

Microalbumin, Urine, Semi-Qualitative

Principle

Albumin is the prominent protein in most renal diseases. Microalbuminuria refers to an albumin concentration in the urine which is greater than normal, but usually not detectable with routine protein dipstick assays. The primary use of a microalbumin level is early detection of nephropathy in diabetic patients. Abnormal albumin excretion is related to both the duration of diabetes and the degree of glycemic control. The amount of albumin in the urine has been a good predictor of later overt nephropathy, especially in IDDM patients. Microalbumin measurements may also be applicable in studies of hypertension, pregnancy, and non-diabetic renal disease.

The Micral Urine Test Strip is useful in monitoring the progression of nephropathy in diabetic patients once it has been diagnosed. This test is not suitable as a diagnostic test and should be used for the yearly microalbumin screen in diabetic patients. **If diagnostic testing is required, send urine specimen to Lab Central (extension 4-7383) for testing.**

The albumin present in the patient's urine binds specifically with a soluble antibody-gold conjugate present on a zone of the test strip. Excess conjugate is retained in a separation zone containing immobilized human albumin. This allows only the patient albumin-conjugate immunocomplex to reach the detection zone. After one minute, the color on the test zone should change from white to red. The intensity of the red color is directly proportional to the amount of albumin in the patient's sample. A comparison is made between the color of the patient test strip and the color scale on the vial label to arrive at a semi-qualitative result.

Specimen Requirement

Note item #7.

1. A concentrated morning specimen is preferred.
2. A random sample or a 24-hour collection is acceptable, with a minimum urine volume of 3 mL.
3. Urine should be collected in a clean, dry, preservative free container. Do not collect samples in containers containing strong oxidizing agents.
4. Perform test as soon as possible after collection. Samples are stable at room temperature for up to 3 days. Samples are stable refrigerated for 14 days.
5. Frozen samples are not acceptable.

6. Turbidity of the urine does not affect the test results.
7. **Single analysis is acceptable for negative results. If the first analysis finds a positive result, the test should be confirmed with 1 or 2 subsequent urine specimens to rule-out a false positive due to test interferences (refer to the procedural section regarding interferences).**

Interferences

1. Exercise, hydration, blood pressure, pregnancy, and posture changes can affect the amount of albumin excreted in the urine.
2. Increased albumin results may occur during illnesses that present with a fever such as Urinary Tract Infection (UTI), acid-base abnormalities, or bleeding into the urinary tract. Testing should not be performed until the acute illness subsides.
3. Oxytetracycline interferes with the assay. It is recommended that the test be repeated once medication had been discontinued.
4. Temperature of the urine may interfere with the assay. Refrigerated samples must be warmed to room temperature prior to testing or the color reaction is diminished.
5. IgA, Alpha-amylase, IgG, Tamm-Horsfall Proteins, Human Leukocytes, Transferrin, Human Erythrocytes, Retinol Binding Protein, Alpha-1-Antitrypsin, Hemoglobin, Bence-Jones Proteins, and Acidic Alpha-1-Glycoprotein do not cross react.

Linearity

1. 0-100 mg/L

Reference Range

1. Male and Female: 0-20 mg/L

Alert Values

1. None

Quality Control

1. Assay Quantimetrix Microalbumin Liquid Controls (QC), Level 1 and Level 2, when a new vial of test strips is opened and each month the vial is open.
2. Test each liquid control level using the patient procedure and document results on QC logsheet.

3. If liquid control fails, repeat failed liquid control. If repeat fails, do not perform patient testing. Contact POCT Coordinator at 4-5497. Document QC results and all action taken in QC Logbook.

Procedure

1. Liquid controls and patient samples must be at room temperature before testing. Use test strips immediately after removing the vial from refrigerator.
2. Dip the test strip into the urine for 5 seconds. Be sure the urine level is between the two black lines on the strip.
3. If testing liquid control, dispense four drops on the sample pad.
4. Allow the strip to sit for 1 minute on a non-absorbent surface.
5. Compare the test pad on the strip to the color scale on the test strip vial. The test pad is located above the MICRAL[®] inscription on the strip. A wet test pad indicates that the reaction has come to an end.
6. If the test pad is still dry after 1 minute, allow the reaction to continue for another 1 to 2 minutes. Compare the test pad to the color scale.
7. Do not read test strip after 5 minutes. Results will not be valid.

Calculations

1. N/A

Results Reporting

1. Report the patient result as Negative, 20 mg/L, 50 mg/L, or 100 mg/L.
2. Individual urine color may cause the patient test strip to have a slightly different color than the color scale on the vial.
3. If the test strip color does not match a particular color block on the color scale, then match the test strip to a color block of equal intensity.
4. If the color development is slightly uneven, then match the average color on the test pad.
5. The Micral Microalbumin Test Strip is a semi-quantitative test used for screening purposes. If qualitative results are required, contact Lab Central at 4-7383 for specimen requirements.
6. Document patient results on patient's chart.

Calibration

1. N/A

Reagents

1. Roche Diagnostics Micral Urine Test Strips:
 - a. Test Strip vials are stable refrigerated (2-8°C) until expiration date on vial.
 - b. Keep vial tightly closed. Do not expose test strips to extreme moisture or heat.
 - c. Do not freeze.
 - d. Mark vial with open date.
2. Quantimetrix Microalbumin Liquid Controls, Level 1 and Level 2:
 - a. Unopened liquid controls are stable refrigerated (2-8°C) until expiration date on vial.
 - b. Opened liquid controls are stable refrigerated (2-8°C) for 6 months, 10 uses, or until expiration date on the vial, whichever occurs first.
 - c. Allow liquid controls to sit at room temperature for 15 to 30 minutes before test is performed.
 - d. Invert liquid controls to gently mix contents, but avoid foaming.
 - e. Immediately recap controls and refrigerate when not in use.
 - f. Discard controls if turbid or there is any evidence of microbial contamination.
 - g. Mark vials with the open date.
 - h. Save QC inserts for 2 years.

References

1. Roche diagnostics Micral Urine Test Strips package insert; Roche Diagnostics, 2000.
2. Quantimetrix Microbumin Microalbumin Liquid Controls Package Insert, Quantimetrix Corporation, 2001.
3. Tietz, N.W. Clinical Guide to Laboratory Tests. 3rd Ed., W.B. Saunders Co., 1995. p. 25.