PHARMA *Southern Africa*

M-Albu-Check-1 Strip

Ref. 27037/ZA

Self-testing device test for the detection of albumin in urine

GENERAL POINTS

Albumin is normally present in the urine in very small quantities or is not detectable. A high albumin level reflects dysfunction of the filtering function of the kidneys. Glucose or triglyceride (fat) concentration and a history of diabetes or hypertension are factors that promote the urinary excretion of albumin.

The M-Albu-Check-1 Strip test is a rapid immunochromatographic test to qualitatively determine albumin in the urine. In less than 10 minutes, it is possible to detect abnormal albumin concentrations in the urine.

PRESENTATION

Each box contains the material necessary to perform one test:

- 1 sealed aluminium pouch containing:
1 strip test and 1 desiccant pouch

Only open the protective pouch when you are ready to use the test. The desiccant pouch should not be used.

- 1 plastic cup for urine sample collection
- 1 instructions manual

Material required but not provided: Timer

PRECAUTIONS

1. This test is exclusively intended for *in vitro* diagnostic. For external use only. DO NOT SWALLOW.
2. Carefully read the instructions before performing the test. The test is only reliable if the instructions are carefully respected.
3. Store between +4°C and +30°C. Do not freeze.
4. Do not use after the expiry date printed on the label and on the protective pouch or if this pouch is damaged.
5. Do not reuse M-Albu-Check-1 Strip.
6. Keep out of reach of children.
7. After use, all the components can be discarded in a dustbin.

PROCEDURE

1 – Collect a little urine in the supplied plastic cup (urine sample height: between 1 cm and 1.5 cm in the cup).

2- Tear the protective pouch (from the notch) and remove the strip only, holding it by the grip end. Dispose of the small desiccant pouch.

3- Dip the strip vertically in the cup containing your urine sample, placing it in the notch provided for that purpose. (Fig. 1) during 5 to 10 seconds.

WARNING:
THE URINE LEVEL MUST NOT EXCEED THE HORIZONTAL BLUE LINE PRINTED ON THE STRIP UNDER THE SMALL ARROWS.

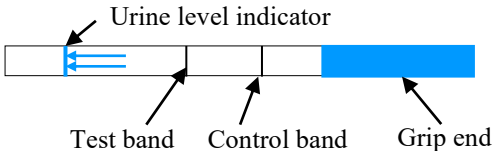
Fig. 1

4- Place the strip horizontally on a flat dry surface and allow the reaction to occur.

5- Read the result after 5 to 10 minutes. Do not interpret the result after 15 minutes.

RESULT INTERPRETATION

For the interpretation of the results, it is necessary to compare the intensity of the coloration of the test band with that of the control band (Fig. 2).



1. Positive result

The intensity of the control band coloration is greater than that of the test band. This result indicates that your urine contains more than 20 mg/L of albumin. Please repeat the assay with a new test. **If again positive, that you should consult a doctor.**

<u>Caution: in some cases, the test band may not develop at all.</u>

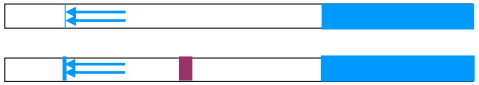
2. Borderline result

The intensity of the test band coloration is equal to that of the control band. This result indicates that your urine contains between 10 and 20 mg/L of albumin**. Please control your urinary albumin level from time to time.**

3. Negative result

The intensity of the test band coloration is greater than that of the control band. This result indicates that your urine contains less than 10 mg/L of albumin.

4. Inconclusive result



If there is no control band visible on the strip, it is not possible to interpret the test, which must be considered as inconclusive. In this case, it is recommended to repeat the test with a new M-Albu-Check-1 Strip and a fresh urine sample.

QUESTIONS AND ANSWERS

How does M-Albu-Check-1 Strip work?
The kidneys filter the blood to remove impurities. Thus, compounds of small size are eliminated in the urine while larger proteins are retained. Albumin is one of those proteins. If the kidneys are functioning normally, albumin is not present in the urine or is only present at very low concentrations (less than 10 mg/L).
The M-Albu-Check-1 Strip test enables determination of abnormal albumin concentrations in the urine.
In case of positive result, it means that the Microalbumin concentration is higher of 20 mg/L (as determined against W.H.O.* reference).
**World Health Organization*

When should I perform the test?
The test should preferably be conducted with the first urine of the morning.

I did not use the first urine in the morning as the leaflet recommends. Will the result of my test still be valid?
The concentration of compounds in the urine is generally higher in the first urine of the morning. For that reason, morning urine samples should preferably be used to obtain the best results. However, the M-Albu-Check-1 Strip test may be conducted on a urine sample obtained at any time of day.

What should I do if the result is positive?
If the result is positive, it means that the test has detected more than 20 mg/L of albumin in your urine. This result may be a temporary change in your physiological state.
Repeat the test several days later. If the positive result is confirmed, consult your physician and show him/her the test and leaflet.

What should I do if the result is borderline?
A borderline result means that the test has detected an albumin concentration greater than 10 mg/L and less than 20 mg/L. This result does not require particular surveillance other than regular control of your urinary albumin level.

I play a sport. Is the result of my test liable to be affected?
Yes, intensive physical exertion induces an increase in urinary albumin level.
You should avoid conducting a M-Albu-Check-1 Strip test in that context.

Are there other circumstances in which the test should not be conducted?
Yes, in the event of fever, severe infection or pregnancy. All those states may be accompanied by an elevated urinary albumin concentration.

Must I observe a particular diet?
Excessive liquid intake the day before the test may induce a false-negative result. Conversely, inadequate fluids intake may induce a false positive result. You should therefore drink normally.

What is the accuracy of M-Albu-Check-1 Strip?
The M-Albu-Check-1 Strip test is accurate and has been used for more than 10 years by professionals (hospitals, laboratories) in the field. Evaluation reports show an overall agreement of at least 88.89% [82.42-93.42] ** with reference methods. Although this test is reliable, false positive or false negative results could be obtained.
***** IC 95%: 95 % Confidence Interval.***

Information on Albumin and kidney disease:

1.https://www.infosante.be/guides/protines-dans-les-urines-protinurie

2.https://www.eurofins-biomnis.com/referentiel/liendoc/precis/MICROALBUMINE.pdf

3.https://www.niddk.nih.gov/health-information/kidney-disease/chronic-kidney-disease-ckd/tests-diagnosis/albuminuria-albumin-urine

4.https://www.mayoclinic.org/tests-procedures/microalbumin/about/pac-20384640

	Read the instructions before use	IVD	For *in vitro* diagnostic use		Do not reuse
	Store between +4°C and +30°C	LOT	Batch number		Expiry date
	Manufacturer				

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CHANGES DESCRIPTION
Changes type:

- N/A Not Applicable (creation)
- Technical change Addition, revision and/or removal of information related to the product.
- Administrative Implementation of non-technical changes noticeable to the end-user.

Changes type	Changes description
N/A	Creation

Note: Minor typographical, grammar, spelling and formatting changes are not reported in the change details.

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