

Microalbumin Dipstick

A rapid test for the qualitative detection of albumin in human urine samples.

Cat.No.	Content
Z08070CE	- 20 tests individually packed (20 x Ref. No: Z08070B). - 1 package insert
Z08071CE	- 5 tests individually packed (5 x Ref. No: Z08070B). - 1 package insert
Z08070B	- 1 test individually packed - 1 package insert

For professional in vitro diagnostic use only

GENERAL INFORMATION

Method	competitive immunochromatographic assay
Shelf life	18 months from date of production
Storage	2-30°C
Sample	human urine samples
Results	after 5 minutes
Sensitivity	20 mg/L

SUMMARY

The Microalbumin Dipstick is a lateral flow, one-step immunoassay for the qualitative detection of microalbumin at a cut-off of 20 µg/mL urine.

This product is used to obtain a visual, qualitative result and is intended for professional use, only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be applied to any microalbumine test result, particularly when preliminary positive results are indicated.

The persistent appearance of small amounts of albumin (microalbuminuria) in urine could be the first indicator of a renal dysfunction. For persons with diabetes, a positive result could be the first indicator of a diabetic nephropathy. Without initiation of therapy, the amount of released albumin will increase (macroalbuminuria) and a renal insufficiency will occur.

In case of type-2 diabetes, the early diagnosis and therapy of diabetic nephropathy is especially important. In addition to the renal dysfunction, cardiovascular risks could occur.

At normal physiological conditions, small amounts of albumin are glomerular filtrated and tubular reabsorbed. The expulsion of 20µg/mL to 200µg/mL is characterized as microalbuminuria. In addition to renal dysfunctions, albuminuria can be caused by physical training, infections of the urinary tract, hypertension, cardiac insufficiency and surgery. If the amount of albumin decreases after disappearance of these factors, the transient albuminuria is without any pathological reason.

TEST PRINCIPLE

The Microalbumin Dipstick is a one-step competitive immunoassay in which immobilized human albumin from the assay competes with albumin which may be present in urine for limited antibody binding sites.

The test device contains a membrane strip which was pre-coated with human albumin on the test band. A colored anti-albumin monoclonal antibody-colloidal gold conjugate pad is placed at the right end of the membrane. In the absence of albumin in the urine, the solution of the colored antibody-colloidal gold conjugate and urine moves upward, chromatographically by capillary action, across the membrane.

This solution then migrates to the immobilized albumin zone in the test band region. The colored antibody-colloidal gold conjugate then attaches to the albumin to form a visible precipitant in the test zone occurs, when the test urine is negative for albumin. When albumin is present in the urine, the albumin antigen competes with the albumin on the test band region for limited antibody sites on the anti-albumin monoclonal antibody-colloidal gold conjugate.

When a sufficient concentration of albumin is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the albumin on the test band region. Therefore, absence of the color band on the test region indicates a positive result. A control band with a different antigen/antibody reaction is also added to the immunochromatographic membrane strip at the control region to indicate that the test has performed properly. This control line should always appear, regardless of the presence of the analyte. This means that negative urine will produce two colored bands, and positive urine will produce only one band. The presence of this colored band in the control region also serves as 1) verification that sufficient volume has been added, and 2) that proper flow was obtained.

STORAGE AND STABILITY

The test kit is to be stored refrigerated or at room temperature 2-30°C (36-

86°F) in the sealed pouch for the duration of the shelf life.

PRECAUTIONS

- For in-vitro diagnostic use only
- For professional use only
- Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.

MATERIAL PROVIDED

- Individually wrapped test dipsticks. Each test dipstick contains a membrane coated with human albumin and a colloidal gold conjugate pad coated with anti-human-albumine monoclonal antibody.
- One instruction sheet

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

SPECIMEN COLLECTION AND HANDLING

Use preferably only morning urine for testing since physical effort can lead to an increase in albumin expulsion. Samples and control materials that have been refrigerated must be equilibrated to room temperature before testing.

ASSAY PROCEDURE

Use first morning urine to perform test, since physical action can increase the amount on albumin in urine.

Specimens that have been refrigerated must be equilibrated to room temperature prior to testing.

Open the pouch immediately before performance of the test.

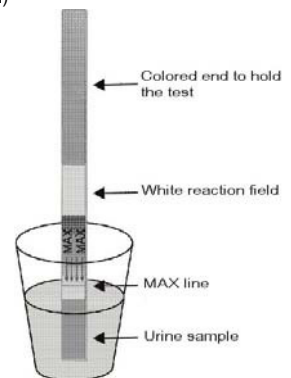
1. Collect the urine specimen in a clean test tube. Ensure that only sufficient quantity of the specimen is collected to allow submerging the red area of the dipstick (about 1 cm)

2. Bring the sealed pouch to room temperature, open the pouch and remove the dipstick. Once opened, the dipstick must be used immediately.

3. Dip the area marked with MAX of the dipstick in the urine specimen submerging only up to the MAX mark.

4. Observe for the release of the colloidal gold complex on the membrane. This would be seen as a pink moving front on the membrane and could take 10 to 15 seconds to appear depending upon the sample.

5. Remove the dipstick and place horizontally on a flat surface.



At the end of five minutes read the results:

INTERPRETATION OF RESULTS

Negative:

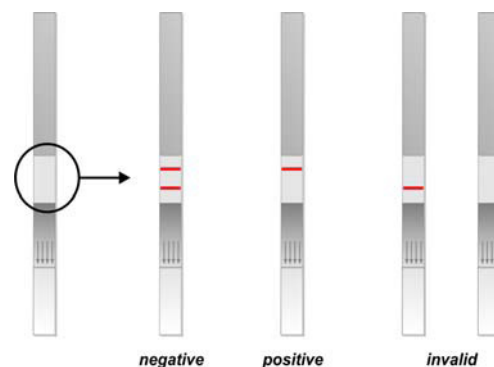
Two colored lines appear. The line in the test region (T) is the drug probe line; the line on the control region (C) is the control line, which is used to indicate proper performance of the strip. The color intensity of the test line may be weaker or stronger than that of the control line.

Positive:

Only one colored line appears in the control region (C). The absence of a test line indicates a positive result.

Invalid:

No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms.



Note: A very faint line in the test region indicates that the albumin in the sample is near the cut-off level of the test. These samples should be re-tested or confirmed with a more specific method before a positive determination is made.

LIMITATIONS

- The assay is designed for use with human urine only.
- A positive result with the test indicates the presence of albumin only, and does not unambiguously indicate a diabetic nephropathy.
- There is a possibility that technical or procedural errors as well as other substances and factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce positive results, or that do not interfere with test performance.
- If it is suspected that the samples have been mislabeled or tampered with, a new specimen should be collected and the test should be repeated.

QUALITY CONTROL

Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources.

PERFORMANCE CHARACTERISTICS

Accuracy

The accuracy of the Microalbumin Dipstick was evaluated in comparison to a commercially available immunoassay at a cut-off of 20µg/mL. 100 urine samples, collected from volunteers, have been tested by both procedures with >98% agreement.

Reproducibility

The reproducibility of the Microalbumin Dipstick was evaluated at 4 different sites using blind controls. Of 50 samples with albumin concentrations <10µg/mL, all were determined negatives. Of 50 samples with albumin concentrations >40µg/mL, all were determined positive.

Sensitivity

The Microalbumin Dipstick has a sensitivity of 20µg/mL urine.

Specificity

The specificity for the Microalbumin Dipstick was tested by adding various compounds that are likely to be present in urine. All compounds were prepared in normal human urine with low amounts of albumin.

The following compounds produced positive results when tested at levels equal to or greater than the concentrations listed below.

- Alfa-Fetoprotein (AFP) 1000µg/mL

The following compounds were found not to cross-react when tested at concentrations up to 1000 µg/ml.

Acetaminophen, Acetone, Amitriptyline, Ampicillin, Aspartame, Aspirin, Atropine, Benzocaine, Bilirubin, Caffeine, Chloroquine, (+)-Chlorpheniramine, (+/-)-Chlorpheniramine, Creatine, Dexbrompheniramine, Dexbromethorphan, 4-Dimethylaminoantipyrine, Dopamine, (+/-)-Ephedrine, (-)-Ephedrine, (+)-Epinephrine, Erythromycin, Ethanol, Furosemide, Glucose, Gualiacol Glyceryl Ether, Hemoglobin, Imipramine, (+/-)-Isoproterenol, Lidocaine, D-Methamphetamine, L-Methamphetamine, (+/-)-3,4-methylenedioxyamphetamine, (1R,2S)-(-)-N-Methyl-Ephedrine, (+)-Naproxen, (+/-)-Norephedrine, Oxalic Acid, Penicillin-G, Pheniramine, Phenothiazine, L-Phenylephrine, D-Phenylethylamine, Procaine, Quinidine, Ranitidine, Riboflavin, Sodium Chloride, Sulindac, Thioridazine, Trifluoperazine, Trimethobenzamide, Tyramine, Vitamin C

LITERATURE

1. Deutsches Ärzteblatt 96; Issue 1-2. 01-1999
2. Lurbe et al: Increase in Nocturnal Blood Pressure and Progression to Microalbuminuria in Type 1 Diabetes. NEJM 2002; 347: 797-805
3. Perkins: Regression of microalbuminuria in type 1 diabetes. NEJM 2003; 348: 2285-2293

