MICROALBUMIN DEVICE (2-30ºC)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADMAU1	20 Tests

Intended Use:
The Microalbumin Rapid Test Device (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.

Summary:
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 is 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.

Test Principle:
The Microalbumin Rapid Test Device (Urine) detects microalbumin through visual interpretation of colour development on the Device. Albumin conjugates are immobilized on the test region of the membrane. During testing, the sample reacts with anti-albumin monoclonal antibodies conjugated to coloured particles and precoated 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 sample, the antibody-coloured particle conjugate will bind to the antibody conjugate, forming a coloured band at the test region of the membrane. Therefore, a coloured band appears in the test region when the urine is negative for 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 on the coloured particles. This will prevent attachment of the coloured particle conjugate to the test region. Therefore, the absence of a coloured band at the test region indicates a positive result. The appearance of a coloured band at the control region serves as a procedural control, indicating that the proper volume of sample has been added and membrane wicking has occurred.

Materials Provided
Individually pouched test devices
Instructions for Use

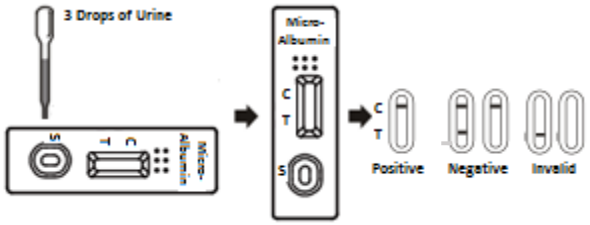
Materials not provided: Timer, specimen collection container, centrifuge

Precautions:
- For professional *in vitro* diagnostic use only.
- Do not use after the expiry date indicated on the kit. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- 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 samples by using a new specimen collection container for each sample obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the samples and kits are handled. Handle all samples as if they contain infectious agents. Observe established precautions for proper disposal of samples. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

Reagent Preparation 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:
- The Microalbumin Rapid Test Device (Urine) is intended for use with human urine specimens only.
- Though urine samples from any time of day can be used, first morning urine specimens are preferred, as they contain the highest concentration of microalbumin.
- 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.

Assay Procedure:
Bring tests, specimens, buffer 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. Place the device on a clean, level surface. Holding the dropper vertically, transfer 3 drops (approximately 120 µl) of urine sample to the sample well of the device. Avoid air bubbles developing in the sample well.
3. Start the timer and wait for coloured band(s) to appear.
4. The test result should be read at 5 minutes. Do not interpret the result after 10 minutes.



Interpretation of Results:

POSITIVE: Only one coloured band appears in the control region (C). No band appears in the test region (T). The absence of a band in the test region indicates that the albumin concentration in the sample is equal to or greater than 20 µg/ml.

NEGATIVE: Two coloured bands appear, one in the control region (C) and one in the test region (T). The band in the test region may vary in intensity but any visible band indicates a negative result, that is, albumin concentration in the sample at less than 20 µg/ml. This is a qualitative test only and cannot determine the absolute concentration of albumin in the sample.

INVALID: The control band fails to appear. Insufficient sample volume added or incorrect capillary movement of sample and reagents are the most common causes of control line failure. Repeat with a new test. If the problem persists, stop using the kit and contact your local distributor.

Quality Controls:
Internal procedural controls are included in the test. A coloured band 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 Microalbumin Rapid Test Device (Urine) is for professional *in vitro* diagnostic use and should only be used for the qualitative detection of microalbumin.
2. The Microalbumin Rapid Test Device (Urine) provides only a preliminary analytical result and clinical diagnosis should not be made on the result alone. A secondary analytical method must be used to obtain a confirmed result.
3. A positive result with the test indicates the presence of albumin only and does not necessarily indicate diabetic nephropathy.
4. A negative result may not necessarily indicate microalbumin-free urine. Negative results can be obtained when albumin is present but below the cut-off level of the test (20 µg/ml).
5. 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.

Performance Characteristics:
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.
Reproducibility
The reproducibility of the Microalbumin Rapid Test Device (Urine) was evaluated in 4 independent studies using unknown samples. Fifty samples with albumin concentration lower than 10 µg/ml, were all determined as negative. Fifty samples with albumin concentration greater than 40 µg/ml, were all determined as positive.
Sensitivity
The Microalbumin Rapid Test Device (Urine) has a sensitivity of 20 µg/ml in urine.
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 human urine with less than cut-off concentration of albumin:

Alfa-fetoprotein (AFP) induced positive results in the Microalbumin Rapid Test Device when tested at ≥ 1000 µg/ml.

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

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

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.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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