



PRODUCT SPECIFICATION

Product Name

First Response® HBsAg Card Test

**Manufacturer: Premier Medical Corporation Private
Limited**

A1-302, GIDC, Sarigam 396155, Dist. Valsad, Gujarat, India.

An ISO 13485 & EN ISO 13485 Certified Company

Product Details			
1	Product Name	:	First Response® HBsAg Card Test
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	PI10FRC

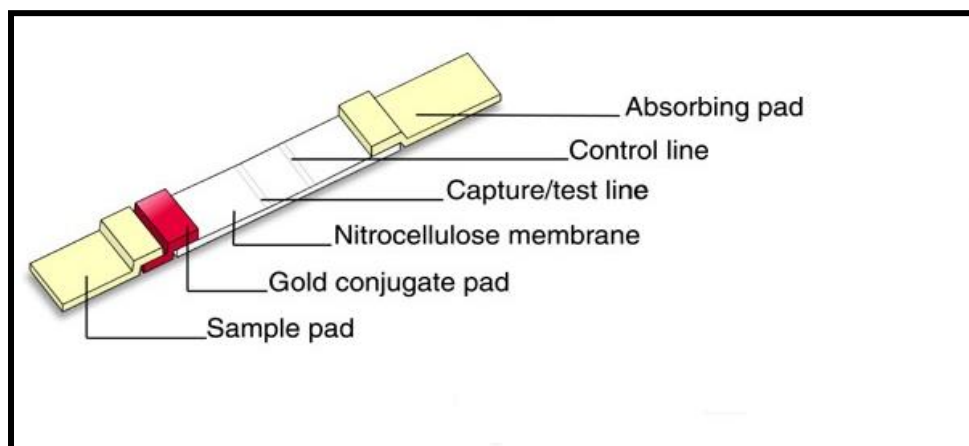
Intended Use:

First Response® HBsAg Card Test is a chromatographic immunoassay for qualitative detection of the Hepatitis B surface antigen in serum/plasma/whole blood (venous & capillary blood) specimens. It is intended for use in medical institution as a aid for diagnosis and management of patients related to the infection with Hepatitis B as well as for primary screening of blood from volunteer donors on the spot.

Assay Principle

First Response® HBsAg Card Test is based on principle of immunochromatography in which nitrocellulose membrane is pre-coated with monoclonal antibodies (test line) specific to Hepatitis B surface antigen in whole blood/serum/plasma samples. When the test sample flows through the nitrocellulose membrane, second monoclonal antibodies specific for Hepatitis B surface antigen conjugated with colloidal gold, binds to Hepatitis B surface antigens in the whole blood/serum/plasma/ samples. This antigen-conjugated antibody complex moves through the nitrocellulose membrane and binds to the immobilized Hepatitis B surface antigen specific monoclonal antibodies at the test line, which leads to the formation of colour line indicating reactive results. The control line will appear irrespective of reactive or non reactive sample.

General Presentation of test strip of First Response® HBsAg Card Test



Storage & Stability

First Response[®] HBsAg Card Test should be stored at 4-30°C. Do not freeze the kit or components. Assay Buffer (opened & unopened) & the unopened Test Device are stable until the expiry date printed on the label, when stored at room temperature 4-30°C. The test device is sensitive to humidity and heat. Perform the test immediately after removing the Test Device from the foil pouch. The shelf life of the kit is as indicated on the outer package. Do not use Test Device and Assay buffer beyond the date of expiry.

Shelf Life:

First Response[®] HBsAg Card Test has shelf life of 24 months.

Performance Characteristics:

First Response[®] HBsAg Card Test has $\geq 99.99\%$ Sensitivity and $\geq 99.99\%$ Specificity.

Operational Characteristics:

Temperature range:

- First Response[®] HBsAg Card Test is stable at temperature range of 4-30°C.
- Operating Temperature range is room temperature.
- Test result interpretation time 20 minutes.

Certification:

- First Response[®] HBsAg Card Test is manufactured by Premier Medical Corporation Private Limited is ISO 13485 & EN ISO 13485 certified company.
- First Response HBsAg Card Test is CE certified product.

Kit components:

Each kit of First Response[®] HBsAg Card Test contains:

- Test devices packed in aluminum pouch with desiccant and specimen transfer device.
- Sterile lancet.
- Alcohol swab.
- Assay buffer bottle.
- Instructions for use.