**TEST PRINCIPLE**

**Creatinine:** In this assay, creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown complex. The concentration of creatinine is directly proportional to the color intensity of the test pad.

**Microalbumin:** The CLIA waived, Inc. 2-1 Creatinine/Microalbumin Rapid Test Strips are for in vitro diagnostic use. They have been determined to be non-hazardous under the guidelines for non-reactive ingredients.

**SUMMARY AND EXPLANATION OF THE TEST**

Microalbuminuria, an abnormal elevation of the urinary albumin excretion rate, is often one of the first signs of renal disease or damage that can lead to renal failure. Patients with hypertension or diabetes have the highest risk of renal disease where microalbumin may be present. Microalbuminuria refers to small detectible amounts of albumin in the urine.

Creatinine is a by-product of muscle metabolism and creatinine excretion into the urine is usually constant. Creatinine measurement is used in the diagnosis and treatment of renal diseases, to monitor renal dialysis, and as a calculation basis for measuring other urine analytes. Though the concentration (or dilution) of urine varies throughout the day, the urinary creatinine level is relatively stable which allows its measurement to be used as a corrective factor in random/spot urine samples. When albumin and creatinine are measured simultaneously from a single-void/random urine sample, the albumin to creatinine ratio (ACR) can be determined. The ACR is the preferred test for screening of microalbuminuria recommended by the American Diabetes Association.

The CLIA waived, Inc. 2-1 Creatinine/Microalbumin Rapid Test Strips are for in vitro diagnostic use. The following table shows the results that can be obtained visually in both conventional and SI units:

**TABLE OF RESULTS**

<table>
<thead>
<tr>
<th>Test to Creatinine Ratio</th>
<th>Alb/Creatinine</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;30 mg/L (Normal)</td>
<td>&lt;30-300 mg/L</td>
<td>&lt;0.4 mg/mmol</td>
</tr>
<tr>
<td>30-300 mg/L</td>
<td>30-300 mg/L</td>
<td>0.4-3.4 mg/mmol</td>
</tr>
<tr>
<td>&gt;300 mg/L</td>
<td>&gt;300 mg/L</td>
<td>&gt;3.4 mg/mmol</td>
</tr>
</tbody>
</table>

**RESULTS**

Results are obtained by direct comparison of the color blocks printed on the bottle label. The color blocks represent nominal values; actual values will vary around the nominal values. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.

**CALCULATIONS**

Determine Albumin/Creatinine Ratio as follows:

\[
\text{Albumin/Creatinine Ratio} = \frac{\text{Albumin result (mg/L)}}{\text{Creatinine result (g/L)}} = \frac{\text{mg Albumin/g Creatinine}}{}
\]

Example: Albumin result <20 mg/L

Creatinine result = 1000 mg/L = 1 g/L

Result = <30 mg/g (Normal)

**STORAGE**

Do not use after expiration date.

**QUALITY CONTROL**

For best results, confirm performance of reagent strips when a new bottle is first opened by testing known negative and positive controls that include values for microalbumin and creatinine. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

**RECOMMENDED HANDLING PROCEDURES**

All unused strips must remain in the original bottle. Transfer to any container may cause reagent strips to deteriorate and become nonreactive. Do not remove desiccant from bottle. Do not open container until ready to use. Opened bottles should be used within 3 months after first opening.

**SPECIMEN COLLECTION AND PREPARATION**

Collect urine in a clean container and test as soon as possible. Do not centrifuge. Use of urine preservatives is not recommended. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately. Allow refrigerated specimen to return to room temperature before testing.

**LIMITATIONS OF PROCEDURE**

1. The strips are to be read visually. No instrument should be used to interpret the results.
2. Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness.
3. The presence of hemoglobin (≥5 mg/dL or visibly bloody urine), bilirubin (≥15 mg/dL or visibly dark brown color urine) may cause erroneous results with the albumin and creatinine tests. Vitamin C over 100mg/dL does not affect the results of microalbumin and creatinine.
4. Substances that cause abnormal urine color, such as drug 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.
5. Urinary albumin excrections can be elevated by exercise, urinary tract infections, and acute illness with fever. It is recommended that individuals avoid strenuous exercise prior to testing.
EXPECTED VALUES

Albumin: Normal albumin levels in random urine are under 20 mg/L. Microalbuminuria is indicated by results of 20-200 mg/L. Values above 200 mg/L indicate clinical albuminuria. The detection of albuminuria at levels at or above 30 mg/L will help clinicians to better diagnose diabetes in its early stages.  

Creatinine: Creatinine is normally present in random urine in concentrations of 10 to 300 mg/dL (0.9 to 26.5 mmol/L).  

Albumin/Creatinine Ratio: Albumin is normally present in urine at concentrations of less than 30 mg albumin/g creatinine (<3.4 mg/mmol). 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).  

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of the CMRTS Strips have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally, the CMRTS Strips have been developed to be specific for the constituent to be measured with the exception of interferences listed above. (See LIMITATIONS OF PROCEDURE)

For visually read strips, accuracy is a function of the manner in which the color blocks on the bottle label are determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for this reason that users are encouraged to develop their own standards of performance.

Accuracy: A total of 86 random urine specimens were collected from outpatients. These samples were assayed for albumin and creatinine using Bayer Clinitek Microalbumin and the CMRTS Strips. In order to cover assay range, some of urine specimens were spiked with known concentrations of albumin and creatinine. Sensitivity is defined as the percentage of positive results obtained by CMRTS Strip to those obtained by the comparative methods, while specificity refers to the percentage of negative results.

The CMRTS detects urinary albumin in concentration as low as 10 mg/L. Percent agreement with Bayer Clinitek Microalbumin in microalbumin test: 91.9%. Positive Agreement: 96.5%. Negative Agreement: 98.3%.

The CMRTS detects urinary creatinine in concentration as low as 100 mg/L. Percent agreement with Bayer Clinitek Microalbumin in creatinine tests: 86%.

Precision: Urine specimens of different levels of concentration of albumin and creatinine were assayed. Each level was assayed 25 times. The following percentages were obtained. Percent agreement of replicate reading in Microalbumin: 96.8% Percent agreement of replicate reading in Creatinine: 92%.

BIBLIOGRAPHY