Kidney Heath Test

Microalbuminuria (MAU) Rapid Test

(Colloidal Gold)

CE 0123

REF IVD-31

ENGLISH

INTENDED USE

The Kidney Health Test (MAU rapid test kit) detects the qualitative levels of albuminuria in urine through an in-vitro diagnostic test. It is used as a supplementary method in the diagnosis of chronic kidney injury (CKI).

PACK FORMATS AND SIZE

Midstream: 1 test/box

BACKGROUND

Microalbuminuria (MAU) is a term to describe a moderate increase in the level of urine albumin. It is also named urine microalbuminuria (UMA or mALB). Albumin is a normal protein in the blood, but under physiological conditions it can be detected in small amounts in the urine. Albumin's molecular weight is 70KD and its isoelectric point (IEP) is about 4.85. MAU occurs when the kidney leaks small amounts of albumin into the urine, which means that increased excretion of albumin (microalbuminuria) is an early indicator of glomerular disease. Research shows that MAU can be caused by diabetic nephropathy, hypertension, and cardiac insufficiency.

PRINCIPLE

The Kidney Health Test (MAU rapid test kit) utilises colloidal gold labelling and immune chromatography, based on the principle of competitive binding, to detect qualitative levels of albumin in human urine. During testing, a urine specimen migrates upward by capillary action. Albumin, if present in the urine specimen at an insufficient concentration, will not saturate the binding sites of antibody coated particles in the test strip. The antibody-coated particles will then be captured by immobilised albumin conjugate, and a visible coloured line will show up in the test line region (T). The coloured line will not form in the test line region if the albumin concentration is sufficient, because it will saturate all the binding sites of anti-albumin antibodies. So, a positive urine specimen will not generate a coloured line in the test line region because of competition, while a negative urine specimen will generate a line in the test line region. To serve as an internal procedural control, the control line region (C) is coated with antibodies which will always conjugate with colloidal gold, to ensure a coloured line will always appear in the control line region (C). It indicates that the correct volume of specimen has been added, membrane wicking has occurred and the procedure has been performed correctly.

MATERIALS

- Midstream test
- Instuctions for use
- Standard colour card
- Product summary

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Urine collection cup

STORAGE AND EXPIRY DATE

- Store the kit at 4-30°C, keep in a cool and dry place, protected from light. Do not freeze.
- See the package with expiry date. Do not use it after the expiry date.

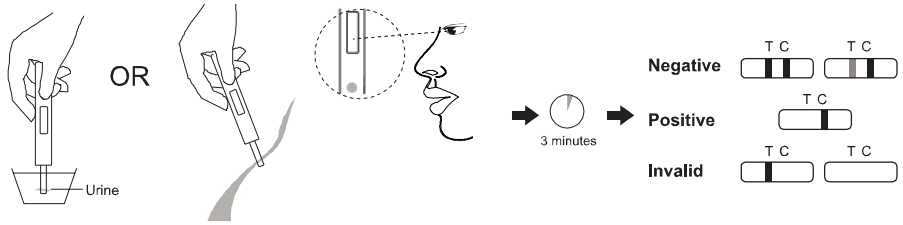
SPECIMEN COLLECTION

- Specimens can be collected directly from urine stream or in a disposable plastic or glass container. Ensure the collection cup is clean and dry.
- To prevent inaccurate results, do not consume a large amount of liquid during the two hours before collecting the urine specimen.
- If there is sediment at the bottom of the container, please centrifuge or filter.
- If you are unable to test immediately, the urine specimen can be refrigerated at 2-8°C for 48 hours. For long term storage, specimens should be kept below -20°C. Avoid repeated freezing and thawing of specimens.
- Before testing, the refrigerated specimen should reach room temperature, or the frozen specimen should be completely thawed.
- Specimens may be infectious or be a potential biological hazard. When collecting another individual's urine, wear disposable gloves and a mask.

PROCEDURE

Testing:

1. Please read the instructions carefully before performing the test. Allow the test kit to reach room temperature before use (20-30°C).
2. Remove the test kit from the foil pouch. The test kit should be used within 15 minutes of opening.
3. Place the absorbent tip in your urine stream or in a collected urine sample for 15 seconds.
4. Remove the tip from the urine, replace the cap and place the test stick on a flat surface.
5. Wait for the coloured line(s) to appear. Read the result at 3-5 minutes. Don't read the result after 10 minutes.



RESULT INTERPRETATION

Negative (-)

Two red lines are visible. One is located in the test line region (T), the other is in control line region (C). A negative result indicates the albumin in urine is less than the cut-off value and does not indicate chronic kidney injury.

Positive (+)
One coloured line appears in the control line region (C). No line appears in the test line region (T). A positive result with the test indicates the albumin in urine is more than the cut-off value.
The result should be considered positive even if there is a faint line in the T line region, like G3-G4 shown in the colour card included. It indicates the concentration of albumin present in the urine is close to the cut-off value and maybe an indication of chronic kidney injury.

Invalid
There is no red line in control region (C). The most likely reasons for this are that the instructions were not followed correctly or the product has been damaged. Please repeat the test with a new cassette. If the problem still persists, refrain from using this batch of product immediately and contact the supplier.

LIMITATION
1. The test is only used for qualitative determination of albumin in urine. A positive result with the test indicates the albumin concentration in urine is more than 20mg/L, and does not necessarily indicate kidney injury.
2. The test is intended for *in vitro* diagnostic use only and cannot be reused.
3. Please read the result 3-5 minutes after taking it and do not read the results after 10 minutes.
4. The test kit provides a presumptive diagnosis. A conformed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS
- Sensitivity: 98%, specificity: 97%, overall accuracy: 98%.
- Cut-off value: The sensitivity was characterised by validating the test performance at the confirmed cut-off value of every test. The cut-off value was determined by the 20 mg/L quality control which produced at least 50% positive results. The results are summarised in the table below.

Quality control materials (concentration)	Results	
	-	+
0mg/L	30	0
-50% Cut-off =10mg/L	30	0
-25% Cut-off =15mg/L	18	12
Cut-off=20mg/L	6	24
+25% Cut-off =25mg/L	1	29
+50% Cut-off =30mg/L	0	30
3X Cut-off =60mg/L	0	30

Interfering Substances: None of the below potential interfering antibiotic, potential interfering endogenous substances, interfering conditions at the concentration tested interfered with the assay. Details are shown in the table below:

Interfering substance (concentration)	Potential interfering endogenous substances	NaCl (60mg/mL)
Cefaclor (100ug/mL)	Creatinine (20mg/mL)	Carbamide (120mg/mL)
Cefdinir (100ug/mL)	VC (2mg/mL)	Hemoglobin (1mg/mL)
Ciprofloxacin (7.4ug/mL)	glutamic acid (2mg/mL)	Interfering condition
kanamycin (60ug/mL)	ethyl alcohol (20mg/mL)	Low pH value (pH=4.5)
azithromycin (120ug/mL)	Glucose (20mg/mL)	High pH value (pH=10)

PRECAUTIONS
1. Only use for in vitro diagnostic, and do not reuse.
2. Do not use if the pouch is damaged.
3. Please test within 15 minutes of unpacking to avoid paper get damp.
4. To avoid the cross contamination of samples, don't touch the nitrocellulose (NC) membrane on the product and each test should use new sample container.
5. Contaminated urine specimen or improper operation may cause incorrect results.
6. Use the product before the expiry date printed on foil pouch.
7. Handle all specimens, used products, packages and droppers as biological activity waste. Do not arbitrarily discard.

LITERATURE REFERENCES

1. Zelnanovitz T, Paggi A, Gross L, et al. The receiver operating characteristics curve in the evaluation of a random urine specimen as a screening test for diabetic nephropathy[J]. Diabetes Care, 1997, 20:516.
2. Hasslacher C, Danne T, Sawicki PT, Walter H. Frühdiagnose der diabetischen Nephropathie. Dtsch Arztebl 1999; 96(1-2): A-51 / B-47 / C-47.
3. Lurbe E, Redon J, Kesani A, Pascual JM, Tacons J, Alvarez V, Batlle D. Increase in nocturnal blood pressure and progression to microalbuminuria in type 1 diabetes. N Engl J Med. 2002 Sep 12; 347(11): 797-805.
4. Perkins BA, Ficociello LH, Silva KH, Finkelstein DM, Warram JH, Krolewski AS. Regression of microalbuminuria in type 1 diabetes. N Engl J Med. 2003 Jun 5; 348(23): 2285-93.

INDEX OF SYMBOLS

	Manufacturer		Tests per kit	EC REP	Authorised Representative in EU
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
4°C 30°C	Store between 4-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		Non-recyclable
21	Pap 21 recyclable material	22	Pap 22 recyclable material		

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