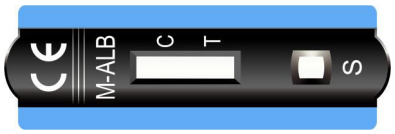
MICROALBUMIN (HSA) TEST
004B121

ulti med Semi-Quantitative Microalbumin (HSA) Test Cassette
For The Detection Of Microalbumin in Urine



INTENDED USE
The ulti med Semi-Quantitative human Serum Albumin (HSA) test is a simple, one step immunochromatographic assay for the rapid, semi-qualitative detection of elevated Microalbumin in urine. For Professional use only.
The sensitivity of the test is 10 µg/ml of human serum albumin.

PRECAUTIONS
The One Step Semi-Quantitative Microalbumin (HSA) test kit can be stored at 4-30°C. If the test kit is refrigerated, it should be brought to room temperature before use. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

MATERIALS PROVIDED
- Microalbumin (HSA) test cassette with disposable dropper in foil pouch (25 per kit box)
- Instructions (1 per kit box)

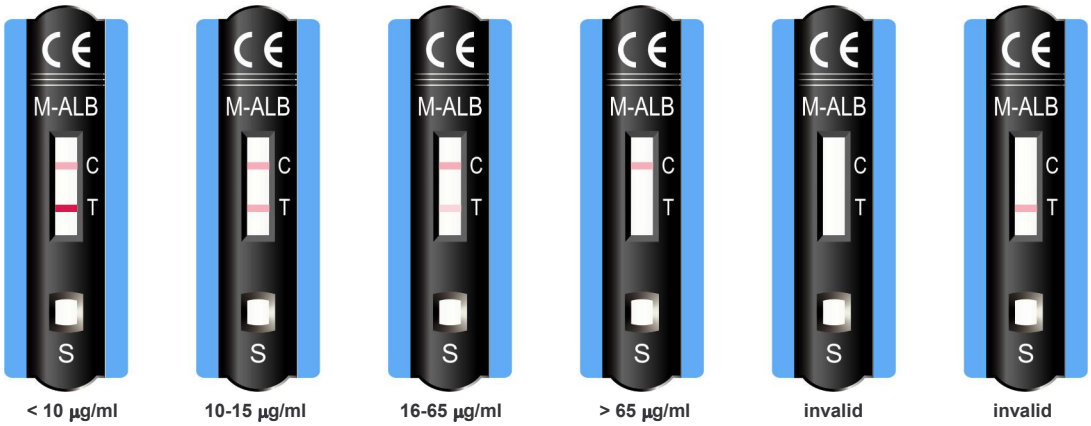
MATERIALS REQUIRED, BUT NOT PROVIDED
- Stop watch
- Container for sample collection

SPECIMEN COLLECTION AND PREPARATION
1. Specimens should be collected in a clean glass or plastic container.
2. Fresh urine specimens do not require any special handling or pre-treatment.
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 should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing

WARNINGS
- For in vitro diagnostic use only.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- Do not use the test kit if the pouch is damaged or the seal is broken.

PROCEDURE
1. Remove the test cassette from the foil pouch, and place it on a flat, dry and clean surface.
2. Hold the sample dropper above the test cassette. Squeeze 2 drops of specimen into the sample well.
3. Interpret the test results at 5 minutes. Do not read after more than 7 minutes.

Caution: The above waiting time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the waiting time should be properly increased.



< 10 µg/ml | **10-15 µg/ml** | **16-65 µg/ml** | **> 65 µg/ml** | **invalid** | **invalid**

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INTERPRETATION OF RESULTS

- A coloured 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.
- 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.

Albumin concentration less than 10 µg/ml: If albumin concentration is less than 10 µg/ml, the "Test Line" colour intensity is darker than the "Control Line" colour intensity (Figure 1).

Albumin concentration is 10 µg/ml to 15 µg/ml: If albumin concentration is 10 to 15 µg/ml, the "Test Line" colour intensity is about the same as the "Control Line" colour intensity (Figure 2).

Albumin concentration is 16 µg/ml to 65 µg/ml: If albumin concentration is higher than 16 µg/ml, the "Test Line" colour intensity is fainter than the "Control Line" colour intensity (Figure 3).

Albumin concentration greater than 65 µg/ml: For albumin concentrations of 65 µg/ml or higher, the "Test Line" will not appear (Figure 4).

Invalid: A distinct coloured line should always appear in the left section of the Result Window. The test is invalid if no colour line forms in the left section of the result window (Figure 5). **Note:** If there is a very faint test line of the Result Window, it indicates that the amount of HSA in the sample is near the cut-off level of the test.

INTERFERENCE DATA

Potentially interfering drugs, protein and glucose were supplemented to normal urine specimens devoid of HSA and to samples with 20 µg/ml of HSA. Standards were analyzed in parallel with all samples containing a specific concentration of a potentially interfering substance.

Substances:

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
Haemoglobin	500 mg/dl	Penicillin	40.000 U/dl	Tetracycline	20 mg/dl

Conclusion: None of the above substances interfered with the results of the semi-quantitative Microalbumin (HSA) test kits.

LIMITATIONS OF THE TEST

Although the One Step Semi-Quantitative Test 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

- Anderson CF and Wochos DN, "The Utility of serum albumin values in the nutritional assessment of hospitalized patients" Mayo Clin Proc, 1982,57:181-4.
- Shapiro M, Rhodes JB, and Beyer PL, "Malnutrition recognition and correction by enteralnutrition" Kans Med, 1983,341-5,356.
- Beng CG and Lim KL, "An improved automated method for determination of serum albumin using bromcresol green" Am J Clin Pathol, 1973,59:14-21.
- Hallbach J, Hoffmann GE, and Guder WG, "Overestimation of albumin in heparinized plasma", Clin Chem, 1991, 37(4):566-8.
- Ihara H, Nakamura H, Aoki Y, et al, "Efects of serum-isolated vs synthetic bilirubin-albumin complexes on dye-binding methods for estimation serum albumin" Clin Chem, 1991, 37(7):1269-72.

	Manufacturer		Contents sufficient for <n> tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
	For single use only		Use by
	Read instructions for use		Store at

Manufacturer:

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