# TECHNICAL SPECIFICATION.

## Product Name

## FIRST RESPONSE® HIV 1+2 / SYPHILIS COMBO 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**

Digitally signed by Matei Andrei
Date: 2022.06.06 13:38:55 EEST
Reason: MoldSign Signature
Location: Moldova

| Product Details | | | |
|---|---|---|---|
| 1 | Product Name | : | First Response® HIV 1+2 /Syphilis Combo Card Test |
| 2 | Product Family | : | In Vitro Diagnostic Tests |
| 3 | Product Code | : | I20FRC |

## Intended use:

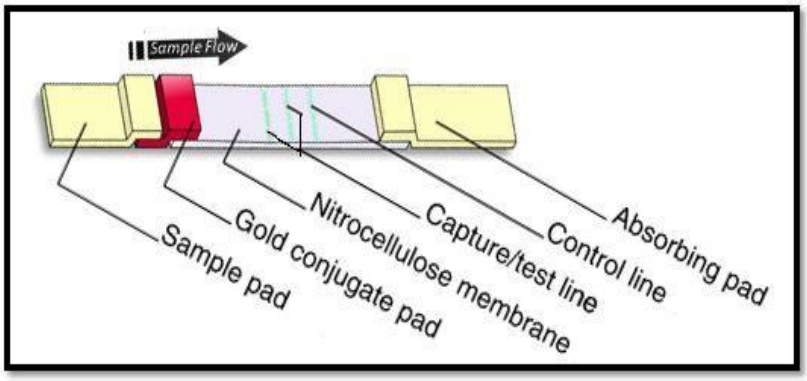
First Response® HIV 1+2 / Syphilis Combo Card Test is intended for use by healthcare professionals and trained user. It is a rapid, qualitative, screening, in vitro diagnostic test for detection of antibodies specific to HIV (type 1 & 2) and *Treponema pallidum* in human serum, plasma or whole blood. The test kit is not automated and does not require any additional instrument. Reactive specimens should be confirmed further with supplemental/ confirmatory tests.

## Assay principle:

First Response® HIV 1+2 / Syphilis Combo Card Test is based on the principle of immunochromatography for qualitative detection of antibodies specific for HIV-1&2 and/or Syphilis. This card test in which nitrocellulose membrane is precoated with recombinant antigens for HIV 1 (gp41) and HIV 2 (gp36) at test line HIV and Recombinant TP antigen (P47, P45, P17, P15) specific for Treponema pallidum at the test line Syp of the device with control line at "C". When a serum or plasma or whole blood specimen is applied to the Specimen well of plastic device, the cocktail of recombinant HIV-1+2 (gp41 & gp36) antigen-colloidal gold conjugate & recombinant Treponema pallidum antigens colloid gold conjugate.

The specimen and Assay diluents move along the membrane chromatographically to the test regions and form a visible line as the antigen-antibody-antigen gold particle complex forms with high degree of sensitivity and specificity. If the specimen contains antibodies to Treponema pallidum, the colored line will appear in the test area at test line Syp, corresponding to Syp line. If the specimen contains antibodies to HIV 1 and/or 2, the colored line will appear in the test area at test line HIV, corresponding to HIV line. The presence of both test line indicates specimen contain antibodies to HIV as well as Treponema pallidum. The absence of the colored line at the test line regions indicates that the specimen is non reactive for HIV and Treponema pallidum, showing a negative result. Control line will appear irrespective of reactive or non reactive specimen. The control line will serve to validate test performance.

**General Presentation of test strip:**




## Storage & Stability:

1) First Response® HIV 1+2 / Syphilis Combo Card Test kit should be stored at 4-30°C.
2) Do not freeze the kit or components.
3) The kit is sensitive to humidity and heat.
4) Assay buffer (opened & unopened) & the unopened test device are stable until the expiry date printed on the label, when stored at 4-30°C.
5) Perform the test immediately after removing the test device from the aluminium pouch.
6) The shelf life of the kit is as indicated on the outer package.

## Shelf Life:

First Response® HIV 1+2 / Syphilis Combo Card Test has shelf life of 24 months.

## Performance Characteristics:

As per WHO Evaluation report the sensitivity and specificity of First Response® HIV 1+2 / Syphilis Combo Card Test is-
For HIV antibodies an initial sensitivity (95% CI) of 100% (98.2% - 100%) and an initial specificity (95% CI) of 99.0% (96.4% - 99.9%) compared to the reference assays. The final sensitivity (95% CI) was 100% (98.2% - 100%) and the final specificity (95% CI) was 99.5% (97.2% - 100%).

For the case of T pallidum an initial sensitivity (95% CI) of 99.0% (96.4% - 99.5) and an initial specificity (95% CI) of 99.0% (96.4% - 99.9%) compared to the reference assays. The final sensitivity (95% CI) was 99.0% (96.4% - 99.9%) and the final specificity (95% CI) was 100% (98.2% - 100%) .

## Operational Characteristics:

**Temperature range:**

- First Response® HIV 1+2 / Syphilis Combo Card Test is stable at temperature range of 4-30°C.

- 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.

# 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 |

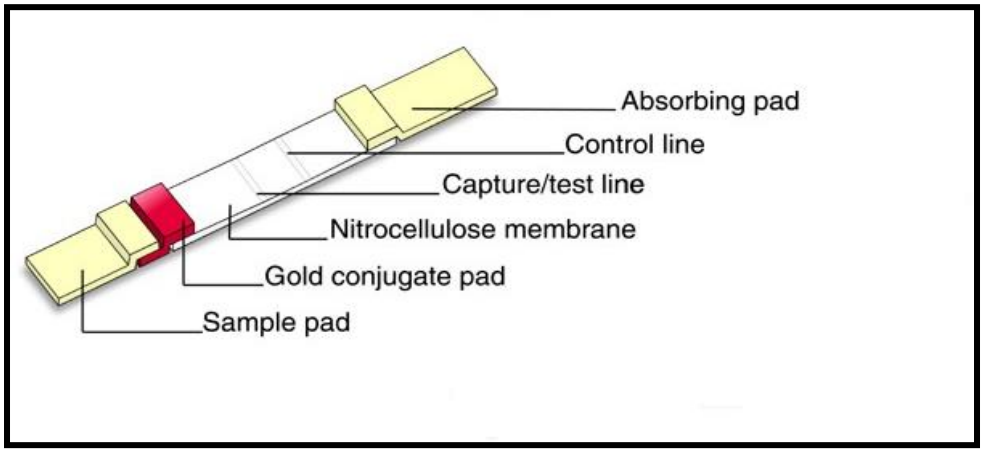
## Intended Use:

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 ≥99.99% Sensitivity and ≥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.

# TECHNICAL SPECIFICATION.

## Product Name

**First Response® 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.