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DIAQUICK Microalbumin Dipstick

for the qualitative detection of albumin in human urine samples

REF	Content
Z08070CE	- 50 Tests individually packed (50x REF Z08070B) - 1 Package Insert

For professional in vitro diagnostic use only

INTENDED USE

The DIAQUICK Microalbumin Dipstick is a rapid chromatographic immunoassay for the qualitative detection of microalbumin in human urine.

SUMMARY

The persistent appearance of small amounts of albumin (Microalbuminuria) in urine could be the first indicator of a renal dysfunction. For persons with diabetes, a positive result could be the first indicator of a diabetic nephropathy. Without initiation of therapy, the amount of released albumin will increase (macroalbuminuria) and renal insufficiency will occur that makes dialysis or kidney transplantation inevitable. In the U.S. and Europe diabetes has become the most common single cause of end-stage renal disease.
In addition to being the earliest manifestation of nephropathy, albuminuria is also a marker of a greatly increased risk for cardiovascular diseases in type-2 diabetes.
About 41 % of patients with type-2 diabetes exhibit a mircoalbuminura. In a first world-wide study (DEMAND) it could be shown that the frequency of microalbuminuria increased with age, hypertension and the duration of the disease. It was less frequent in patients with good glycemic control.
This high prevalence of microalbuminuria shows the importance of a regular annual screening of diabetes patients. For type-1 diabetes patients, screening should start about 5 years after the onset of the disease. For type-2 diabetes patients screening should be started at the time of diagnosis because of the uncertainty of dating the start of the disorder.
At normal physiological conditions, small amounts of albumin are glomerular filtrated and tubular reabsorbed in the kidneys. The expulsion of 20 µg/mL to 200 µg/mL urine is characterized as microalbuminuria. In addition to renal dysfunctions, microalbuminuria can also be caused by physical training, infections of the urinary tract, hypertension, cardiac insufficiency and surgery. If the amount of albumin decreases after disappearance of these factors, this transient albuminuria is of no pathological relevance. 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.

TEST PRINCIPLE

The DIAQUICK Microalbumin Dipstick is a one-step 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 colour-labelled anti-albumin monoclonal antibody is placed at the lower end of the membrane. With the urine the 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 of the antibody is more and more inhibited and the colour 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 coloured band in the T-region indicates a positive test result.
A control line with a different antigen/antibody reaction is also added to the immunochromatographic membrane strip at the control region (C-region) to indicate that the test has been performed properly. The presence of the control line serves as 1) verification that sufficient volume has been added, and 2) that proper flow was obtained. The control line should always appear, regardless of the presence or absence of albumin.
This means that negative urine will produce two coloured lines, whereas positive urine with elevated levels of albumin will produce only one coloured line.

MATERIALS PROVIDED

- test strips
- package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- specimen collection container
- timer

REAGENTS

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

WARNINGS AND PRECAUTIONS

- For professional in-vitro diagnostic use only
- Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
- Do not use after the expiration date, if the tube has been damaged, or if the tube has not been closed properly.
- The components of the test (e.g. antibodies / albumin / chemicals) do not cause any danger if the test is used according to the instructions.

STORAGE AND STABILITY

The DIAQUICK Microalbumin Dipstick can be stored refrigerated or at room temperature (2 – 30 °C). The tests are stable through the expiration date printed on the sealed pouch. The test strips must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

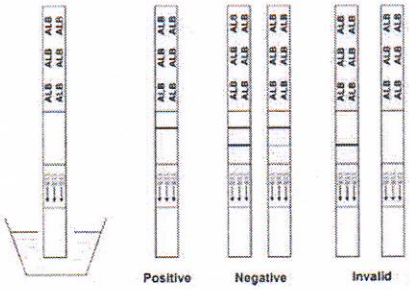
SPECIMEN COLLECTION AND HANDLING

Use first morning urine to perform the test, since physical action might increase the amount of albumin in the urine. Specimens or controls that have been refrigerated must be equilibrated to room temperature prior to testing.

ASSAY PROCECURE

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

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, **immerse the test strip vertically in the urine specimen for at least 10-15 seconds.** Do not pass the maximum line (MAX) on the test strip when immersing the strip.
3. Place the test on a non-absorbent flat surface, start the timer and wait for the coloured line(s) to appear. **Read results at 5 min.** Do not interpret results after 10 min.



INTERPRETATION OF RESULTS

NEGATIVE: Two lines appear. One coloured line should be in the control line region (C), and another visibly coloured line should be in the test line region (T). This indicates that the albumin concentration is below the detectable level (< 20 µg/mL) of the assay.

***NOTE:** The shade of colour in the test region (T) may vary, but it should be considered negative whenever there is even a faint coloured line. 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.

POSITIVE: One coloured line appears in the control line region (C). No line appears in the test line region (T). This indicates that the albumin concentration exceeds the detectable level (≥ 20 µg/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 using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The assay is designed for use with human urine only. Please note that the use of water for quality control purposes results in control lines that are less intense than the test result line.
- A positive result with the test indicates the presence of albumin only, and does not unambiguously indicate a diabetic nephropathy.
- If it is suspected that the samples have gone bad or have been mislabelled a new specimen should be collected and the test should be repeated.
- Positive results should be confirmed by a quantitative method that takes into consideration the rate of albumin secretion or the albumin-to creatinine ratio.

PERFORMANCE CHARACTERISTICS

ACCURACY

The accuracy of the DIAQUICK Microalbumin Dipstick was evaluated in comparison to a commercially available immunoassay at a cut-off of 20 µg/mL. 100 urine samples from volunteers were tested with both procedures. The agreement was > 98 %.

REPRODUCIBILITY

The reproducibility of the test was evaluated at 4 different sites using blind controls. Of 50 samples with albumin concentrations < 10 µg/mL, all were determined to be negative. Of 50 samples with albumin concentrations > 40 µg/mL, all were determined to be positive.

SENSITIVITY

The DIAQUICK Microalbumin Dipstick has a sensitivity of 20 µg/mL in urine.

SPECIFICITY

The specificity of 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

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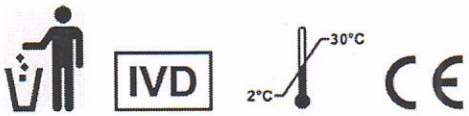
The following compounds were found not to cross-react when tested at concentrations up to 1000 µg/mL:

Paracetamol	Aceton	Amitriptyline
Ampicillin	Aspartame	Aspirin
Atropine	Bilirubin	Caffeine
Chloroquine	(+)-Chlorpheniramin	(+/-)-Chlorpheniramine
Creatine	Desoxyephedrine	Dexbrompheniramine
Dexbromethorphan	4-Dimethylaminoantipyrine	Dopamine
Ecgonine	Ecgonine Methyl Ester	(+/-)-Ephedrine
(-)-Ephedrine	(+)-Epinephrine	Erythromycin
Ethanol	Furosemide	Glucose
Guaiacol Glyceryl Ether	Haemoglobin	Imipramine
(+/-)-Isoproterenol	Lidocaine	(1R,2S)-(-)-N-Methyl-Ephedrine
(+)-Naproxen	(+/-)-Norephedrine	Oxalic Acid
Penicillin-G	Pheniramine	Phenothiazine
L-Phenylephrine	D-Phenylethylamine	Procaine, Quinidine
Ranitidine	Sodium Chloride	Sulindac
Thioridazine	Trifluorperazine	Trimethobenzamide
Tyramine	Vitamin C	

LITERATURE

1. Deutsches Ärzteblatt 96; Issue 1-2. 01-1999
2. Lurbe et al: Increase in Nocturnal Blood Pressure and Progression to Microalbuminuria in Type 1 Diabetes. NEJM 2002; 347: 797-805
3. Perkins: Regression of microalbuminuria in type 1 diabetes. NEJM 2003; 348: 2285-2293



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