PreventID® **Micro-Albumin**

Manual (FOR PROFESSIONAL USE)

REF KST79030GP

Intended Use

The **PreventID® Micro-Albumin** is a simple, one step immunochromatographic assay for the semi-quantitative determination of elevated albumin in urine (micro-albuminuria). The sensitivity of the test is 20 µg/mL of human serum albumin (HSA). For professional use only.

Introduction

Almost half of all insulin dependant diabetics develop a **diabetic nephropathy** (DNP) with protein in the urine and a decline in the filtration rate during the course of their disease. In order to prevent an advanced loss of kidney function, the diabetic nephropathy must be detected early, because it is only in the early phase of the disease (micro-albuminuria) and through specifically-aimed therapeutic intervention that the kidney damage can be reversed.

A **micro-albuminuria** is defined as a slight increase in the excretion of albumin in the urine (20-200 mg/L), caused by a disturbance in the glomerular filtration barrier. A micro-albuminuria may have various causes: it may be the concomitant product of profound physical stress, of fever, cardiac insufficiency or poor regulation of hypertension. After the elimination of the triggering factors, the levels return to normal. A constant, detectable, prolonged micro-albuminuria, in comparison, suggests damage to the glomerular filter.

Test Principle

The sample migrates from the specimen pad to the colloidal gold pad, which contains the gold conjugates. Albumin in the analyte binds to the mouse-anti-albumin colloidal gold.
When the antibody-antigen-colloidal gold complexes are transported across the membrane and reach the respective immobilised albumin on the membrane – test line (T) – , it is unable to react, because the antibody of the gold conjugate is already attached by the albumin in the urine. When the applied urine sample contains a less than certain concentration of albumin, the anti-albumin antibody of the gold conjugate will attach to the immobilised human albumin on the membrane, thus form a strong visible test line. As the albumin level in the urine sample increases, the less visible the test line becomes. In case there is sufficient albumin in the urine sample, the test region of the membrane will remain colourless.
The liquid colloidal gold conjugate also passes the immobilised control/reference line (C), as the concentration of the anti-rabbit are fixed as an integral part of the liquid colloidal gold conjugate, a fixed visible intensity of C line is developed.

Materials

Materials Provided

- Test strips, individually packed TEST
- Manual

Materials Required but not Provided: Timer or stop watch, sample container

Storage and Stability

Store the test between 4 °C and 30 °C; do not freeze. The test strip is sensitive to humidity as well as to heat. Perform the test immediately after removing the test strip from the pouch. Do not use it beyond the expiry date.

Precautions

1. For *in vitro* diagnostic use only.
2. Do not eat or smoke while handling specimen. Wear protective gloves and wash hands thoroughly after performing the test.
3. Avoid splashing or aerosol formation while handling specimen and performing the test.
4. All samples and materials used should be treated as potentially infectious and disposed in a biohazard container. Clean all contaminated objects and surfaces carefully.
5. Do not use test if the pouch is torn or if the membrane of the test strip is visibly damaged.
6. Read the instruction carefully before performing the test.
7. If you have any questions please contact Preventis GmbH.

Specimen Collection and Specimen Preparation

1. Fresh urine specimens do not require any special handling or pretreatment.
2. Specimens should be collected in a clean and dry sample container.
3. If testing will not be performed immediately, specimens should be refrigerated.
4. Specimens should be brought to room temperature before testing.
5. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying. Frozen urine or urine with additions must not be used for this test.

Test Procedure

1. Remove the test strip from the pouch.
2. Hold the test strip vertically and carefully dip it into the urine for 5–10 seconds (arrow in direction of the bottom). Do not immerse the test strip past the maximum line *(Fig. 1)*. Leave it in urine enough time so that the purple color migrate over the control line.
3. Interpret the test results at **5 minutes.**
   Do not read after 7 minutes.

   Caution: The above interpreting time is based on reading the test results at room temperature of 15 to 30 °C.

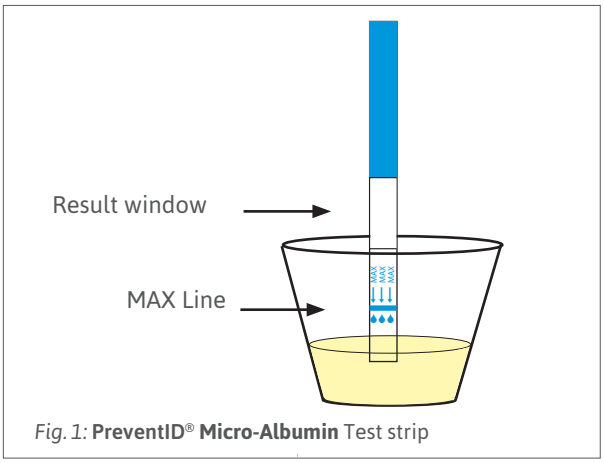

Fig. 1: **PreventID® Micro-Albumin** Test strip

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Test Interpretation *(Fig. 2)*

Note: PreventID® Micro-Albumin is a competitive test: the colour intensity of the purple line at (T) correlates inversely to the concentration of albumin in the sample. The more intensive the colour at (T), the less content of albumin in the urine sample.

1. A colour line will appear at the left section of the result window to show that the test is working properly. This line is the **control line (C)**.
2. The right section of the result window indicates the test results. If another colour line appears at the right section of the result window, this line is the **test line (T)**.

Negative:

Albumin value less than 20 µg/mL: The appearance of two purple lines within the result window indicates a negative test result. No micro-albumin above the cut-off level has been detected. The colour of the test line may be lighter or darker than that of the control line *(Fig. 2b)*.

Positive:

Albumin value greater than 20 µg/mL: The appearance of only one purple control line (C) within the result window indicates the result is positive, i.e. the specimen contains micro-albumin at a concentration above the cut-off level *(Fig. 2c)*.

Invalid:

A distinct purple control line (C) should always appear in the left section of the result window. If after performing the test no purple colour line is visible within the result window, this result is considered invalid *(Fig. 2d)*. Not following the procedures correctly or using a test strip that has deteriorated can cause invalid results. It is recommended that the specimen be re-tested.

Note: samples with a high concentration of rheumatoid factors may result in a nonspecific positive test result.

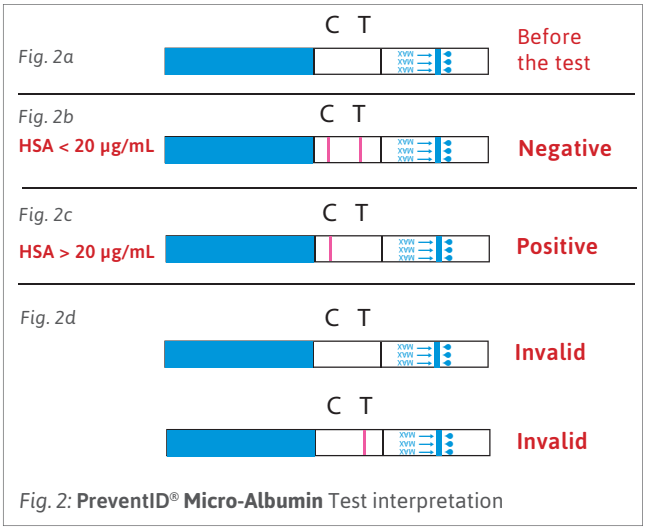

Fig. 2: **PreventID® Micro-Albumin** Test interpretation

Test Characteristics

Sensitivity

The absolute sensitivity of the **PreventID® Micro-Albumin** is determined by commercially available Human Albumin control, diluted by albumin negative human urine to the following albumin concentrations: 8µg/mL, 12µg/mL, 18µg/mL and 65µg/mL. With a concentration of 20 µg/mL or higher the test indicates results as positive.

Specificity

The specificity was assessed by studying urine samples from albumin negative subjects containing other blood proteins and microorganisms such as Hemoglobin, Transferrin, Campylobacter fetus, Campylobacter jejunii and E. coli. Urine samples that were negative to albumin were spiked with the above proteins and microorganisms. These samples were tested using the **PreventID® Micro-Albumin** test by a replicate of 10.
The added substances or microorganisms did not influence the test results.

Interference Data

Potentially interfering drugs, protein and glucose were supplemented to normal urine specimens devoid of HSA, as well as 20 µg/mL of HSA. Standards were analyzed in parallel with all samples containing a specific concentration of an interfering substance. None of the following substances interference with the results of the **PreventID® Micro-Albumin**.

Acetaminophen, 20 mg/dl
Acetylsalicylic acid, 20 mg/dl
Ascorbic acid, 20 mg/dl
Atropine, 20 mg/dl
Caffeine, 20 mg/dl
Glucose, 2000 mg/dl
Hemoglobin, 500 mg/dl
Penicillin, 40,000 U/dl
Tetracycline, 20 mg/dl

Test Limitations

The amount of albumin secreted in the urine can be found in healthy individuals for various reasons: physical exertion, increased blood pressure, pregnancy or acute infections can affect the albumin level in urine. Therefore – if the test result is positive – two further urine samples on different days should be tested, possibly with quantitative laboratory tests.
Although the **PreventID® Micro-Albumin** is very accurate in detecting HSA, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

References

1. Mogensen CE, Cohen JJ, Harrington JT, et al. Microalbuminuria as a predictor of clinical diabetic nephropathy. Kidney Int 1987;31:673-89.
2. Mogensen CE. Natural history of renal functional abnormalities in human diabetes mellitus: from normoalbuminuria to incipient and overt nephropathy. In: Brenner BM, Stein JH, ed. The Kidney in Diabetes Mellitus. New York: Churchill Livingstone, 1989:19-49.
3. National Committee for Clinical Laboratory Standards. Evaluation of Precision Performance of Clinical Chemistry Devices, Approved Guideline, Volume 19, No. 2, NCCLS Publication EP5-A. Villanova, PA (1999).
4. Burton C, Harris KP: The role of proteinuria in the progression of chronic renal failure. Am J Kidney Dis 1996 Jun; 27(6): 765-75 [Medline].

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Status: 2018-12-03

US: all products: Research Use Only. Not for use in diagnostic procedures.

Temperature limitation	Manufacturer
In vitro diagnostic device	Lot number
Catalogue number	Expiry date
To be used with	Do not reuse
Read user instructions	Contains sufficient for <n> tests

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