RapidSpot HBsAg

A rapid visual qualitative test for the detection of infectious hepatitis surface antigen (HBsAg) in human serum

INTRODUCTION:
The RAPIDTEST HBsAg Spot Test is a rapid direct binding test for the visual detection of hepatitis B surface antigen (HBsAg) in serum as an aid in the diagnosis of hepatitis B infection. Test results are read visually without any instrument.

This test is based on the principle of sandwich enzyme immunoassay for the semi-quantitative determination of HBsAg in serum. Monoclonal and polyclonal antibodies were employed to specifically identify HBsAg with extremely high sensitivity. As little as 1 ng/mL can be detected in 10-15 minutes.

The formation of a large spot (●) or a line of three smaller dots (•••) provides an easy readout for positive and negative test results. The three smaller dots (•••) also serve as an internal control. The center dot is a weak positive control and the two outside dots are the strong positive control. They only appear when all reagents are working and the sequence of adding reagents are performed correctly.

MATERIALS PROVIDED:
1. Test devices
2. Reagent 1 Enzyme Conjugate
3. Reagent 2 Washing Solution
4. Reagent 3 Colour Developer

MATERIALS REQUIRED BUT NOT PROVIDED:
1. Specimen collection containers
2. Timers
3. Pipettor
4. Pipette tips

STORAGE:
The kit should be stored at 2-8°C. After opening the package, it may be stored at room temperature not high than 30°C for one week. Reagent 1 Enzyme Conjugate must be stored at 2-8°C at all time.

SPECIMEN COLLECTION:
No special patient preparation is necessary. Collect blood into container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.

If the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator or freezer. Do not freeze and thaw the specimen repeatedly. Mix samples thoroughly after thawing.

TEST PROCEDURE:
Bring all reagents, test devices, specimens, references, and other materials to room temperature prior before testing. Do not mix the caps from different reagent vials.

1. Using a pipettor, add 300-400 µl serum sample to the test well. Allow the specimen to soak through completely.
2. Add 2 drops Reagent 1 Enzyme Conjugate. Allow the solution to soak through. Wait 10 minutes
3. Add 8 drops Reagent 2 Washing Solution to the test well. Allow the solution to soak through.
4. Remove and discard pre-filters.
5. Add 3 drops Reagent 3 Colour Developer to the test well. Allow the solution to soak through and add another 5 drops of Reagent 3.

NOTE: A dark background colour make develop after adding the first 3 drops of Reagent 3. Add the next 5 drops Reagent 3 to reduce background colour and enhancing the weak positive results.

6. Wait for 3 - 5 minutes and read results.

INTERPRETATION OF RESULTS:

Negative:
Only three small dots (•••) are visible.

Strong Positive:
All three small dots and a large spot are visible. And the large spot is darker than all three small dots.

Weak positive:
The large spot is darker than the small center dot but weaker than two outer dots.

Inconclusive:
Only the large spot is visible or both the large dot and the three small dots are not visible. Repeat test.