



# 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

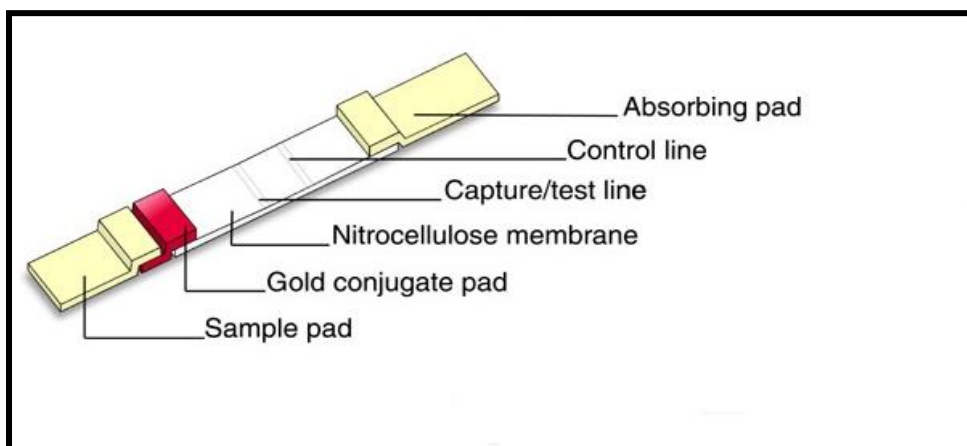
### **Intended Use:**

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**



- Operating Temperature range is room temperature.
- Test result interpretation time 15 minutes.

**Certification:**

- First Response® HIV 1+2 / Syphilis Combo Card Test is WHO pre-qualified product.
- First Response® HIV 1+2 / Syphilis Combo Card Test is manufactured by Premier Medical Corporation Pvt Ltd is ISO 13485 & EN ISO 13485 certified company.

**Kit components:**

First Response® HIV 1+2 / Syphilis Combo Card Test contains:

- Test devices packed in aluminum pouch with desiccant,
- Specimen Transfer Device.
- Sterile lancets.
- Alcohol swabs.
- Instruction for use in English language.
- Assay buffer bottle.

PI10FRC30CE	First Response® HBsAg Card Test	CE Certified	30T/kit
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# TECHNICAL SPECIFICATION.

## **Product Name**

**First Response<sup>®</sup> Syphilis Anti-TP 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® Syphilis Anti TP Card Test
2	Product Family	Rapid Diagnostic Tests
3	Product Code	PI08FRC

**Intended Use:**

First Response® Syphilis Anti-TP Card Test is intended for use by healthcare professionals and qualified laboratory personnel. It is a rapid, qualitative, screening, in vitro diagnostic test for the detection of antibodies of all classes specific to *Treponema pallidum* in human serum, plasma or Venous or capillary whole blood. The test can be used as an aid in the diagnosis of Syphilis infection. The product can be used for symptomatic, asymptomatic, and pregnant women populations. The test kit is not automated and does not require any additional instruments. The test is intended to be used at Point of care and/or laboratory settings. Reactive specimens should be confirmed by supplemental testing.

**Assay Principle**

When the test specimen and assay buffer are added to the specimen well, they flow along the colloidal gold-coupling antibody-*Treponema pallidum* antigen complex present at the conjugate pad". If *Treponema pallidum* specific antibodies i.e IgG or IgM are present in the sample, they will further form a complex of colloidal gold-coupling antibody-*Treponema pallidum* antigen-anti-*Treponema pallidum* antibody which will migrate through the nitrocellulose membrane, when it encounters at test band (which contains *Treponema pallidum* antigen) the complex binds with antigen at test line forming colloidal gold-coupling antibody-*Treponema pallidum*- anti-*Treponema pallidum* antibody-antigen complex giving reactive result. This will make the purple-colored line visible at the test band. While in the case of non-reactive specimen, there is no antibody-*Treponema pallidum*-anti-*Treponema pallidum* antibody-antigen complex to bind with the test band and the purple coloured line will not appear. At the control line, the goat-anti mouse IgG will bind with the colloidal gold-coupling antibody-*Treponema pallidum* complex forming a purple colored line. Here the coupling antibody used in the colloidal gold conjugation with *Treponema pallidum* antigen is a mouse IgG. Thus irrespective of the reactive or non-reactive result the control line will appear.

**Storage & Stability**

First Response® Syphilis Anti-TP Card Test should be stored at 4-30°C. Do not freeze the kit or components. 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® Syphilis Anti-TP Card Test has shelf life of 24 months.

**Performance Characteristics:**

First Response Syphilis Anti-TP Card Test has 100 % sensitivity and 100 % specificity.

**Operational Characteristics:****Temperature range:**

- First Response Syphilis Anti-TP Card Test is stable at temperature range of 4-30°C.
- Operating Temperature range is room temperature.
- Test result interpretation time 20 minutes.

**Kit components:**

Each kit of First Response® Syphilis Anti-TP Card Test contains:

- Test devices packed in aluminum pouch with desiccant,
- Specimen Transfer Device.
- Sterile lancets.
- Alcohol swabs.
- Instruction for use in English language.
- Assay buffer bottle.

**Certification:**

First Response® Syphilis Anti-TP Card Test is WHO Prequalified product.

First Response® Syphilis Anti-TP Card Test is CE certified product.

First Response® Syphilis Anti-TP Card Test is manufactured by Premier Medical Corporation Pvt Ltd is ISO 13485 & EN ISO 13485 certified company.

PI08FRC25	First Response® Syphilis Anti - TP Card Test	WHO PQed	25T/kit
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