VBL ONE STEP URINARY HSA TEST STRIP

VBL ONE STEP Urinary HSA Test Strip is a colloidal gold/antibody complex based immunoassay designed for the semi-quantitative determination of human serum albumin (HSA) in urine. It is intended for the early detection of microalbuminuria (slightly elevated quantities of albumin in urine) before the appearance of overt symptoms of renal disease.

SUMMARY AND EXPLANATION OF THE TEST

Microalbuminuria (MAU) is associated with the development of clinical proteinuria, chronic renal failure, and premature cardiovascular mortality in patients with insulin-dependent, type I diabetes mellitus. MAU is also associated with cardiovascular morbidity and mortality in patients with non-insulin-dependent, type II diabetes mellitus. In addition, MAU has received increasing attention as a risk indicator in hypertensive patients without diabetes mellitus. Therefore, an increase in urinary albumin excretion has an important predictive value, and it affords the opportunity, through treatment, to slow down the progression of disease. However, the level of urinary HSA above which renal disease is likely to develop is still not clearly defined. In many studies, there is a range of threshold urinary albumin between 10-20 μg/ml. Microalbuminuria above 20 μg/ml is a good predictor of diabetic nephropathy.

PRINCIPLES OF THE PROCEDURE

The VBL ONE STEP HSA Test Strip consists of a chromatographic absorbent device and a specific monoclonal antibody against human serum albumin. In five minutes, elevated level of HSA in the urine is detected.

Urine migrates through the absorbent area and along the test membrane. HSA present in the urine is bound to antibody-dye conjugate forming an antibody-antigen complex. In zone (T) of the membrane, immobilized human albumin capture free antibody-dye conjugate not already bound to analyte from the urine sample. As a consequence of this, the more HSA in the urine sample, the lighter the pink-rose color in zone (T) will be. The dye-conjugate not bound in zone (T) is captured by the non-specific antibody immobilized in the control ZONE (C) of the membrane, and the more HSA in the urine sample, the darker the pink-rose color in zone (C) will be.

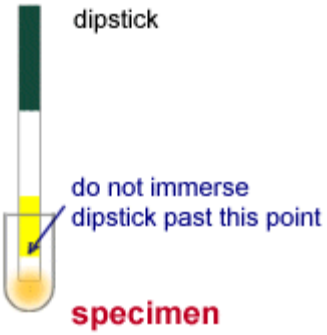
TEST STORAGE

Store the test below +28^{o}C, do not freeze. Prior to use bring test and components to room temperature.

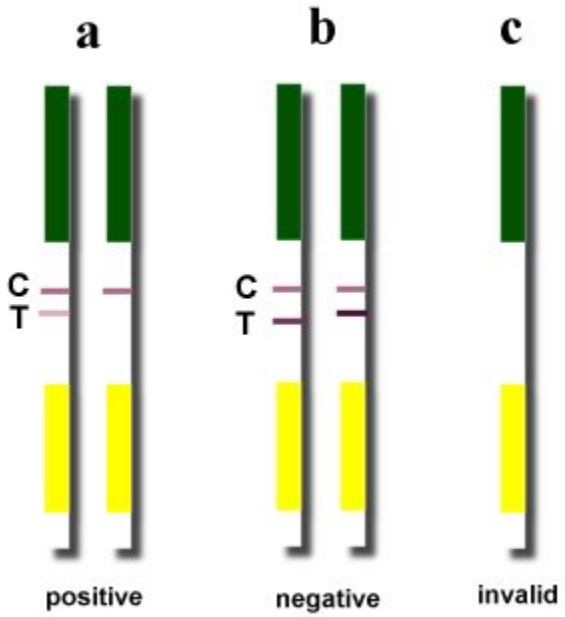
TEST PROCEDURE

1. Collect urine sample at room temperature, and remove test strip from the pouch.

2. Dip the test strip with yellow end down into a container.
3. Read results at 5 minutes.



INTERPRETATION OF RESULTS



A positive or negative result is determined by comparing the color intensity of the test line and control line that appear at five minutes. When the color intensity of Zone (T) is the same as Zone (C), it indicates the concentration of HSA in urine to be at 10 mg/ml.

a. **POSITIVE**: the test band's color intensity is lighter than the control band or non-existent indication the HSA level is above the 10 μg/ml cutoff.
b. **NEGATIVE**: the test band is equal to or darker than the control band indicating the HSA level is at or below the cutoff point of 10 μg/ml.
c. **Invalid**: if there is no rose-color band visible in the control window, then the test result is invalid. It is recommended that the specimen be retested.

IMPORTANT: In order to prevent any incorrect results, do not interpret results after ten minutes.

REFERENCES

1. Agrawal et al. Journal of Hypertension; 14:223-228 (1996)
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4. Parving et al. Acta Endocrinol (Copenh); 100: 550-5 (1982)
5. Christensen et al. Diabetes; 32: Suppl 2: 64-78 (1983)