Micro-Albumin Test

Product-#: D-ALBS-U11-002

Rapid test for the semiquantitative detection of human albumin in urine

INTENDED USE

The DIMA® Microalbumin Test (semiquantitative) is an immune-chemical lateral flow test. It serves the semi-quantitative detection of small quantities of albumin in urine. Within a concentration range of 20 mg/l – 100 mg/l the color intensity of the test result line decreases continuously, so that the albumin quantity can be read off on the basis of a color scale. Albumin concentrations above these values are indicated by the complete disappearance of the test result line.
The DIMA® Microalbumin Test (semiquantitative) is exclusively intended for professional use and is visually evaluated. The product serves as a first screening of urine samples and provides a provisional analytic result, since fluctuations in the urine concentration are not considered. Positive test results above 20 mg/l should therefore be confirmed by a more specific quantitative method. Clinical consideration and a professional judgment should be applied to the interpretation of each micro albumin test, particularly if a preliminary positive test result is present.

INTRODUCTION

The persistent appearance of small amounts of albumin (Microalbuminuria) in urine could be the first indicator of a renal dysfunction. At normal physiological conditions, small amounts of albumin are glomerular filtrated and tubular reabsorbed in the kidneys. The expulsion of 20 µg/ml to 200 µg/ml urine is characterized as microalbuminuria. With the DIMA Microalbumin Test such small concentrations are already securely captured.
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 renal insufficiency will occur that makes dialysis or kidney transplantation inevitable. In the U.S. and Europe diabetes has become the most common single cause of end-stage renal disease.
About 41% of patients with type-2 diabetes exhibit a mircoalbuminura. In a first world-wide study (DEMAND) it could be shown that the frequency of microalbuminuria increased with age, hypertension and the duration of the disease. It was less frequent in patients with good glycemic control. This high prevalence of microalbuminuria shows the importance of a regular annual screening of diabetes patients.
For type-1 diabetes patients, screening should start about 5 years after the onset of the disease. For type-2 diabetes patients screening should be started at the time of diagnosis because of the uncertainty of dating the start of the disorder.
In addition to being the earliest manifestation of nephropathy, albuminuria is also a marker of a greatly increased risk for cardiovascular diseases in type-2 diabetes.
In addition to renal dysfunctions, microalbuminuria can also 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, this transient albuminuria is of no pathological relevance.
As there seems to be a marked day-to-day variability in albumin excretion it is generally recommended to repeat the test. If at least 2 out of 3 collections within a 3-6 month period show elevated albumin levels the patient is very likely to have a microalbuminuria.

PRINCIPLE

The DIMA® Microalbumin Test (semiquantitative) is a competitive immunoassay, in which immobilized human albumin of the test competes with the albumin which may be present in the urine for a limited number of antibody binding sites.
The test strip is in the test line region (T-region) coated with human albumin. At the contact side of the membrane resides a pad with color marked anti-albumin antibodies. With the added urine, which flows by capillary action along the membrane, the antibodies arrive at the T-region. If no albumin is present in the urine, the anti-bodies bind to the immobilized albumin on the membrane, forming a reddish colored line.
If, however, albumin is present in the urine, it competes with the albumin of the T-region for the binding sites of the antibody. With an increasing albumin concentration in the urine, the bonding of the antibody in the T-region is more and more prevented and the color intensity of the test result line becomes continuously weaker. This reduction of color intensity can be traced via the provided color scale, with whose assistance the color intensity can be assigned to a certain albumin concentration (semi-quantitative evaluation). If the test result line has completely disappeared, the albumin concentration is above the range suitable for the semi-quantitative evaluation. The test result can then be considered positive.
As control function the test strip contains in addition a control line in the control region (C-region). Here a different antigen anti-body reaction leads to the development of a red colored line. The control line indicates that 1) the amount of liquid was sufficient and 2) the capillary flow was properly obtained. The control line should always appear and is formed regardless of the albumin concentration in the sample material. The color intensity of the control line is insignificant for the semi-quantitative evaluation.
The presence of albumin in the urine sample is indicated by the test up to 100 mg/l via a weakening of the color intensity of the test result line. This dilution of the color intensity is read off by means of the enclosed color scale thereby enabling an allocation of the albumin concentration. Values of 20 mg/l or higher should be considered positive test results which make further examinations necessary.

MATERIALS SUPPLIED

- Individually pouched test strips
- One instruction sheet
- Color scale on the inner plate of the box

MATERIALS REQUIRED

- Specimen collection containers
- Timer

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 single 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 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) do not cause any danger if the test is used according to the instructions.
- For evaluation use only the enclosed color scale of the appropriate package.

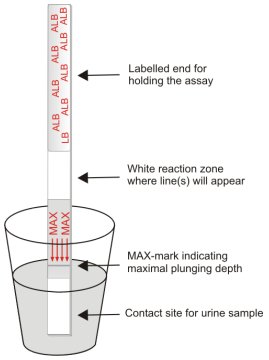
SPECIMEN COLLECTION AND STORAGE

- 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 labelled 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. Read the test result after 5 Minutes, by comparing the color intensity of the test result line within the T-range with the color scale. The evaluation should take place no later than 10 minutes after the test. Please adhere strictly to this time. Longer

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or shorter response times affect the color intensity of the test result line and obstruct a safe semi-quantitative evaluation.

INTERPRETATION OF RESULTS

Please note that for a valid result the appearance of the control line in the C-range is absolutely necessary, since the correct sequence of the test is indicated by this line. The color intensity of the control line is insignificant for the result interpretation and can slightly vary from test to test. The actual test result is indicated by the test result line in the T-range of the test strip. Their color intensity decreases continuously up to an albumin concentration of 100 mg/l. An alignment with the color scale on the inner plate of the box makes a semi-quantitative evaluation of the test possible. Please use only the color scale of the appropriate package!

Positive test result:

The color intensity of the test result line is identical or paler than the color for 20 mg/l on the color scale (see inner plate of the box). A match with the color intensity of the color scale makes the classification of the result into the different concentration ranges possible. At concentrations above 100 mg/l no test line develops anymore. Such samples are to be considered in any case as positive, even if they are not semi-quantitative evaluable.

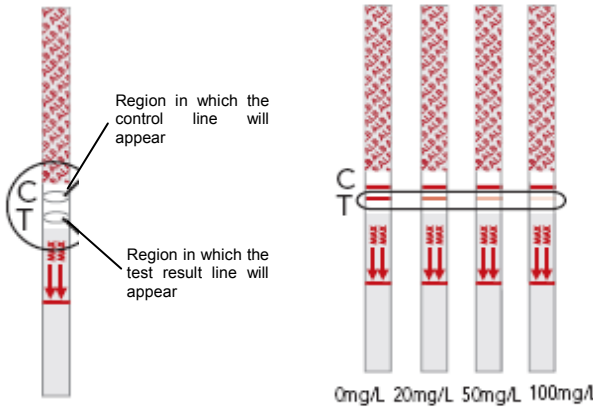
Negative test result:

The color intensity of the test result line is equivalent to the color for 0 mg/l on the color scale. In this case the sample does not contain traceable quantities of albumin. If the color Intensity of the test result line is paler than the 0 mg/l value but more intensive than the color for 20 mg/l on the color scale, the albumin concentration is in a range which can be considered harmless. Such results are to be likewise considered as negative test results.

Color Scale

Use only the color scale on the inner plate of the box!

For the interpretation of the result please match the color intensity of the test result line with the color scale



Invalid test result:

No control line is developed in the control region C. Under no circumstances should a test without control line be evaluated, even if the test result line is recognizable. Repeat the screening with a new test strip.

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 OF THE TEST

- The assay is designed for use with human urine only. Solely urine should be used as sample material, since a safe semi-quantitative evaluation is otherwise not warranted.
- 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

The performance characteristics for the DIMA® Microalbumin Test (semiquantitative) were determined by spiked urine samples. This resulted in the following performance characteristics:

Diagnostic sensitivity:	> 99 %
Diagnostic specificity:	83,3 %
Positive predictive value:	88,9 %
Negative predictive value:	> 99 %
Reproducibility:	92,9 %

Specificity

The specificity of the DIMA® Microalbumin Test (semiquantitative) was tested with the compounds mentioned below, which are likely to be present in urine. They were added to normal urine with only small albumin quantities. The following compounds produced a positive result starting from a concentration of 1,000 µg/ml

- Alfa-Fetoprotein (AFP)

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)-(-)-N-Methyl-Ephedrine, (+)-Naproxen, (+/-)-Norephedrine, Oxalic Acid, Penicillin-G, Pheniramine, Phenothiazine, L-Phenylephrine, D-Phenylethylamine, Procaine, Quinidine, Ranitidine, Sodium Chloride, Sulindac, Thioridazine, Trifluorperazine, 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

SYMBOLS

IVD	For *in-vitro* diagnostic use only		For single use only
Σ	Content		Expiry date
LOT	Lot number		Storage temperature
	Manufacturer		Carefully read package insert

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