

ONE STEP® URINE TEST (MICROALBUMINURIA TEST)

INTENDED USE

Microalbuminuria Test is a competitive binding lateral flow immunochromatography test. This test provides semi-quantitative measurement of Micro-Albumin in human urine.

SUMMARY AND EXPLANATION OF THE TEST

The analytical determination of the protein albumin in urine is important because increased values indicate an increased risk of developing end-stage renal diseases and cardiovascular disease among people with diabetes. Albumin in urine is also a sensitive indicator of renal damage caused by exposure to nephrotoxic substances.

The most significant and well-documented of these abnormalities is a subtle increase in the urinary albumin excretion rate, known as Micro-Albuminuria. Microalbuminuria is not measurable by conventional techniques for detecting proteinuria. It is believed that microalbuminuria represents a reversible stage of renal dysfunction. It is believed that overt proteinuria reflects irreversible disease. Proteinuria typically appears about twenty years after the onset of diabetes, whereas microalbuminuria can be detected within the first ten years. Microalbuminuria (30-150 ug/min) has been established as a marker predictive of subsequent development of diabetic nephropathy.

Periodic monitoring (2-3 times/year) of urinary albumin levels in the diabetic patient is therefore recommended so that the initial escalation of renal damage can be detected and appropriate treatment regimens can be instituted.

Radial immunodiffusion, immunoturbidimetric, immunonephelometric method and RIA have been used for the quantitative albumin assay in urine.

This Micro-Albumin semi-Quantitative test using a chromatography method, provides a convenient, sensitive and specific assay for albumin and is free of interference from other analytes normally found in urine specimens.

PRINCIPLE OF THE TEST

The One-Step® test utilizes a competitive immunoassay system and immunochromatographic detection assay, to be performed simultaneously. If albumin is present in the sample in the concentration above the cut-off level, a labeled specific monoclonal antibody-dye complex will not be formed. If albumin is present in the sample in a concentration less than the cut-off level, a labeled specific monoclonal antibody-dye complex will be formed. This complex is then captured by a

specific monoclonal antibody immobilized in the Test Zone ("T"), producing a visible pink-rose color band on the membrane. On the other hand, a color band will always appear at the control zone ("C").

MATERIALS PROVIDED

1. Test Device
2. Package Insert (Instructions for Use)

MATERIALS REQUIRED BUT NOT PROVIDED

- Timing Device
- Specimen collection container

SPECIMEN COLLECTION AND STORAGE

1. Fresh urine samples are preferred.
2. A sample for testing may be kept refrigerated overnight.

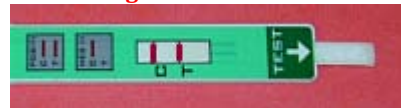
QUALITY CONTROL

Although the test contains an internal quality control function (pink/rose color band in the control region), Good Laboratory Practice recommends the daily use of an outside control to ensure proper performance. Quality control samples should be tested according to the quality control requirements established by your laboratory.

INTERPRETATION OF RESULTS

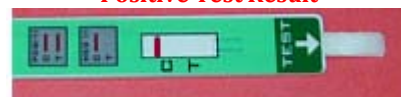
Negative Result: If there is a dark-rose color band in the control region (marked with a "C"), *and* a dark-rose color band in the test region (marked with a "T"), *Albumin is not present* and the specimen is negative.

Negative Test Result



Positive Result: The absence of a color band in the test region next to the letter "T" indicates the presence of detectable Albumin.

Positive Test Result



Invalid Result: If no control band appears within five minutes, the result is invalid and should be ignored. A visible control band is needed in all cases to confirm proper test operation. No control band indicates either the test procedures were not followed correctly, or the test reagents failed.



INSTRUCTIONS FOR TESTING

1. Remove the Dipstream Test from the packet.
2. Hold the wick in your urine stream or place in collection container so that it remains upright. The Test should remain in urine for a period of 10 to 15 seconds. Note: No urine should come in contact with the results window area.
3. Place the Dipstream Test on a flat surface with the Result Windows facing up.
4. As the test begins to work, you will see the formation of a reddish purple line in the Control Window (the window furthest from the end dipped into the urine) indicating the test is working properly. Within 3 to 5 minutes, read final results. Do Not Interpret the Results after 10 minutes.

WARNINGS AND PRECAUTIONS

1. Wear disposable gloves while handling Specimens. Wash hands thoroughly afterwards.
2. Wipe up spills thoroughly using an appropriate intermediate to high level disinfectant.
3. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious, in a biohazard container.
4. Avoid splashing or aerosol formation.
5. Do not use the test after the expiration date.
6. For in vitro diagnostic use only.

EXPECTED VALUES

1. It is recommended that each laboratory should determine its own normal and abnormal range.
2. Timed overnight samples and 24 hour samples have been commonly used to study microalbuminuria. The upper limits of urinary albumin excretion in healthy adults are approximately 26 mg/24 hour (18ug/min) and 9 ug/min in overnight samples. Urinary albumin concentration in normal adults subjects:

| | |
|----------------------|-----------------------|
| First Daytime | 6.72 mg/L (1.89-23.9) |
| Cumulated (24 hours) | 5.33 mg/L (1.31-22.7) |

In healthy subjects, albumin is ordinarily present in urine in a very low range. Sustained values greater than about 15-30 mg/L are usually regarded as abnormal.

3. Urinary albumin from 123 diabetics patients were reported with ranges 4.8-209 mg/L and mean values 46.8-61.4 mg/L.

PERFORMANCE CHARACTERISTICS

Cut-off:

The cut-off concentration of the Microalbuminuria assay is estimated to be 18 ug/ml.

Specificity

The addition of each of the following compounds to urine samples does not interfere with the measuring of albumin by using the Microalbuminuria Assay:

| MATERIAL TESTED | TEST CONCENTRATION |
|-------------------------|--------------------|
| Glucose | 40 ug/mL |
| Ascorbic Acid | 2 mg/mL |
| Transferrin | 30 ug/mL |
| Creatinine | 10 mg/mL |
| Uric Acid | 1.5 mg/mL |
| Retinol Binding Protein | 1 mg/mL |

The antibody used in the Microalbuminuria test is highly specific for human albumin. Cross reactivity with albumin from other species and human proteins other than albumin was not detected (such as rat albumin, bovine albumin, chicken ovalbumin, rabbit albumin and human IgG)

LIMITATIONS OF THE TEST

1. The test is for in vitro diagnostic use only.
2. The test is limited to the detection of albumin levels in urine.
3. The test is a semi-quantitative screening assay and is not suggested for use in determining the quantitative levels.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.

References

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