



TECHNICAL SPECIFICATION.

Product Name

First Response® HCV 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® HCV Card Test
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	PI03FRC

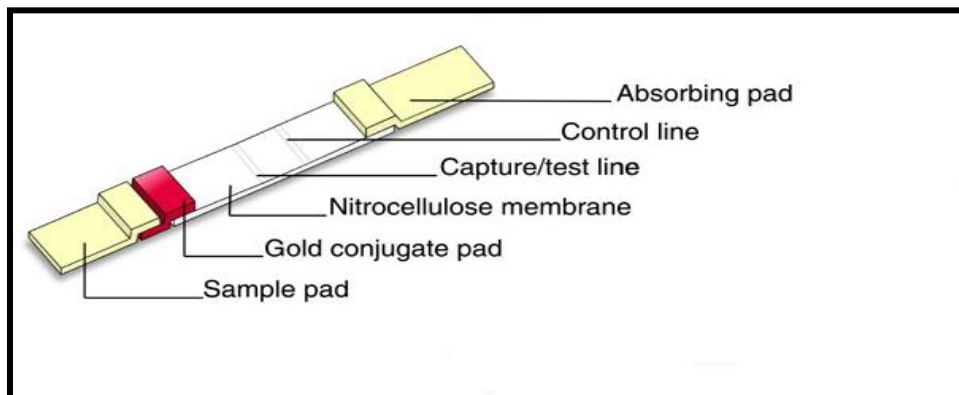
Intended Use:

First Response® HCV Card Test is a chromatographic immunoassay for the qualitative detection of the antibodies against hepatitis C virus (HCV Ab) in human serum, plasma or whole blood specimens. It is intended to be performed by trained users (In either laboratory or point of care settings) as an aid for diagnosis and management of patients related to infection with hepatitis C as well for primary screening of blood from volunteer donors on the spot. The test kit is not automated and does not require any additional Instrument. Reactive samples should be confirmed by supplemental testing.

Assay Principle

First Response® HCV Card Test is based on the principle of immunochromatographic lateral flow device in a cassette format. Colloidal gold conjugated recombinant HCV Antigen are dried and immobilized on the pad. HCV antigens are immobilized at the Test Zone (T) and Control line protein are immobilized at the Control Zone (C). When the specimen and assay buffer is added, it migrates by capillary diffusion rehydrating the gold conjugate. If specimens contain Anti-HCV antibodies it will bind to gold conjugated recombinant HCV antigen. These complexes will continue to migrate laterally on the strip until the Test zone (T) where complex are captured by the HCV antigens and form a visible red colored line. The unbound gold conjugate will continue to move and bind with control line protein at the Control Zone (C) forming a visible red colored line. If no HCV antibodies in the sample, only a red colored line appears at the Control Zone (C), which indicates the validity of the test.

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



Storage & Stability

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

Performance Characteristics:

First Response[®] HCV Card Test has 100% sensitivity and 100% specificity.

Operational Characteristics:

Temperature range:

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

Kit components:

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

- Test devices packed in aluminum pouch with desiccant.
- Specimen Transfer device.
- Sterile lancet.
- Alcohol swab.
- Instructions for use in English language.
- Assay buffer bottle.