HBsAg FIA Rapid Test Device
(Whole Blood/Serum/Plasma)
FI2-HBSAG-001

A quantitative rapid test for the detection of Hepatitis B surface antigen (HBsAg) in whole blood, serum or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE
The HBsAg FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative detection of Hepatitis B surface antigen (HBsAg) in whole blood, serum or plasma as an aid in the diagnosis of Hepatitis B infections.

SUMMARY
Hepatitis B virus (HBV) infection is the most common cause of liver disease worldwide. Approximately 2 billion have serological evidence of past or present infection with the highest prevalence found in east Asia and sub-Saharan Africa.[1] Around 257 million people are living with chronic hepatitis B and an estimated 887,000 deaths annually are attributable to HBV, mostly due to decompensated cirrhosis and hepatocellular carcinoma. In sub-Saharan Africa,5- 10% of the adult population is living with chronic HBV infection.[2]
Hepatitis B is an infection of the liver caused by the HBV. HBV is transmitted by exposure to infectious blood or body fluids (e.g. saliva, semen). Forms of transmission include unprotected sexual activity, blood transfusion, mother-to-infant transmission, or consuming contaminated food. Timely diagnosis is critical for reducing the burden of HBV-related mortality and morbidity. Effective screening is also crucial to reduce transmission and increase public awareness. Laboratory diagnosis of HBV includes detection of markers such as HBsAg, HBsAb, HBcAb, HBeAg and HBeAb in the serum.[3] Detection of HBsAg in the serum is indicative of HBV infection and this marker is the most frequently used in testing for HBV infection.[4]

PRINCIPLE
The HBsAg FIA Rapid Test Device is a quantitative membrane-based fluorescence immunoassay for the detection of HBsAg in human whole blood, serum or plasma specimens. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains HBsAg, it attaches to the fluorescent microspheres-conjugated with recombinant Anti-HBsAg antibodies. Then the complex will be captured by the capture Anti-HBsAg antibodies coated on the nitrocellulose membrane (Test line). The concentration of HBsAg in the specimen correlates with the fluorescence signal intensity captured on the Test line, which can be read by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). The test results of the HBsAg FIA Rapid Test will be displayed on the Fluorescence Immunoassay Device screen.

REAGENTS
The test device contains Anti-HBsAg coated with cellulose nitrate membrane as the capture reagent and recombinant Anti-HBsAg which is conjugated with fluorescence particles as the detection reagent.

PRECAUTIONS
1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda HBsAg FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device by approved medical professionals.

STORAGE AND STABILITY
1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS
- 25 x foil wrapped HBsAg test devices
- 25 x Specimen collection tubes with extraction buffer
- 1 x ID card (HBsAg)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED
- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION
For Venipuncture Specimens
1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Do not leave 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.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
5. EDTA K2, Heparin sodium, Sodium Citrate, and Potassium Oxalate can be used as the anticoagulant for collecting the specimen. A clean tube without anticoagulants can be used to collect serum specimens.

DIRECTIONS FOR USE
Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode. *Standard Test* mode is a 'set and forget' method where the test will automatically be read after 15 minutes. *Quick* Test mode provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests concurrently.
Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. Remove the test cassette from the sealed foil pouch and start testing as soon as possible.
4. **Whole Blood/Serum/Plasma:** Transfer **75 µl of whole blood, serum, or plasma** into the buffer tube, mix the specimen and the buffer well.
5. **Add diluted specimen with a Pipette**: Pipette **75 µl** of diluted specimen into the sample well of the test Device. Start the timer at the same time.
6. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS
The result of tests for HBsAg is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

Linearity range of HBsAg is 0.5-200 IU/mL. Reference range:< 0.5 IU/mL

EXPECTED VALUES

Concentrations	Clinical Reference
<0.5 IU/mL	Negative
≥0.5 IU/mL	Positive

Each laboratory should determine the applicability of the reference range through experiments and establish its own reference value range if necessary to ensure that it can correctly reflect the situation of a particular population.

QUALITY CONTROL

Each Biopanda HBsAg FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The HBsAg FIA Rapid Test Device is for *in vitro* diagnostic use only. This test should be used for detection of HBsAg in whole blood, serum or plasma specimens.
2. The HBsAg FIA Rapid Test Device will only indicate the presence of HBsAg in the specimen.
3. The results of HBsAg Tests are based on measuring the levels of HBsAg in a specimen. For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute or chronic infection.

PERFORMANCE CHARACTERISTICS

1. **Accuracy**
   The test deviation is ≤15%
2. **Analytical sensitivity**
   The HBsAg FIA Rapid Test Device can detect levels of HBsAg as low as 0.5 IU/mL in whole blood, serum or plasma specimens.
3. **Linearity range**
   Linearity Range is 0.5-200 IU/mL
4. **Precision**
   Intra-lot precision
   Within-run precision has been determined by using 10 replicates of 2 different concentrations HBsAg control, C.V. is ≤ 15%.
   Inter-lot precision
   Between-run precision has been determined by using 10 replicates for each of three lots using 2 different concentrations HBsAg control, C.V. is ≤15%.
5. **Interfering Substances**
   The following substances do not interfere with the test results at the indicated concentrations: Ascorbic Acid at 200 mg/L, Hemoglobin at 10 g/L, Triglyceride at 30 g/L, Bilirubin at 1000 mg/dL, Uric Acid at 200 mg/L.
6. **Method comparison**
   The assay was compared with Abbott HBsAg reagent kit with 100 samples. The correlation coefficient (R) is 0.956.

REFERENCES

1. World Health Organization, 2017a. Global Hepatitis Report 2017. World Health Organization, Geneva.
2. World Health Organization, 2016.Global Health Sector Strategy on Viral Hepatitis 2016-2021. World Health Organization, Geneva.
3. M.S. Odimayo, S.I. Nwadioha, A.O. Ajayi, Hepatitis B serologic markers among individuals with hepatitis B surface antigen seropositivity in Makurdi, Nigeria, Int. J. Med. Med. Sci. 6 (5) (2016) 340–344.
4. A.S. Lok, B.J. McMahon, Chronic hepatitis B, practice guidelines committee, American association for the study of liver diseases, Hepatology 34 (2011) 1225–1241.

Index of Symbols

	Manufacturer	Σ	Tests per kit	2	Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
4°C 30°C	Store between 4-30°C	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's HBsAg FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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