



TECHNICAL SPECIFICATION.

Product Name

First Response® HIV 1+2/HCV Combo Card Test

**Manufacturer: Premier Medical Corporation Private
Limited**

**Unit II: 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/HCV Combo Card Test
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	PI24FRC

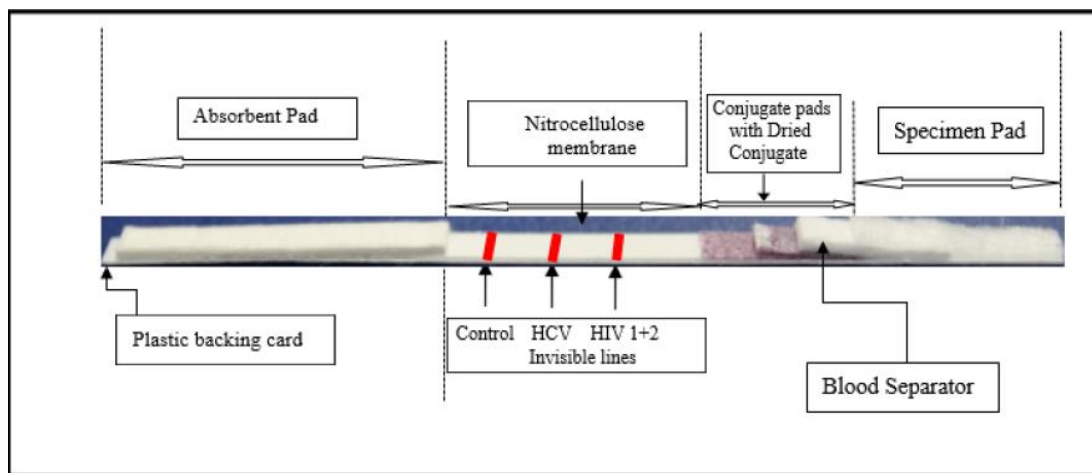
Intended Use:

First Response® HIV 1+2/ HCV Combo Card Test is intended for use by healthcare professionals and is a rapid, qualitative, screening, in vitro diagnostic test for detection of antibodies of specific to HIV (type 1 & 2) and Hepatitis C virus (HCV Ab) in human serum, plasma or whole blood. The test kit is not automated and does not require any additional instrument. Reactive samples should be confirmed further with confirmatory tests like ELISA, Western Blot.

Assay Principle

First Response® HIV 1+2 / HCV Combo Card Test is based on the principle of immunochromatography for qualitative detection of antibodies specific for HIV-1&2 and/or Hepatitis C. 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 HCV antigen specific for Hepatitis-C virus at the test line HCV of the device with control line at “C”. When a serum or plasma or whole blood specimen is applied to the Sample Well of plastic device, the cocktail of recombinant HIV-1+2 (gp41 & gp36) antigen - colloidal gold conjugate & recombinant HCV antigens colloid gold conjugate, the specimen sample and sample 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 Hepatitis-C Virus, the colored line will appear in the test area at test line HCV, corresponding to HCV 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 HCV. The absence of the colored line at the test line regions indicates that the specimen is non-reactive for HIV and Hepatitis-C, showing a negative result. Control line will appear irrespective of reactive or non-reactive sample. The control line will serve to validate test performance.

Graphical presentation of test strip of First Response® HIV 1+2/HCV Combo Card Test



Storage & Stability

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

Operational Characteristics:

Temperature range:

- First Response® HIV 1+2 / HCV Combo Card Test is stable at temperature range of 4-30°C.
- Operating Temperature range is room temperature.
- Test result interpretation time 20-25 minutes.

Certification:

- First Response® HIV 1+2 / HCV Combo Card Test is manufactured by Premier Medical Corporation Private Limited, is ISO 13485 & EN ISO 13485 certified company.

Kit components:

Each kit of First Response® HIV 1+2 / HCV 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.