SCREEN®

SCREEN IFA TEST MICROALBUMINURIA
(Urine)
Package Insert

REF: SC-1330-20	English

A rapid test for measuring Microalbumin in urine with the use of SCREEN® fluorescence Immunoassay Analyzer.
For professional in vitro diagnostic use only.

INTENDED USE

The Microalbumin Test Cassette (Urine) is based on Fluorescence Immunoassay to measure Microalbumin in Urine.

SUMMARY

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.1 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, to additional factors of influence like physical activity, infections of the urinary tract, high blood pressure, heart insufficiency or surgical interferences(besides damages of renal structures).
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 Microalbumin Test Cassette (Urine) detects Microalbumin based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. Microalbumin in the urine will compete with the Microalbumin antigen coated on the membrane. The less Microalbumin in the sample, the more chance that fluorescent microspheres-conjugated anti-Microalbumin antibodies can be captured by the Microalbumin antigen coated on the membrane (Test line). The concentration of microalbumin in the sample is inversely related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of Microalbumin in the sample can be calculated by Analyzer to show Microalbumin concentration in specimen.

REAGENTS

The test includes anti-Microalbumin antibody coated fluorphores and Microalbumin antigen coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The SCREEN® Microalbumin Test Cassette (Urine) should only be used with the SCREEN® Analyzer by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C before the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze**.
4. 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 PREPARATION

Use preferably only fresh morning urine for testing since physical effort can lead to an increase in albumin expulsion. Urine sample should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Samples that have been refrigerated must be equilibrated to room temperature before testing. Avoid repeated freezing and thawing of urine samples.

MATERIALS

Materials Provided

- Test Cassettes
- Package Insert
- ID Card
- Specimen Collection Tubes with Buffer

Materials Required But Not Provided

- Timer
- Centrifuge
- SCREEN® Fluorescence Immunoassay Analyzer
- Pipette
- Specimen Collection Containers

DIRECTIONS FOR USE

Refer to SCREEN® Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the Test. The test should be conducted in room temperature.
Allow the test, specimen and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyzer power. Then according to the need, select “Standard test” or “Quick test” mode.
2. Take out the ID card and insert it into the Analyzer port.
3. Pipette **75μL of urine** into the buffer tube; mix the specimen and the buffer well.
4. Transfer **75μL diluted sample** into the sample well of the test cassette.
5. There are two test modes for SCREEN® Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer for details.

“Quick test” mode: After **10 minutes** of adding sample, Insert the test cassette into the Analyzer, click “**QUICK TEST**”, fill the test information and click **"NEW TEST"** immediately. The Analyzer will automatically give the test result after a few seconds.
“Standard test” mode: Insert the test cassette into the Analyzer immediately after adding specimen, click “**STANDARD TEST**”, fill the test information and click **"NEW TEST"** at the same time, The Analyzer will automatically countdown **10 minutes**. After the countdown, the Analyzer will give the result at once.

INTERPRETATION OF RESULTS

Results read by SCREEN® Fluorescence Immunoassay Analyzer.
The result of tests for Microalbumin is calculated by SCREEN® Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer.
Linearity range of Microalbumin Test is 5~300 mg/L.
Reference range: < 20 mg/L.

QUALITY CONTROL

Each Microalbumin Test Cassette (Urine) contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test cassette was inserted and read properly by SCREEN® Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on SCREEN® Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an “N/A” message on SCREEN® Fluorescence Immunoassay Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Microalbumin Test Cassette (Urine) is for professional in vitro diagnostic use, and should only be used for the quantitative detection of Microalbumin.
2. The Microalbumin Test Cassette (Urine) will only indicate the presence of Microalbumin in the specimen and should not be used as the sole criterion for evaluating microalbuminuria.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results of Microalbumin Rapid Tests are based on measuring the levels of Microalbumin in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXTENDED RESULTS

Concentrations	Clinical Reference
< 20 mg/L	Healthy
> 20 mg/L	Kidney damage

PERFORMANCE CHARACTERISTICS

1. Accuracy
The test deviation is ≤±15%.
2. Sensitivity
The Microalbumin Test Cassette (Urine) can detect levels of Microalbumin as low as 5 mg/L in Urine**.**
3. Detection range
5 - 300 mg/L
4. Linearity range
5 ~ 300 mg/L , R≥0.990
5. Precision
Intra-lot precision
Within-run precision has been determined by using 10 replicates of 2 specimens containing 20 mg/L, 50 mg/L of Microalbumin. C.V. is ≤ 15%.
Inter-lot precision
Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 20 mg/L, 50 mg/L of Microalbumin. C.V. is ≤15%.
6. Method comparation
The assay was compared with commercial Turbidimetric Inhibition Immuno Assay test with 100 samples. The correlation coefficient(r) is 0.990.

BIBLIOGRAPHY

1. "Person—microalbumin level (measured), total micrograms per minute N[NNN].N". Retrieved 2007-07-05.

INDEX OF SYMBOLS

	Consult Instructions For Use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 4-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		

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Number: 146401601
Effective Date: 2021-06-22