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Semi-Quantitative HSA Test Disk

For Urine

REF

Catalog No.R11-569

IVD

FOR INVITRO DIAGNOSTIC USE ONLY

INTENDED USE

The Immunospec 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 **Immunospec** Semi-Quantitative HSA test kit can be stored at room temperature or 4-30°C (40-86°F). If 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.

SPECIMEN COLLECTION D PREPARATION

1. Specimens should be collected in a clean glass or plastic container.
2. Fresh urine specimens do not require any special handling or pretreatment.
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.

WARNINGS

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

PROCEDURE

1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk. Squeeze 2 drops of specimen into the sample well (Figure 1).
3. Interpret the test results at 5 minutes. Do not read after 7 minutes.

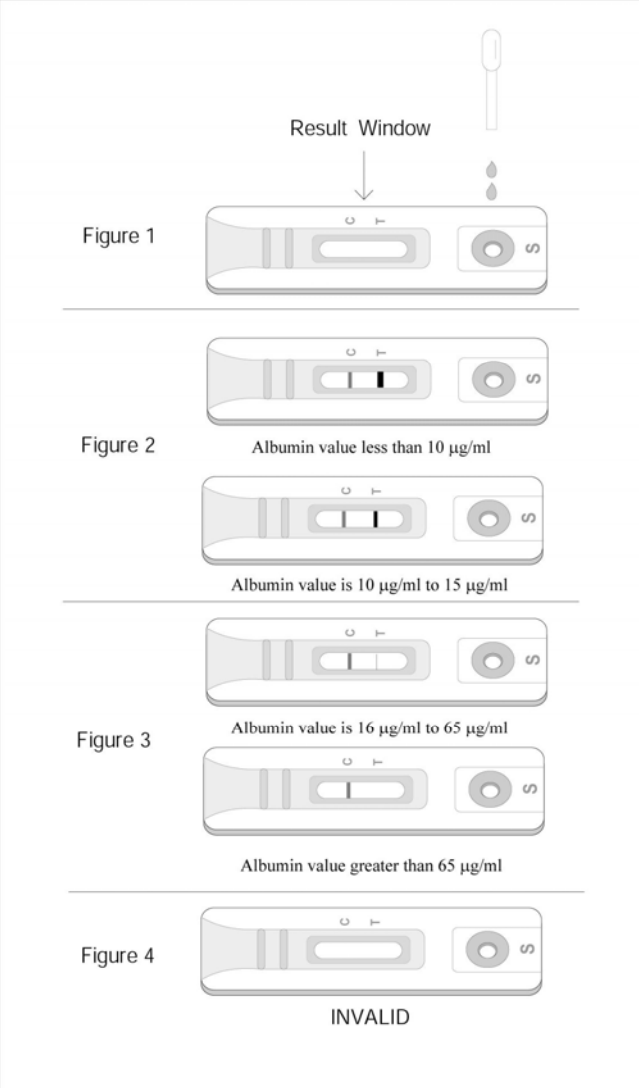
Caution: The above interpreting time is based on reading the test results at room temperature of 15 to 30 °C. If your room temperature is significantly lower than 15 °C, then the interpreting time should be properly increased.

INTERPRETATION OF RESULTS

1. A color band will appear at the left section of the result window to show that the test is working properly. This band is the Control Band.
2. The right section of the result window indicates the test results. If another color band appears at the right section of the result window, this band is the Test Band.

Albumin value less than 10 µg/ml: For albumin concentration is less than 10 µg/ml, the "Test Line" color intensity is darker than the "Control Line" color intensity (the top drawing in Figure 2).

Albumin value is 10 µg/ml to 15 µg/ml: For albumin concentration is 10 to 15 µg/ml, the "Test Line" color intensity is about the same as the "Control Line" color intensity (the bottom drawing in Figure 2).



Albumin value is 16 µg/ml to 65 µg/ml: For albumin concentration is higher than 16 µg/ml, the "Test Line" color intensity is fainter than the "Control Line" color intensity (the top drawing in Figure 3).

Albumin value greater than 65 µg/ml: For albumin concentration is 65 µg/ml or higher, the "Test Line" color band will not appear (the bottom drawing in Figure 3).

Invalid:
A distinct color band should always appear in the left section of the Result Window. The test is invalid if no color band forms in the left section of the result window (Figure 4).

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.

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
Hemoglobin, 500 mg/dl
Penicillin, 40,000 U/dl
Tetracycline, 20 mg/dl

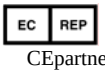
Conclusion: None of the above substances interfered with the results of the semi-quantitative HSA test kits.

LIMITATIONS OF THE TEST

Although the Immunospec Semi-Quantitative Test is very accurate in detecting, 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. 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.
2. Shapiro M, Rhodes JB, and Beyer PL, “Malnutrition recognition and correction by enteralnutrition” Kans Med, 1983,341-5,356.
3. 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.
4. Hallbach J, Hoffmann GE, and Guder WG, “Overestimation of albumin in heparinized plasma”, Clin Chem, 1991, 37(4):566-8.
5. 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.



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