



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

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:

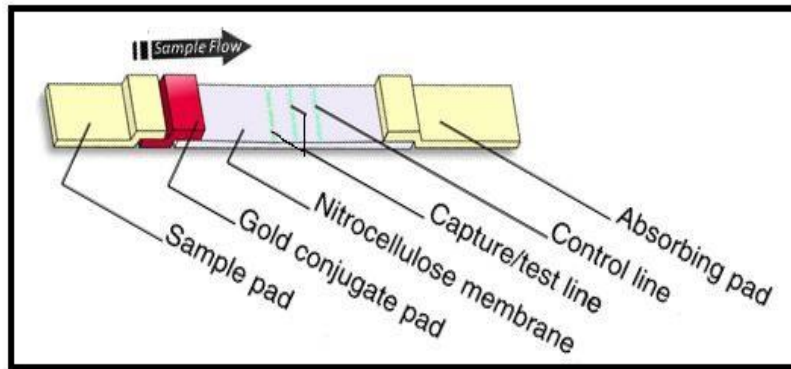
First Response® HIV 1+2 / Syphilis Combo Card Test is intended for use by healthcare professionals and trained user. It is a rapid, qualitative, screening, in vitro diagnostic test for detection of antibodies specific to HIV (type 1 & 2) and *Treponema pallidum* in human serum, plasma or whole blood. 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.