Atlas Medical CE

Microalbumin Test Strip

IVD *For In-Vitro diagnostic and professional use only*

2 30°C **Store at 2-30 °C**

Intended Use

Microalbumin Rapid Test Strip (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of microalbumin in human urine specimens. This kit is intended for use as an aid in the diagnosis of renal dysfunction.

Introduction

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

For the first screening of urine samples and provides a preliminary analytical result. A positive result indicates elevated levels of albumin above the cut-off but does not correct for alterations in the urine concentration. Positive results should therefore be confirmed by a more specific quantitative method. Clinical consideration and professional judgment should be applied to any Microalbumin test result, particularly when preliminary positive results are indicated.

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 membrane of the strip has been pre-coated with human albumin in the test result line region (T-region). A pad containing a color-labelled anti-albumin monoclonal antibody is placed at the right end of the membrane. With the urine the antibodies move towards the test result line region by capillary action. If no albumin is present in the urine it will attach to the immobilized albumin. This can be seen by the formation of a red test result line. Therefore, a line in the T-region indicates that no albumin is present in the urine or that the albumin concentration is below the cut-off.

If albumin is present in the urine, it competes with the immobilized albumin in the T-region for the limited antibody sites. With increasing concentrations of albumin in the sample the binding of the antibody is more and more inhibited and the color of test result line becomes weaker. When the amount of albumin is equal or more than the cut-off, 20 µg/ml, it will prevent the binding of the antibody to the immobilized albumin and the line vanishes. Therefore, the absence of a colored band in the T-region indicates a positive test result.

A control line with a different antigen/antibody reaction is also added to the immunochromatographic membrane strip at the control region (C-region) to indicate that the test has been performed properly. The presence of the control line serves as 1) verification that sufficient volume has been added, and 2) that proper flow was obtained. The control line should always appear, regardless of the presence or absence of albumin. This means that negative urine will produce two colored lines, whereas positive urine with elevated levels of albumin will produce only one colored line.

Materials

Materials provided

- Individually pouched test strips
- Package insert

Materials required but not provided

- Specimen collection container.
- Timer.
- Centrifuge.

Precautions:

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package.
- 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 for each urine sample.
- Do not use after the expiration date or if the pouch has been damaged.
- The components of the test (e.g. antibodies / albumin / chemicals) do not cause any danger if the test is used according to the instructions.

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.

Specimen Collection and Storage:

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

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

PROCEDURE

The test should be performed immediately after opening the protective pouch. Refrigerated test should be brought to room temperature before opening to avoid condensation of moisture on the test.

1. Open the pouch and remove the dipstick by holding it at the colored end. Mark the test for identification reasons if necessary. Avoid touching the white membrane in the middle of the test strip.
2. Dip the other end of the dipstick into the urine sample for at least 10 seconds. Make sure that the test is not submerged beyond the MAX mark. The urine should not have any direct contact to the white membrane because this would destroy the assay. To ensure that the liquid uptake was sufficient we recommend waiting for the release of the colored antibodies before removing the test from the liquid. That can be either seen by a pink front moving across the membrane or by the formation of the control line.
3. Remove the dipstick and place it horizontally on a flat Non-adsorbent surface that does not withdraw any liquid from the assay (e.g. the pouch). Start the timer.
4. At the end of five minutes read the result. Do not interpret the result later than 10 minutes after starting the assay.

Interpretation of results:

POSITIVE RESULT:

Only one colored line appears in the control region (C). The absence of a test result line indicates a positive result meaning that the albumin concentration of the sample is elevated.

NEGATIVE Two colored lines appear. The line in the

RESULT: 

test region (T) is the test result line for albumin; the line on the control region (C) is the control line, which is used to confirm proper performance of the strip. The color intensity of the test line may be weaker or stronger than that of the control line.

INVALID RESULT: 

No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms. The sample should be tested with a new strip.

NOTES: 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 or negative determination is made.

Quality Control

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

Limitations:

- The assay is designed for use with human urine only. Please note that the use of water for quality control purposes results in control lines that are less intense than the test result line.
- A positive result with the test indicates the presence of albumin only, and does not unambiguously indicate a diabetic nephropathy.
- If it is suspected that the samples have gone bad or have been mislabelled a new specimen should be collected and the test should be repeated.
- Positive results should be confirmed by a quantitative method that takes into consideration the rate of albumin secretion or the albumin-to creatinine ratio.

Performance Characteristics:

A. Accuracy

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

B. Reproducibility

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

C. Sensitivity

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

D. Specificity

The specificity of the Microalbumin Rapid Test Strip (Urine) was tested with compounds 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) 1000 µg/mL

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

Paracetamol, Aceton, Amitriptyline, Ampicillin, Aspartame, Aspirin,Atropine, Bilirubin, Caffeine, Chloroquine, (+)-Chlorpheniramin, (+/-)-Chlorpheniramine, Creatine, Desoxyephedrine, Dexbrompheniramine, Dexbromethorphan, 4-Dimethylaminoantipyrine, Dopamine, Ecgonine, Ecgonine Methyl Ester, (+/-)-Ephedrine, (-)-Ephedrine, (+)-Epinephrine, Erythromycin, Ethanol, Furosemide, Glucose, Guaiacol Glyceryl Ether, Hemoglobin, Imipramine, (+/-)-Isoproterenol, Lidocaine, (1R,2S)-(-)-NMethyl-Ephedrine, (+)-Naproxen, (+/-)-Norephedrine, Oxalic Acid, Penicillin-G, Pheniramine, Phenothiazine, L-Phenylephrine, DPhenylethylamine, Procaine, Quinidine, Ranitidine, Sodium Chloride,Sulindac, Thioridazine, Trifluorperazine, Trimethobenzamide, Tyramine,Vitamin C

References

1. Deutsches Ärzteblatt 96; Issue 1-2. 01-1999
2. Lurbe E, Redon J, Kesani A, Pascual JM, Tacons J, Alvarez V, Batlle D. Increase in nocturnal blood pressure and progression to microalbuminuria in type 1 diabetes. N Engl J Med. 2002 Sep 12; 347(11): 797-805.
3. Perkins BA, Ficociello LH, Silva KH, Finkelstein DM, Warram JH, Krolewski AS. Regression of microalbuminuria in type 1 diabetes. N Engl J Med. 2003 Jun 5; 348(23): 2285-93.

Atlas Medical
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com

PPI1856A01
Rev A (02.09.2019)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry