



TECHNICAL SPECIFICATION.

Product Name

First Response® HCV Card Test (Self 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 (Self Test)
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	PI03FRCST

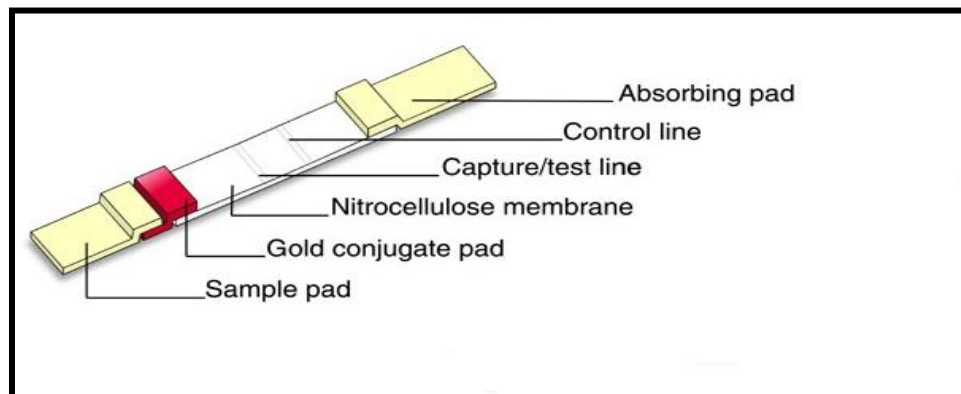
Intended Use:

First Response[®] HCV Card Test (Self Test) is an in vitro diagnostic medical device that is intended to use for self-testing by untrained/lay user as an aid to detect antibodies specific to HCV in human whole blood. The test kit is not automated and does not require any additional instruments.

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 is 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 specimen, 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 (Self Test)



Storage & Stability

First Response[®] HCV Card Test (Self Test) kit should be stored between 4°C and 30°C.

The kit is sensitive to humidity and heat. Perform the test immediately after removing the test device from the aluminum pouch.

The shelf life of the test device is indicated on the outer package.

Shelf Life:

First Response® HCV Card Test (Self Test) has shelf life of 24 months.

Performance Characteristics:

First Response® HCV Card Test (Self Test) is evaluated by FIND.

Operational Characteristics:**Temperature range:**

- First Response HCV Card Test (Self 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 (Self Test) is manufactured by Premier Medical Corporation Private Limited is ISO 13485 & EN ISO 13485 certified company.

Kit components:

Each kit of First Response® HCV Card Test (Self Test) contains:

- Test devices packed in aluminum pouch with specimen transfer device and desiccant.
- Sterile safety lancets.
- Alcohol swabs.
- Dry swab
- Disposable biohazard bag
- Single use assay buffer vial
- Instruction for use in English language.
- Bandage