140mm 140mm

210mm

Hepatitis B Field Use Rapid Test Kit

(Whole Blood/Serum/Plasma)

Catalog No. IT1009F

Intend Use

iCARE Hepatitis B Field Use Rapid Test Kit is a test for the qualitative detection of the Hepatitis B Surface Antigen (HBsAg) in whole blood/serum/plasma as an aid in the diagnosis of Hepatitis B infection. Hepatitis B is an infection of the liver caused by the Hepatitis B virus (HBV), and is transmitted by infected blood and bodily fluids (e.g. semen, saliva), through sexual contact, sharing injection needles, and childbirth. Signs and Symptoms of Hepatitis B include itchy skin, body aches, joint pains, fatigue, loss of appetite, nausea, vomiting, dark urine and jaundice (yellow colorations of skin and eyes). These appear after about 3 months from the point of infection and can last for weeks or months.

Precautions

1.Do not use the test kit beyond the expiration date.

2.Do not use the kit if the pouch is punctured or not well sealed.

3.For in vitro use only. Do not swallow.

4.All specimens from the body should be treated as potentially infectious.

5.Contaminated blood may give incorrect test results.

6.Discard after first use. The test cannot be used more than once.

DISPOSAL: The used device has the risk of infection. Please dispose all used contents properly.

Each Kit Contains:

- Test cards individually foil pouched with a desiccant
- Plastic dropper
- Sample diluent
- Safety lancet
- Alcohol swab
- Package insert

Material Required But Not Provided:

Timer

Storage And Stability

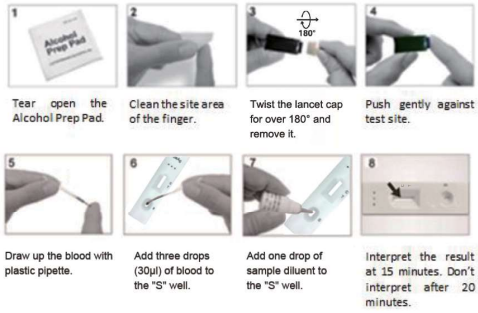
The kit must be stored at 2~30°C.

Do not open pouch until you are ready to test the sample.

Do not open pouch until you are ready to test the sample.

Assay Procedures:

1. Bring the Hepatitis B test card, sample diluent, alcohol swab, safety lancet, plastic dropper to room temperature.
2. Take out the test card from the sealed pouch.
3. To perform the test, please follow the steps closely as follow (from picture 1 to picture 8).



Assay Procedures at Clinics

1. Bring all reagents and specimens to room temperature.
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen or control.
4. **For whole blood / serum / plasma testing:** Dispense the sample or control (approximately 30 µl) into the well on the card using the plastic dropper provided, then add 1 drop of sample diluent into the well immediately.
5. Interpret test results at 15 minutes. A positive result may be interpreted early, however read any negative at 15 minutes to ensure sample is negative and not a low concentration of Hepatitis B surface antigen. Do not interpret the result after 20 minutes.

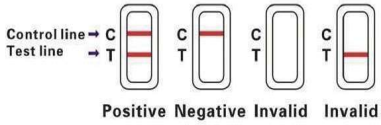
It is recommended to run a known positive control and negative control in each performance to ensure the assay procedure.

Reading The Test Results

1.**Positive:** Both purplish read test band and purplish read control band appear on the membrane. The lower the antibody concentration, the weaker the test band.

2.**Negative:** Only the purplish red control band appears on the membrane. The absence of a test band indicates a negative result.

3.**Invalid:** There should always be a purplish red control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test device.



Note: *It is normal to have a slightly lightened control band with very strong positive samples as long as it is distinctly visible.*

Performance Characteristics

Clinical studies have been carried out to determine the correlation of Hepatitis B Rapid Test to EIA and RIA tests:

Table-1: Comparison with EIA (1070 specimens)

iCARE HBsAg Test	EIA Positive	EIA Negative
Positive	356	8
Negative	4	702
Total	360	710

Sensitivity = 98.88 % (356/360)
Specificity = 98.87 % (702/710)
Predictive value of a positive test = 97.80 % (356/364)

Table-2: Comparison with RIA (493 specimens)

iCARE HBsAg Test	RIA Positive	RIA Negative
Positive	138	2
Negative	0	353
Total	138	355

Sensitivity = 100.00 % (138/138)
Specificity = 99.43 % (353/355)
Predictive value of a positive test = 98.57 % (138/140)

Detection limit:

The iCARE Hepatitis B Field Use Rapid Test Kit can detect HBsAg at concentration as low as 1.0 ng/ml (including both ad and ay subtype).

Limitations

Although the association between the presence of HBsAg and infection is strong, available methods for HBsAg detection are not sensitive enough to detect all potentially infectious units of blood or possible hepatitis infections.

Bibliography

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4. David GS. Present W, Martinis J, Wang R, Bartholomew R, Desmond W, and Sevier ED, Monoclonal antibodies in the detection of hepatitis infection, Med. Lab. Sci. 38:341-348. 1981.
5. Goodall AH, Miescher G. Meek FM, Janossy G, Thomas HC, Monoclonal antibodies in a solid phase radiometric assay for HBsAg Med. Lab. Sci. 38:349-354, 1981
6. Kennedy RC. Ionscu-Matiu I, Alder-Storthz K, Henkel RD, Sanchez Y, Dreesman GR, Characterization of Anti- Hepatitis B Surface Antigen Monoclonal Antibodies, Intervirology. 19:176-180, 1983.

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Note: An extra lancet is provided in the package in case that the safety lancet is misused.