

Self-Stik 1M

Microalbumin urine dip and read test strip For in Vitro Diagnostic Use

INTENDED USE

Self-Stik reagent strip is designed to provide qualitative and semi-quantitative results for **microalbumin** in random urine samples. Self-Stik reagent strip is a dip-and-read test strip intended for in vitro diagnostic use with urine specimens. The strip features solid-phase reagent areas on a plastic support for the qualitative and semi-quantitative testing of microalbumin. Results can be visually compared to color charts representing each concentration range

WARNINGS AND PRECAUTIONS

Self-Stik reagent strips are for in vitro diagnostic use. The "universal precautions" recommended by the Centers for Disease Control should be adhered to whenever blood or body fluids are handled. These precautions include wearing gloves. Exercise the normal precautions required for handling all laboratory reagents

SUMMARY AND EXPLANATION

Microalbuminuria refers to an abnormally increased excretion rate of albumin in the urine. It is a marker of endothelial dysfunction and increased risk for cardiovascular morbidity and mortality especially. Patients with the highest risk of renal disease where microalbumin may be present is hypertension and diabetes. It is one of the first signs of renal diseases and renal damage that can lead to renal failure.

Self-Stik reagent strips are ready to use upon removal from the bottle. No additional reagents or laboratory equipment is required. The reagent strips are packaged in a plastic vial containing desiccant. The test strips must be tightly capped in the plastic vial to assure reagent reactivity. The directions must be followed exactly, and it is necessary to use fresh, well-mixed and uncentrifuged urine for optimal results.

CHEMICAL PRINCIPLES OF THE PROCEDURE

Microalbumin: At a constant pH, this test is based on dye binding using a high affinity sulfonephthalein dye; the development of any blue color is due to the presence of microalbumin. The resulting color ranges from pale green to aqua blue.

REAGENTS (based on dried weight at time of impregnation)

Microalbumin: 2.3 % w/w sulfonephthalein color; 91.2% w/w buffer; 6.5 % w/w nonreactive ingredients.

STORAGE AND HANDLING

- Store at room temperature between 2°C-30°C (38°F- 86°F).
- Do not store the strips in the refrigerator or freezer.
- Keep away from moisture, heat, and direct sunlight.
- Do not remove the desiccant from the bottle. Replace the cap promptly and tightly after taking out a strip.
- Do not touch the test area of the strip.

PROCEDURES FOR HANDLING THE STRIPS

All unused strips must remain in the original bottle. Transferring to any other container may cause reagent strips to deteriorate and become non-reactive. Do not remove the desiccant from the bottle. Do not open the container until ready to use. After taking out the test strips, replace the cap promptly and tightly. Do not touch the test area of the strip. The work area should be clean and free of detergents and other contaminants. Do not reuse.

SPECIMEN COLLECTION AND PREPARATION

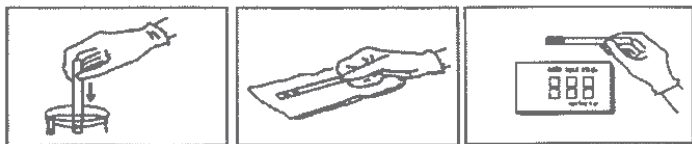
Use a clean, dry, unused vessel to collect the urine. Test the urine as soon as possible after collection. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let the refrigerated specimen return to room temperature before testing..

PROCEDURE

This procedure **MUST BE FOLLOWED EXACTLY** to achieve reliable test results

1. Confirm that the product is within the expiration date shown on the label.
2. Remove enough strips from the bottle for immediate use and replace the cap tightly.
3. Inspect the strip. Discoloration or darkening of reagent areas may indicate deterioration. In such cases, do not use the strip.
4. Dip the test strip completely for no more than 1 second in fresh, well-mixed, and uncentrifuged urine. Excessive urine on the test strip may give rise to a wrong result. Remove the excessive urine by touching the plastic film on the rim of the vessel. While removing, touch the side of the strip against the rim of the urine container to remove excess urine. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine and avoid running over.

5. Compare each reagent area to its corresponding color blocks on the color chart of the bottle label in good light. Proper reading time (30-60 sec.) is critical for optimal results
6. Obtain results by direct color chart comparison. Changes in color that appear only along the edges of the test areas or after more than two minutes have passed are of no diagnostic significance. Correctly dispose of the analyzed strips as medical waste.



QUALITY CONTROL

The strips must be properly stored and handled before and during the testing. For best results, the reaction of reagent strips should be confirmed by testing known positive and negative specimens every time a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance. It is recommended that users follow federal, state, and local guidelines for quality control

RESULTS

Results are obtained by direct comparison with color blocks. Definitive diagnostic decisions should not be based on any single test result..

TABLE OF RESULTS

Test	Displayed Results	
	Conventional Units	S.I. Units
Microalbumin	10 mg/L (1 mg/dL)	10 mg/L ±
	30 mg/L (3 mg/dL)	30 mg/L +
	80 mg/L (8 mg/dL)	80 mg/L ++
	150 mg/L (15 mg/dL)	150 mg/L +++

LIMITATIONS OF PROCEDURES

Substances that cause abnormal urine color (azo dyes, nitrofurantoin, riboflavin) may affect readability. The presence of **hemoglobin** ($\geq 5\text{-mg dL}$) and **bilirubin** ($\geq 15\text{-mg/dL}$) may cause error results. Vitamin C over 500-mg/dL does not affect the results of microalbumin.

EXPECTED VALUES

Microalbumin: Normal Albumin levels in random urine are under 20 mg/L ⁵. Microalbuminuria is indicated by results in the range between 20 mg/L-200 mg/L. Values above 200mg/L indicate clinical albuminuria. The detection of albuminuria at levels at or above 30~mg/L helps clinicians diagnose diabetes in its early stages.

PERFORMANCE CHARACTERISTICS

Specific performance characteristics (sensitivity, specificity, accuracy) have been determined in laboratory and clinical tests. In a study of 94 random urine specimens, agreement greater than 96% within the color blocks was obtained for microalbumin compared to other methods.

BIBLIOGRAPHY

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