SPECTRUM

The Creative Approach to Bioscience

# HBsAg Rapid Test Cassette

## (Serum/ Plasma / Whole Blood)

REF: 1217 001 25 test

## INTENDED USE

The HBsAg Rapid Test Cassette (Serum/Plasma / whole blood) is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in serum, plasma or whole blood.

## SUMMARY

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. Previous designations included the Australia or Au antigen . the presence of HBsAg in serum, plasma or whole blood is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.

The HBsAg Rapid Test Cassette (Serum,Plasma and whole blood) is a rapid test to qualitatively detect the presence of HBsAg in serum ,plasma or whole blood specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum , plasma or whole blood.

## TEST PRINCIPLE

The HBsAg Rapid Test Cassette (Serum/Plasma/whole blood) is a qualitative,lateral flow immunoassay for the detection of HBsAg in serum,plasma or whole blood. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, the serum plasma or whole blood specimen reacts with the particle coated with anti-HBsAg antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

## REAGENTS AND MATERIALS PROVIDED

The test Cassette contains anti-HBsAg particles and anti-HBsAg coated on the membrane.

1. Test Cassettes with droppers
2. Buffer
3. Package inserts.

## MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge

## WARNINGS AND PRECAUTIONS

•For professional in vitro diagnostic use only. Do not use after expiration date

• Do not eat, drink or smoke in the area where the specimens and kits are handled.

• Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.

• Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

• Humidity and temperature can adversely affect results.

### SYMBOLS IN PRODUCT LABELLING

| | | | |
|---|---|---|---|
| EC REP | Authorised Representative | | Temperature Limitation |
| IVD | For in-vitro diagnostic use | | Use by/Expiration Date |
| LOT | Batch Code/Lot number | | CAUTION. Consult instructions for use |
| REF | Catalogue Number | | Manufactured by |
| | Consult instructions for use | | |

## REAGENT PREPARATION AND STORAGE INSTRUCTION

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

## SPECIMEN COLLECTION AND PREPARATION

- The HBsAg Rapid Test Cassette can be performed using whole blood(from venipuncture or fingerstick),serum or plasma.
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately75μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
  - Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
    - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
    - Allow3 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

## TEST PROCEDURE

**Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma** specimen:

- Hold the dropper vertically and transfer **3 drops of serum or plasma** (approximately 75 μL) to the specimen well of test Cassette and start the timer. See illustration below.

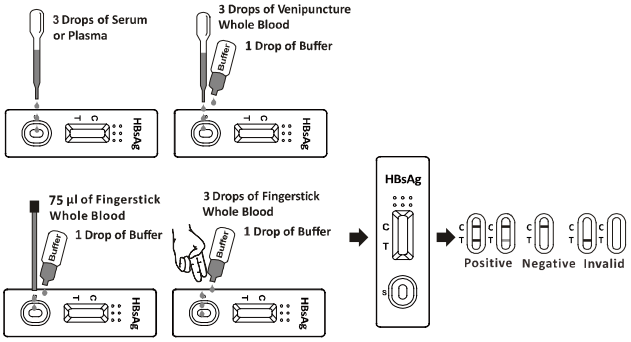
For **Venipuncture Whole Blood** specimen:

- Hold the dropper vertically and transfer **3drops of whole blood** (approximately 75μL) to the specimen area, then **add 1 drop of buffer** (approximately 40 μL), and start the timer. See illustration below.

For **Fingerstick Whole Blood** specimen:

- To use a capillary tube: Fill the capillary tube and **transfer approximately 75μL of fingerstick whole blood specimen** to the specimen area of test cassette, then add **1 drop of buffer (approximately 40 μL)** and start the timer. See illustration below.
- To use hanging drops: Allow**3 hanging drops of fingerstick whole blood s**pecimen (approximately 75μL) to fall into the specimen area of test cassette, then add **1 drop of buffer (approximately 40 μL) a**nd start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read results at 15 ~30 minutes.** Do not interpret the result after 30 minutes.




## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**POSITIVE:* Two distinct colored lines appear**. One colored line should be in the control region (C) and another colored line should be in the test region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration ofHBsAg present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

**NEGATIVE: One colored line appears in the control region (C).**No apparent colored line appears in the test region (T).

**INVALID: Control line fails to appear.**Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL

**Internal Quality Control**

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

**External Quality Control**

It is recommended that a positive and negative external control be run every 20 tests, and as deemed necessary by internal laboratory procedures. Some commercial controls may contain interfering preservatives; therefore, interpretation of results with external quality controls should be done with caution.

**Procedure for External Quality Control Testing**

1. Hold the Control vial vertically and add 2 full drops of Control to the Specimen well (S) as in procedure Step 2.
2. Continue with Step 3 of Directions For Use. If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

## LIMITATIONS OF TEST

1. The HBsAg Rapid Test Cassette is for professional in vitro diagnostic use only. The test should be used for the detection of HBsAg in,serum ,plasma or whole blood specimen. Neither the quantitative value nor the rate of HBsAg concentration can be determined by this qualitative test.
2. The HBsAg Rapid Test Cassette will only indicate the presence of HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. The HBsAg Rapid Test Cassette cannot detect less than 1 PEI ng/ml of HBsAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B infection.

## Expected Values

The HBsAg Rapid Test Cassette (Serum/Plasma/ Whole Blood) has been compared with a leading commercial HBsAg EIA test. The correlation between these two systems is over 99%.

## PERFORMANCE CHARACTERISTICS

***Sensitivity***

The HBsAg Rapid Test Cassette (Serum/Plasma/ Whole Blood) has been tested with a sensitivity panel ranging from 0 to 300 ng/mL. All 10 HBsAg subtypes produced positive results on the HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma). The test can detect 5ng/mL of HBsAg in 15 minutes, and 1 ng/mL of HBsAg in 30 minutes.

**Specificity**

Antibodies used for the HBsAg Rapid Test Cassette (Serum/Plasma/ Whole Blood)) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg Rapid Test Cassette (Serum/Plasma/ Whole Blood) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

***HBsAg Reference Method***

| Method | | ELISA | | Total Results |
|---|---|---|---|---|
| HBsAg Rapid Test Cassette (Serum/Plasma/Whole blood) | Result | Positive | Negative | |
| | Positive | 145 | 5 | 150 |
| | Negative | 0 | 150 | 150 |
| | | 145 | 155 | 300 |

Relative Sensitivity: > 99.0%
Relative Specificity: 96.7%
Accuracy: 98.3%

***Precision***

***Intra-Assay***

Within-run precision has been determined by using 15 replicates of three specimens containing 0 ng/mL, 1 ng/mL and 5 ng/mL of HBsAg. The negative and positive values were correctly identified 98% of the time.

***Inter-Assay***

Between-run precision has been determined by using the same three specimens of 0 ng/mL, 1ng/mL and 5 ng/mL of HBsAg in 15 independent assays. Three different lots of the HBsAg Rapid test (Serum/Plasma.whole blood) has been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 98% of the time.

## REFERENCES

1. Blumberg, B.S. The Discovery of Australian Antigen and its relation to viral hepatitis. Vitro. 1971; 7: 223

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