Atlas Medical

Microalbumin Test Device

IVD *For in vitro diagnostic and professional use only*

Store at 2-30 °C CE

Intended Use:
Microalbumin Rapid Test Device (Urine) is a rapid visual immunoassay for the qualitative, detection of microalbumin in human urine specimens. 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 renal dysfunction, some cardiovascular risks are also present.
In normal physiological conditions, small amounts of albumin are glomerularly filtrated and tubularly reabsorbed. The expulsion of 20 µg/mL to 200 µg/mL in urine is characterized as microalbuminuria. In addition to renal dysfunction, albuminuria can be caused by physical training, infection of the urinary tract, hypertension, cardiac insufficiency and surgery.

Principle:
Microalbumin Rapid Test Device (Urine) detects microalbumin through visual interpretation of color development on the device. Albumin conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-albumin monoclonal antibodies conjugated to colored particles and pre-coated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there is insufficient microalbumin in the specimen, the antibody-colored particle conjugate will bind to the antibody conjugate, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the microalbumin. If microalbumin is present in the urine at a sufficient concentration, it competes with the immobilized conjugate on the test region for limited antibody binding sites. This will prevent attachment of the colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band 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
Materials provided
- Individually pouched test device.
- Plastic Dropper.
- Package inserts.

Materials required but not provided:
- Specimen collection container.
- Timer.
- Centrifuge.

Packaging Content
REF **8.16.52.0.0001 (1 Test cassette, individually pouched)**
REF **8.16.52.0.0020 (20 Test cassette, individually pouched)**

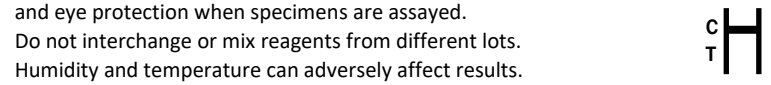
Precautions:
- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package.
- Do not use the test if the foil pouch is damaged.
- Do not reuse the test.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to 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. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulation.

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.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

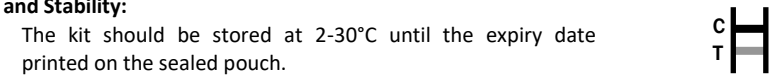
Specimen Collection and Storage:
- Microalbumin Rapid Test device (Urine) is intended for use with human urine specimens only.
- Though urine specimens from any time of day can be used, first morning urine specimens are preferred, as they contain the highest concentration of microalbumin.
- Urine specimens must be collected in clean, dry containers.
- 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 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. Add 3 drop of specimen (approximately 120 µl)to the specimen well (S) of the device
3. As the test begins to work, color will migrate across the membrane. timer and wait for the colored band(s) to appear.
4. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

Interpretation of results:

POSITIVE RESULT:


Only one colored band appears, in the control region (C). No colored band appears in the test region (T).

NEGATIVE RESULT:


Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID RESULT:
Control band fails to appear. Results from any test which has not produced a control band at the specified read 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.

NOTES:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. 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.

Quality Control:

- Internal procedural controls are included in the test. The appearance of a colored band 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:

- Microalbumin Rapid Test Device (Urine) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of microalbumin.
- The Microalbumin Rapid Test Device (Urine) provides only a quantitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result.
- A positive result with the test indicates the presence of albumin only, and does not necessarily indicate diabetic nephropathy.
- A negative result may not necessarily indicate microalbumin-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test (20 µg/mL).
- 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.
- The test is designed for use with human urine only. Testing with pure water may lead to false or invalid results.

Performance Characteristics:

A. Accuracy

The accuracy of the Microalbumin Rapid Test Device (Urine) 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 Microalbumin Rapid Test Device (Urine) 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 Microalbumin Rapid Test Device(Urine) has a sensitivity of 20µg/mL in urine.

D. Specificity

The specificity of the Microalbumin Rapid Test Device (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:

Acetaminophen	(±)-Ephedrine
Acetone	(+)-Epinephrine
Amitriptyline	Erythromycin
Ampicillin	Ethanol
L-Ascorbate	Furosemide
Aspartame	Glucose
Aspirin	Guaiacol glyceryl ether
Atropine	Hemoglobin
Benzocaine	Imipramine
Bilirubin	(±)-Isoproterenol
Caffeine	Lidocaine
Chloroquine	D-Methamphetamine
(±)-Chlorpheniramine	L-Methamphetamine
Creatine	(±)-3,4-Methylenedioxy-methamphetamine (MDMA)
Dexbrompheniramine	N-Methyl-ephedrine
Dextromethorphan	(+)-Naproxen
4-Dimethylaminoantipyrine	Procaine
Dopamine	Quinidine
Oxalic acid	Sulindac
Pheniramine	Riboflavin
(±)-Norephedrine	Sodium chloride
Penicillin-G	Trimethobenzamide
D-Phenylethylamine	Thioridazine
Phenothiazine	Trifluoperazine
L-Phenylephrine	Tyramine
Ranitidine	

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.

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

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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