

HBsAg

Rapid Diagnostic Test for the detection of
Hepatitis B virus surface antigen in human serum/ plasma
Dipstick
one step test

Two site sandwich immunoassay for the detection of Hepatitis B virus surface antigen

- Detects all subtypes of HBV
- Highly sensitive and specific
- Built in control band for confident reporting
- Test results are comparable to ELISA test
- Test results in 15 minutes
- Simple assay one step procedure
- Easy interpretation of results
- Clear cut demarcation between positive and negative
- Can be stored at 4°C to 30°C
- Suitable for blood bank and pathology laboratory
- Can be used at Point of care

Sensitivity : 0.5 ng/ml

Specificity : 100%

Shelf life : 2 Years

Storage : 4°C to 30°C



TEST PROCEDURE AND INTERPRETATION OF TEST RESULTS

Test Procedure :

1. Collect serum / plasma specimen in a clean test tube.
Ensure that sufficient quantity of the specimen is collected to allow submerging only the red area of the dipstick (about 1 cm high) .



2. Dip the dipstick in the test specimen, submerging only the red area. Wait for 15 minutes .



At the end of fifteen minutes, read the results as follows .

Interpretation of test results :

Negative :



Appearance of one pink-purple colored band on the dipstick .

Positive :

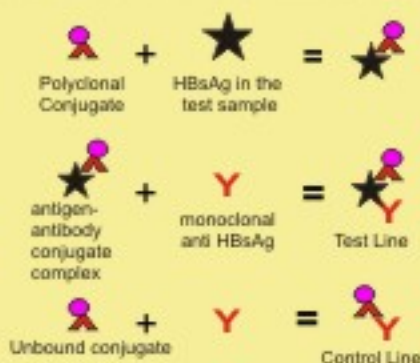


Appearance of two distinct pink-purple colored bands on the dipstick .

Invalid :

If no pink-purple colored band appears on the dipstick, repeat the test with a new dipstick .

TWO SITE SANDWICH IMMUNOASSAY :



1. As the test sample moves on the membrane the colored polyclonal anti-HBsAg-colloidal gold conjugate, detects and captures the HBsAg from the test sample.
2. Further on the membrane , the antigen-antibody conjugate complex gets captured by another monoclonal anti- HBsAg antibody on the test line.
3. The unbound antibody conjugate moves further on the membrane and get captured by another antibody on the control line.

Performance characteristics:

SENSITIVITY : 100%
SPECIFICITY : 100%
Detection Limit : 0.5ng/ml
Pack size : 25 dipsticks



Manufactured by
SSA DIAGNOSTICS & BIOTECH SYSTEMS
GOA (INDIA)
(Unit of KEE GAD Biogen Pvt. Ltd.)