Micro Albumin Urine Test Strip

(Urine)

IVD CE

PRODUCT CODE
US003

INTENDED USE:
Is dip-and-read test strips that are intended for qualitative and semiquantitative detection of Creatinine, Albumin in urine specimens .

CLINICALLY SIGNIFICANT:
Microalbuminuria refers to an albumin concentration in the urine which is greater than normal, but usually not detectable with routine protein dipstick assays which permit measurement of albumin at levels of 15 mg/dL or greater. There are multiple renal disease etiologies in which laboratory findings include proteinuria.11 Albumin is the prominent protein in most renal disease Monitoring low concentrations of albumin in the urine is helpful for early detection in patients at risk for renal disease.Those at risk for renal disease in which albuminuria may be present include, but are not limited to, patients with type 1 and type 2 diabetes, hypertension, and renal disease in pregnancy. Further studies indicate that normalization of blood glucose and blood pressure can prolong the progression from microalbuminuria to clinical nephropathy

PRINCIPLE:
The albumin present in the urine specifically binds with a soluble antibody-gold conjugate present on a zone on the test strip. Excess conjugate is retained in a separation zone containing immobilized human albumin. This allows only the conjugate-albumin immunocomplex from the sample to reach the detection zone. After one minute, the intensity of the color produced (white to red) is directly proportional to the albumin content in the urine.

Reagent Composition
For Each Urine Test Strip
Monoclonal Antibodies: Anti-human albumin IgG labeled with colloidal gold (mouse) 6 µg/cm2
Fixed albumin..... 9.5 µg/cm2

Precautions and Warnings
For in vitro diagnostic use.
Dispose of used test strips according to the regulations for potentially infectious materials. The remaining packaging components can be disposed as ordinary packaging materials.

Storage and Stability
Strips can be stored refrigerated or at room temperature. Expiration dates will differ. If stored refrigerated: Store at 2 to 8 °C.
Do not freeze. In order to avoid exposure to moisture, the vial must be tightly and immediately closed after removal of strips, using the original stopper. Do not use after the expiration date printed on the vial and box.
If stored at room temperature: The strips expire 6 months from the date taken out of refrigeration.

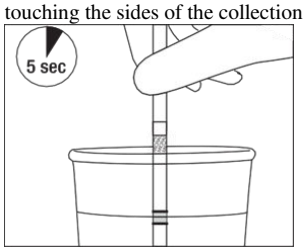
Specimen Collection and Preparation

When performing a test using Bioresearch test strips, the urine specimen should be collected in a clean, dry container. When a urine culture is ordered, it is necessary to collect the specimen in a sterile container. Perform the culture prior to testing for microalbuminuria as the test strip will contaminate the specimen. Due to the physiological variation of albumin, it is recommended that three separate morning (midstream) urine samples be collected and analysed within a given week. If testing cannot be performed within three days of collection, the urine sample should be refrigerated. Urine that has been refrigerated (for a maximum of two weeks) must be brought to at least 10 °C before testing. Any turbidity of the urine does not affect the test results. The use of urine preservatives with this product has not been valuated; therefore, the use of preservatives is not recommended.
Urine samples that have been allowed to stand at room temperature for more than 3 days or refrigerated for more than 14 days are considered unacceptable for analysis. The sample should not be frozen.

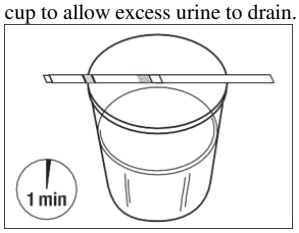
Procedure
Materials Provided: One vial containing 30 test strips. A visual comparison color scale for reading test results is printed on the vial label.

Materials Required, But Not Provided:
A timer and a clean specimen collection container. It is also recommended that commercial control products be used for
quality control checks.

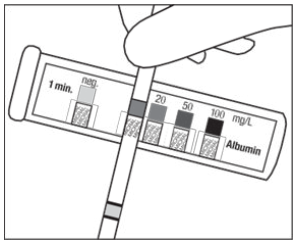
Assay:
Use strips immediately after removing vial from refrigerator.
1. Dip the test strip into the urine for 5 seconds. Make sure that the urine level is between the two black lines. Withdraw the strip carefully and avoid touching the sides of the collection cup.



2. Place the strip on a non-absorbent surface or across the top of the collection cup to allow excess urine to drain.



3. After approximately 1 minute, match the color of the test pad above the inscription with the color scale on the test strip vial. A wet detection area indicates that the reaction has come to an end. Since individual urine color can differ, the detection pad hue compared to the vial label may vary. In such a case, a particular color block should be assigned only if the intensity is at least equal to the intensity of the color block on the vial label. If the color development is slightly uneven, the average color is relevant. Comparison of the color reaction with the color scale is possible for up to 5 minutes, then the color disintegrates.



Calibration
Calibration of Bioresearch microalbumin urine test strips by the user is not required.
Quality Control
Each laboratory should establish its own goals for adequate standards of performance.
Commercially prepared control solutions should be used on a regular basis, as established by your institution's quality control protocols. The value range of the controls should be within the test strip reading range of 0-100 mg/L.
Results
Results are obtained by direct visual comparison with the color scale printed on the vial label. The levels of the color blocks are as follows: Neg., 20 mg/L, 50 mg/L and 100 mg/L. The visual color chart is intended to represent semi-

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quantitative findings and serves as a screening mechanism. If quantitative results are desired to confirm a positive result, it is recommended that further testing of the urine be carried out utilizing a reference procedure.
Determination of albumin concentrations above 100 mg/L: In order to determine albumin concentrations above 100 mg/L, the urine sample can be diluted by mixing one part of urine with two parts of water. The original albumin concentration is then calculated by multiplying the result obtained by 3.

Limitations

The amount of albumin excreted in the urine can vary according to changes in posture, amount of hydration, physical activity, blood pressure in the individual, and during pregnancy. Because of this individual variation, it is recommended that at least three separate samples be collected and analyzed within a given week to obtain
an accurate assessment of the patient. 21 Urine samples should not be obtained following strenuous physical activity.
A wet detection pad indicates that the reaction has come to an end. If the detection pad is still dry after one minute despite correct immersion depth and duration, check the color development after another
one or two minutes.
Acute illnesses that present with fever are known to cause an increase in urinary albumin excretion, such as urinary tract infection or bleeding into the urinary tract.
Urine from menstruating females will occasionally yield a false positive result. Therefore, a decision of the usefulness of the test must be made by the professional. It is recommended that testing of individuals be performed when there is no longer a condition.
No cross-reactivity exceeding 0.5% has been found with IgA, IgG, human leukocytes and erythrocytes.

Expected Values

The albumin concentration of an average urine specimen should not exceed 15–20 mg/L.
Clinical diabetic nephropathy is indicated when microalbuminuria (> 20g/L) is present in at least two of the three morning urine samples.
A normal microalbuminuria value does not rule out renal disease.

Performance Characteristics

RIA (Radioimmunoassay)

Random urine specimens were collected from patients under the care of endocrinologists and who presented themselves at clinics or hospitals. These samples were assayed by a quantitative RIA method and by Bioresearch test strips. The following results were obtained:

n = 464
Sensitivity = 93.7 %
Specificity = 94.2 %
Accuracy = 94.0 %

Immunoprecipitin

Random, 24-hour, and first morning urine specimens were collected from patients under the care of endocrinologists and who presented themselves at clinics or hospitals. These samples were assayed by a quantitative immuno-precipitin method and by Bioresearch test strips. The following results were obtained:

1. Random Urine Specimens
   n = 464
   Sensitivity = 90.4 %
   Specificity = 91.4 %
   Accuracy = 90.9 %
2. 24-Hour Urine Specimens
   n=464
   Sensitivity = 95.1 %
   Specificity = 96.4 %
   Accuracy = 95.9 %
3. First Morning Urine Specimens
   n = 268
   Sensitivity = 93.5 %
   Specificity = 91.5 %
   Accuracy = 92.2 %

SYMBOLS OB LABEL

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
Σ	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFERENCE

1. Borch-Johnsen K., Wenzel H., Viberti G.C., Morgenson C.E. "Is screening and intervention for microalbuminuria worthwhile in patients with insulin dependent diabetes?" BMJ. 1993; 306:1722-1725.

2. Jensen JS, Feldt-Rasmussen B; Strandgaard S, Schroll M, Borch-Johnsen K: Arterial hypertension, microalbuminuria, and risk of ischemic heart disease. Hypertension 2000; 35: 898-903.

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