30–299 mg/g creatinine. Microalbuminuria is indicated at a ratio result of 30–300 mg/g (3.4–33.9 mg/mmol) (Abnormal) and clinical albuminuria at a ratio result of > 300 mg/g (> 33.9 mg/mmol) (High Abnormal) 7.

Creatinine is normally present in urine at concentrations of

- 20 mg/dL (0.9 mmol/L); the absence of creatinine in a specimen cannot be determined.
- 50 mg/dL (2.6 mmol/L) (Abnormal)
- 100 mg/dL (5.1 mmol/L) (High Abnormal)

In contrived urines, the ratio generally detects albumin at a concentration of less than 30 mg albumin/g creatinine (3.4 mg albumin/mmol creatinine). Microalbuminuria is indicated at a ratio result of 30–300 mg/g (3.4–33.9 mmol/mmol) (Abnormal) and clinical albuminuria at a ratio result of > 300 mg/g (> 33.9 mmol/mmol) (High Abnormal). 8

**EXPECTED VALUES:**

<table>
<thead>
<tr>
<th>Test</th>
<th>Abbreviation</th>
<th>Conventional</th>
<th>SI Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>ALB</td>
<td>10–300 mg/dL</td>
<td>&gt; 30 mg/L</td>
</tr>
<tr>
<td>Creatinine</td>
<td>CRE</td>
<td>10–300 mg/dL</td>
<td>&gt; 30 mg/L</td>
</tr>
<tr>
<td>Albumin-to-Creatinine Ratio</td>
<td>A:C</td>
<td>&lt; 3 mg/mg</td>
<td>Normal</td>
</tr>
</tbody>
</table>

% Positive | Percent Agreement
--- | ---

**SPECIFIC PERFORMANCE CHARACTERISTICS:** Specific performance characteristics are based on clinical and analytical studies. In clinical specimens, the sensitivity of the reagent tests and their respective reference assays depends upon the presence or absence of inhibitory factors typically found in urine (see LIMITATIONS OF PROCEDURES section). Each instrumental result represents a range of values. Because of specimen variability, specimens with analyte concentrations that fall between nominal levels may give results at either level.

The performance characteristics of the CLINITEK Microalbumin 2 test on the CLINITEK Status systems, CLINITEK 50, and CLINITEK 100 Analyzers was determined at multiple hospital clinical laboratories with urine specimens from patients presenting for routine urinalysis. CLINITEK instrument albumin results were compared to the results obtained with a commercially-available immunoassay test; the creatinine results were compared to hospital clinical laboratories with urine specimens from patients presenting for routine urinalysis.

**ALBUMIN-TO-CREATININE RATIO:**

<table>
<thead>
<tr>
<th>Test Pad with:</th>
<th>Accuracy</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLINITEK Status</td>
<td>66%</td>
<td>86%</td>
<td>12%</td>
</tr>
<tr>
<td>n = 1596</td>
<td>n = 1195</td>
<td>n = 398</td>
<td></td>
</tr>
<tr>
<td>CLINITEK 50</td>
<td>87%</td>
<td>90%</td>
<td>8%</td>
</tr>
<tr>
<td>n = 1544</td>
<td>n = 779</td>
<td>n = 765</td>
<td></td>
</tr>
<tr>
<td>CLINITEK 100</td>
<td>85%</td>
<td>83%</td>
<td>7%</td>
</tr>
<tr>
<td>n = 1596</td>
<td>n = 798</td>
<td>n = 798</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Pad with:</th>
<th>Accuracy</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLINITEK Status</td>
<td>86%</td>
<td>81%</td>
<td>19%</td>
</tr>
<tr>
<td>n = 1635</td>
<td>n = 1196</td>
<td>n = 439</td>
<td></td>
</tr>
<tr>
<td>CLINITEK 50</td>
<td>86%</td>
<td>86%</td>
<td>4%</td>
</tr>
<tr>
<td>n = 1544</td>
<td>n = 741</td>
<td>n = 803</td>
<td></td>
</tr>
<tr>
<td>CLINITEK 100</td>
<td>85%</td>
<td>83%</td>
<td>6%</td>
</tr>
<tr>
<td>n = 1596</td>
<td>n = 738</td>
<td>n = 858</td>
<td></td>
</tr>
</tbody>
</table>

**PHYSIOLOGY:** Albumin is normally present in urine at concentrations of less than 20 mg/dL (< 0.9 mmol/L). Microalbuminuria is defined as an albumin excretion rate of 30–299 mg/g creatinine. Microalbuminuria is indicated at a ratio result of 30–300 mg/g (3.4–33.9 mg/mmol) (Abnormal) and clinical albuminuria at a ratio result of > 300 mg/g (> 33.9 mg/mmol) (High Abnormal).

**BIBLIOGRAPHY:**
