ACRO BIOTECH, INC

Micro-Albumin Semi-quantitative Rapid Test Cassette (Urine)

Package Insert

A rapid test for the semi-quantitative detection of Micro-Albumin in urine.
For professional in vitro diagnostic use only.

INTENDED USE

The Semi-quantitative Micro-Albumin Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the semi-quantitative detection of micro-albumin in human urine.

SUMMARY

This product is used to obtain a visual, semi-quantitative result and is intended for professional use only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result.

The steady expulsion of small quantities of albumin with the urine can be the first sign of kidney damage. In the healthy kidney albumin is usually glomerular filtrated and tubular reabsorbed, so that it is hardly detectable in urine. With a damaged kidney this process is disordered. The expulsion of albumin in the range of 20 - 200 mg/L is characterized as microalbuminuria. With this microalbumin test such small concentrations are already securely captured. Especially with diabetics positive results could point to a beginning diabetic nephropathy. Without appropriate therapeutic intervention it will lead for a high percentage of patients to a progression of this complication. The expulsion of albumin increases continuously (= macroalbuminuria) and ends finally after several years in a renal failure, which makes dialysis or a kidney transplant inevitable. In the USA and Europe diabetes is the main cause for terminal kidney failure. A study (DEMAND), accomplished world-wide, shows that approx. 41% of type-2 diabetics exhibit a microalbuminuria. The frequency of microalbuminuria increases with age, blood pressure and diabetes duration, and is the rarer, the better the blood sugar is adjusted. The high prevalence of the illness reveals how important a microalbuminuria annual screening is for diabetics. For type-1 diabetics the first measurements are usually recommended 5 years after initiation of the illness. For type-2 diabetics the screening should start directly with the first outset of the diagnosis, since it is unknown, how long the illness already exists. The diagnosis of a microalbuminuria is also of special importance, since it can be not only the first sign of a beginning nephropathy but also an indicator for an increased risk for cardiovascular illnesses for type-2 diabetics. An increase of albumin expulsion can be due, beside damages of renal structures, to additional factors of influence like physical activity, infections of the urinary tract, high blood pressure, heart insufficiency or surgical interferences.

If the increased albumin expulsion disappears after removal of these factors, it concerns only a transient albuminuria without any pathological reason.

Since the albumin expulsion can vary substantially from day to day, at least 2 of 3 urine samples, which were collected over a period of 3-6 months, should show increased albumin values, before a microalbuminuria is diagnosed.

PRINCIPLE

The Semi-quantitative Micro-Albumin Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Human albumins may be present in the urine specimen compete against the albumin conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Albumin, if present in the urine specimen below 20ug/mL, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized human albumin and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Albumin level exceeds 20ug/mL because it will saturate all the binding sites of anti-albumin antibodies.

An albumin-positive urine specimen will not generate a colored line in the test line region because of albumin competition, while an albumin-negative urine specimen or a specimen containing a albumin concentration less than the 20ug/mL will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred

REAGENTS

The test cassette contains Albumin antibody particles and Albumin antigen coated on the membrane.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Use preferably only morning urine for testing since physical effort can lead to an increase in albumin expulsion. Samples and control materials that have been refrigerated must be equilibrated to room temperature before testing.

MATERIALS

Materials provided

- Test cassettes
- Package insert
- Color Card
- Droppers

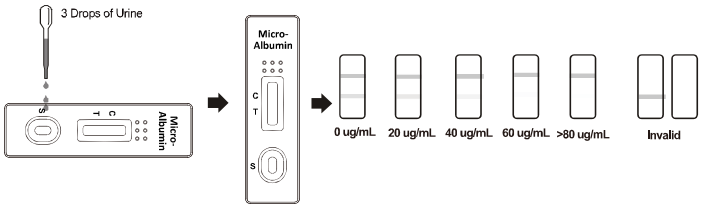
Materials not provided

- Specimen collection containers
- Timer

DIRECTIONS FOR USE

Allow the test, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine (approx.120µ L)** to the specimen well(S) of test cassette and start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the line(s) to appear. Read the results at 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. Longer or shorter response times affect the color intensity of the test result line and obstruct a safe semi-quantitative evaluation.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two lines appear or only one line. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T) or no line apparent in the test region (T).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: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). 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.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the diagnostic test immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, 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

1. The Semi-quantitative Micro-Albumin Rapid Test Cassette (Urine) for in vitro diagnostic use only.
2. The Semi-quantitative Micro-Albumin Rapid Test Cassette (Urine) is used for professional only.
3. To avoid cross contamination a separate collection container should be used for each specimen.
4. For evaluation use only the enclosed color scale of the appropriate package.
5. Use preferably only morning urine for testing since physical effort can lead to an increase in albumin expulsion.

EXPECTED VALUES

The Semi-quantitative Micro-Albumin Rapid Test Cassette (Urine) has been compared with a leading commercial Albumin ELISA test. The correlation between these two systems is 92.0%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The specimen correlation used a specimen number (n) equal to 151 (91 positive specimens and 60 negative specimens confirmed by ELISA). Specimens were rated as either positive or negative at 5 minutes. Do not interpret the results after 10 minutes. Results were presented in table below.

Method		ELISA		Total Results
Albumin Test Cassette	Results	Positive	Negative	
	Positive	89	10	99
	Negative	2	50	52
Total Results		91	60	151

Relative Sensitivity: 97.8% (95%CI*: 92.3%-99.7%)
Relative Specificity: 83.3% (95%CI*: 71.5%-91.7%)
Accuracy: 92.0% (95%CI*: 86.5%-95.8%) *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of six specimens containing 0µg/ml, 20µg/ml, 40µg/ml, 60µg/ml, 80µg/ml and 100µg/ml of Albumin. The negative and positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by using the same six specimens of 0µg/ml, 20µg/ml, 40µg/ml, 60µg/ml, 80µg/ml and 100µg/ml of Albumin in15 independent assays. Three different lots of the Micro-Albumin Rapid Test Dipstick(Urine) has been tested using these specimens. The specimens were correctly identified >99% of the time.

Interfering Substances

The Semi-Quantitative Micro-Albumin Rapid Test Dipstick (Urine) has been tested for possible interference substance for example Acetaminophen, Acetone, Amitriptyline and so on. No interference was observed at the concentration of 150µg/ml.

Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

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