Micro-Albumin

Rapid test for the detection of human albumin in urine

Product-#: D-ALB-U11-002

INTENDED USE

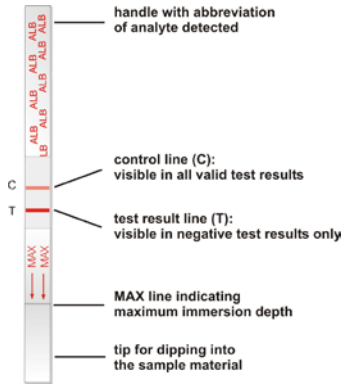
The DIMA® Microalbumin Rapid Test is a rapid visual immunoassay for the qualitative, presumptive detection of albumin in human urine specimens at a cut-off of 20 µg/ml. This kit is intended for use as an aid in the diagnosis of renal dysfunction.

INTRODUCTION

The persistent appearance of small amounts of albumin in urine (microalbuminuria) may be the first indicator of a renal dysfunction. For diabetic patients, positive results may be the first indicator of a diabetic nephropathy. Without therapy, the amount of released albumin will increase (macroalbuminuria) and renal insufficiency will occur.
In cases of Type 2 diabetes, the early diagnosis and therapy of diabetic nephropathy is especially important. In addition to being the earliest manifestation of nephropathy, albuminuria is also a marker of an increased risk for cardiovascular diseases in type-2 diabetes.
In normal physiological conditions, small amounts of albumin are glomerularly filtrated and tubularly reabsorbed. The expulsion of 20 µg/mL to 200 µg/mL albumin in urine is characterized as microalbuminuria. In addition to renal dysfunction, a transient albuminuria might also be caused by physical training, infection of the urinary tract, hypertension, cardiac insufficiency and surgery.

PRINCIPLE

The DIMA® Microalbumin Rapid Test is a 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 lower end of the membrane. With the urine the colored antibodies move towards the test result line region by capillary action. If no albumin is present in the urine they 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 sites of the colored antibody become more and more saturated. The binding of the antibody at the T-region 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 line in the T-region indicates a positive test result.
The appearance of a colored line at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.



MATERIALS SUPPLIED

- individually pouched test strips
- Package insert

MATERIALS REQUIRED

- Specimen collection containers
- Stop watch or timer

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- Read the entire procedure carefully prior to any testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens and used testing materials in accordance with local regulations. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The components of the test (e.g. antibodies/chemicals) do not cause any danger if the test is used according to the instructions.

SPECIMEN COLLECTION AND STORAGE

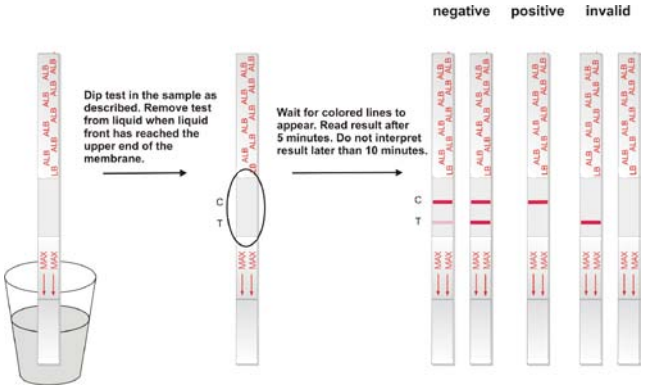
- The DIMA® Microalbumin Rapid Test is intended for use with human urine specimens only.
- Use **first morning urine** to perform the test, since physical exercise might increase the amount of albumin in urine.
- Urine specimens must be collected in clean, dry containers. Use new specimen collections containers for each sample to avoid cross contaminations. Ensure that the volume of specimen collected is sufficient to submerge the dip region of the strip.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch and use it as soon as possible. For best results, the assay should be performed within one hour.
2. Hold the strip by the end, where the abbreviation of the analyte is printed. To avoid contamination, do not touch the membrane of the strip.
3. Holding the strip vertically, dip the tip of the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip.

   As the test begins to work, color will migrate across the membrane.
4. After the liquid front has reached the upper end, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and wait for the colored line(s) to appear.
5. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



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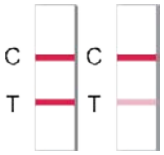
INTERPRETATION OF RESULTS

Positive result

Only **one colored line** appears, in the control region (C). No colored line appears in the test region (T). The absence of a test result line indicates a positive result meaning that the albumin concentration of the sample is elevated (≥ 20 µg/ml).

Negative Result



Two colored lines appear on the membrane. One line appears in the control region (C) and another line appears in the test region (T). This indicates that the albumin concentration of the sample is below the cut-off (20 µg/ml) of the assay.

Invalid Result

Control line fails to appear. Results from any test which has not produced a control line at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

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 or negative determination is made. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.

QUALITY CONTROL

- An internal procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The DIMA® Microalbumin Rapid Test is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of microalbumin.
2. The DIMA® Microalbumin Rapid Test provides only a preliminary analytical result. Positive results should be confirmed by a quantitative method that takes into consideration the rate of albumin secretion or the albumin-to creatinine ratio.
3. A positive result with the test indicates the presence of albumin only, and does not necessarily indicate diabetic nephropathy. Note that conditions like physical exercise, infection of the urinary tract, hypertension, cardiac insufficiency and surgery might lead to transiently elevated albumin levels.
4. 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.
5. As with all rapid assays a final diagnosis should not be based on the result of the assay alone. All clinical findings and symptoms should be considerated.
6. The test is designed for use with human urine only. Testing with pure water for quality purposes may lead to false or invalid results.

PERFORMANCE CHARACTERISTICS

A. Accuracy
The accuracy of the DIMA® Microalbumin Rapid Test was evaluated in comparison to a commercially available immunoassay at a cut-off of 20 µg/ml. 100 urine samples from volunteers were tested by both procedures and showed >98% agreement.

B. Reproducibility
The reproducibility of the DIMA® Microalbumin Rapid Test was evaluated at 4 different sites using blind controls. Of 50 samples with albumin concentrations lower than 10 µg/ml, all were determined to be negatives. Of 50 samples with albumin concentrations greater than 40 µg/ml, all were determined to be positive.

C. Sensitivity
The DIMA® Microalbumin Rapid Test has a sensitivity of 20 µg albumin/ml in urine.

D. Specificity
The specificity of the DIMA® Microalbumin Rapid Test was tested with compounds that might 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:

Acetaminophen	(±)-Ephedrine	L-Phenylephrine
Acetone	(+)-Epinephrine	D-Phenylethylamine
Amitriptyline	Erythromycin	Procaine
Ampicillin	Ethanol	Quinidine
L-Ascorbate	Furosemide	Ranitidine
Aspartame	Glucose	Riboflavin
Aspirin	Guaiacol glyceryl ether	Sodium chloride
Atropine	Hemoglobin	Sulindac
Benzocaine	Imipramine	Thioridazine
Bilirubin	(±)-Isoproterenol	Trifluoperazine
Caffeine	Lidocaine	Trimethobenzamide
Chloroquine	N-Methyl-ephedrine	Tyramine
(±)-Chlorpheniramine	(+)-Naproxen	
Creatine	(±)-Norephedrine	
Dexbrompheniramine	Oxalic acid	
Dextromethorphan	Penicillin-G	
4-Dimethylaminoantipyrine	Pheniramine	
Dopamine	Phenothiazine	

LITERATURE REFERENCES

1. Hasslacher C, Danne T, Sawicki PT, Walter H. Frühdiagnose der diabetischen Nephropathie. Dtsch Arztebl 1999; 96(1-2): A-51 / B-47 / C-47.
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.

EXPLANATION OF SYMBOLS

IVD	For in-vitro diagnostic purposes only	2	For single use only
▼	Content		Expiration date
LOT	Charge number		Storage temperature
	Observe the instruction sheet		Manufacturer

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