



**OneStep
 Microalbumin
 RapiCard™ InstaTest**

REF 110511

PIC ID110511VV86

IVD See External Label 30°C 25 Tests

Microalbumin RapiCard™ InstaTest	
Principle	Immuno-chromatographic Assay
Detection	Qualitative
Sensitivity	20 µg/ml

PRODUCT FEATURES

- High Sensitivity and Specificity**
- Built in Internal Controls**
- Simplified Workflow, Non-invasive, and Safe**
- Rapid and Faster Results**

INTENDED USE

The OneStep Microalbumin RapiCard™ InstaTest (Urine) is a rapid chromatographic immunoassay for the qualitative detection of micro-albumin in human urine.

SIGNIFICANCE AND 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 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 20µg/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.

ASSAY PRINCIPLE

The OneStep Microalbumin RapiCard™ InstaTest (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 20µg/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 20µg/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 an albumin concentration less than the 20µg/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.

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.

REAGENTS

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

Materials provided with the kit

- Test cassettes
- Droppers
- Package Inserts

Materials required but not provided

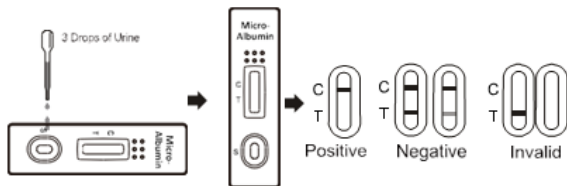
- Specimen collection container
- Timer



ASSAY PROCEDURE

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. 120µL) 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 results at 5 minutes. Do not interpret the result after 10 minutes.



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.

RESULTS

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). This indicates that the albumin concentration of the sample is below the cut-off (20µg/ml) of the assay.

POSITIVE: Only one line appears. Only one line appears in the control region (C), no color line appears in the test region (T). The absence of a test result line indicates a positive result meaning that the albumin concentration of sample is elevated ($\geq 20\mu\text{g/ml}$).

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.

LIMITATIONS OF THE ASSAY

1. The OneStep Microalbumin RapiCard™ InstaTest (Urine) is for professional in vitro diagnostic use only, and should only be used for the qualitative detection of micro albumin.
2. The OneStep Microalbumin RapiCard™ InstaTest (Urine) provides only a preliminary analytical result. Positive result 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, hyper tension, 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 considerate.
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.

EXPECTED VALUES

The OneStep Microalbumin RapiCard™ InstaTest (Urine) has been compared with a leading commercial Albumin ELISA test. The correlation between these two systems is 95%.

PERFORMANCE CHARACTERISTICS

Accuracy

The accuracy of the OneStep Microalbumin RapiCard™ InstaTest(Urine) was evaluated in comparison to a commercially available immunoassay at a cut- off of 20µg/ml. 100 urine samples from volunteers were tested by both procedures and showed >98% agreement.

Reproducibility

The reproducibility of the OneStep Microalbumin RapiCard™ InstaTest (Urine) was evaluated at 4 different sites using blind controls. Of 50 samples with albumin concentrations lower than 10µg/ml, all were determined to be negatives. Of 50 samples with albumin concentrations greater than 40 µg/ml, all were determined to be positive.

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**Sensitivity**

The OneStep Microalbumin RapiCard™ InstaTest (Urine) has a sensitivity of 20µg albumin/ml in urine.

Specificity

The specificity of the OneStep Microalbumin RapiCard™ InstaTest (Urine) 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
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
Creatine	(±)-Norephedrine	Oxalic acid
4-Dimethylaminoantipyrine	(±)-Chlorpheniramine	(+)-Naproxen

Penicillin-G	Acetone	Pheniramine
(+)-Epinephrine	D-Phenylethylamine	Phenothiazine
Dopamine	Dexbrompheniramine	Dextromethorphan

PRECAUTIONS

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

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

STORAGE CONDITIONS



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.

REFERENCES

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

- 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.
- 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.

MANUFACTURER AND BRAND DETAILS

 <p>ISO 13485:2016 Quality Management for Medical Devices CERTIFIED</p>	
 <p>Diagnostic Automation/Cortez Diagnostics, Inc. 21250 Califa Street, Suite 102 and 116, Woodland Hills, California 91367 USA</p>	
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