MICROALBUMINURIA CARD

Semiquantitative Determination of Microalbuminuria

20 tests   **REF** 4041

PRINCIPLE

In patients with diabetes mellitus, a slight albuminuria (microalbuminia) is predictive of diabetic nephropathy, early overall mortality and increase cardiovascular mortality. In non-diabetic population, microalbuminuria have implicated association with hypertension, obesity, blood glucose concentrations and plasma triglyceride concentration

The one-step *Microalbumine card* is a rapid, qualitative one-step assay for the detection of albumine in urine specimens.

The method relies on competitive binding between albumine fixed on dye conjugate and free albumine present in the urine. When albumine is present in the sample, it competes with the albumine dye conjugate for a limited antibody sites on the test membrane.

A urine sample that contains sufficient level of albumine will reduce or even prevent the formation of a line in the test region.

A negative urine sample will allow the formation of a clearly visible line in the test region.

The color intensity of control line is used to quantify the ealbumine concentration in the sample.

REAGENTS

Components of the kit: **REF** 4041
Cards   **20**
Pipettes   **20**
STABILITY: the test card should be stored at 4-30°C. Do not freeze.

SAMPLE

Urine. For optimal detection, a first morning urine specimen is preferred since this sample type is reportedly less biologically variable than random samples.
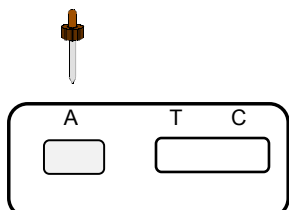STABILITY: 24 hours at a 4-8°C, 1 month at -20°C.

ASSAY PROCEDURE

1. Bring all specimens and cards to room temperature before the assay.
2. Remove the requested number of cards from the sealed pouch.
3. Label each card with the patient's name.
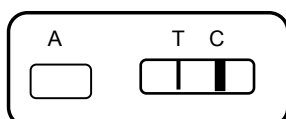

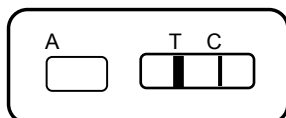**urine**   **5 drops**

4. Dispense, holding the pipette vertically, **4 full drops (150 µl)** of urine to the sample well **A**.
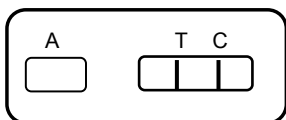**5.** Read the results after 10 minutes.

INTERPRETATION OF RESULTS

POSITIVE

NEGATIVE

BORDERLINE

Positive: the color intensity of the C band is stronger than the test line T (albumine concentration is higher than 20 mg/L).
Negative: the color intensity of T band is stronger than C band (albumine concentration is lower than 10 mg/L).
Borderline: the color intensity of the T and C band is equivalent (albumine concentration is between 10 and 20 mg/L).

PERFORMANCE

A study was made on 200 samples using Behring-Dade BN-100 nephelometer.

Comparaision of results:

BN-100 Micro-albumine card	<8.8 µg/ml	8.8-15 µg /ml	15.1-20 µg /ml	20.1-25 µg /ml	>25 µg /ml
Negative (-)	100	2	1	0	0
Borderline (+/-)	13	6	3	2	1
Positive (+)	2	15	11	4	40
Total	115	23	15	6	41

The table shows a very good concentration between boths methods. For concentrations below <8.8 µg/ml, only 2 samples over 115 samples show positive results (false positive results),

For concentrations above >20 µg /ml, none of the samples showed negativ eresults (false negative results).

METHOD LIMITS

1) **Glucose:** negative urine spiked with 50 to 250 mMol of glucose showed repeatedly negative results.
2) **pH:** negative and positive urine were assayed at pH ranging from 2.5 to 9.5. Obtained results were always in accordance with expected results.
3) **Bilirubin:** negative urine spiked with 25 to 375 µMol of bilirubin showed repeatedly negative results.
4) **Haemoglobin:** negative urine spiked with 15 to 210 µMol of Haemoglobin showed repeatedly negative results.
5) **Immunoglobulins**: negative urine spiked with 30 to 200 µg/ml of gammaglobulins showed repeatedly negative results.

TEST LIMITATIONS AND NOTES

1) (*) Dangerous reagents are marked by an asterisk. Refer to MSDS.
2) In case of fever, acute infection, pregnancy or intensive sport practice, albumine concentration in urine may be increased. Do not run the test in the above conditions.
3) Insufficient (less than 1 liter per day) or excessive liquid absorption during the day before running the test may generate false positive or false negative results.
4) A clean, well-rinsed container should be used for urine collection as detergent may interfere in the normal reaction.

REFERENCES

– Mogensen CE, Christensen CK. N Engl J Med 1984; 311 : 89-93.
– How JEA, Browning MCK ; Fraser CG. Clin Chem 1987; 33: 2034-8.

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