



# **TECHNICAL SPECIFICATION.**

## **Product Name**

**First Response® HIV 1-2.0 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

<b>Product Details</b>			
1	Product Name	:	First Response® HIV 1-2.O Card Test (Self Test)
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	PI05FRCST

**Intended Use:**

First Response® HIV 1-2.O 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 HIV-1 and HIV-2 in human whole blood. The test kit is not automated and does not require any additional instruments.

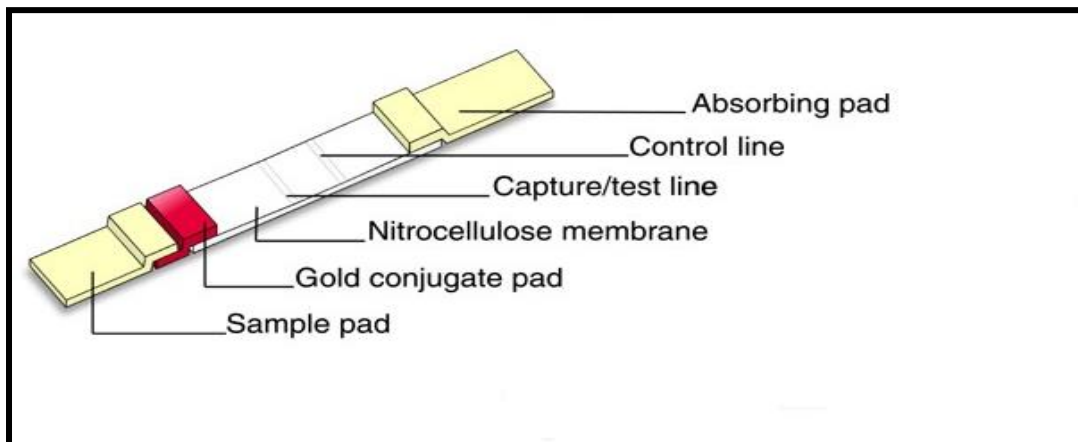
**Assay Principle**

The First Response® HIV 1-2.O Card Test (Self Test) is a 3rd generation lateral flow chromatographic immunoassay. The test cassette consists of two lines:

1) Control line “(C)” which is pre-coated with a control reagent. 2) Test line "T" is pre-coated with recombinant HIV-1(gp41) and HIV-2 recombinant antigens (gp36) for the detection of antibodies specific to HIV-1 and HIV-2. When a correct volume of blood specimen is dispensed into the sample well of the test device, followed by the addition of the correct volume of assay buffer, blood specimen flows across the strip. A red colored line forms in the test line “T” area of the result window if HIV-1 and HIV-2 antibodies are detected. If no HIV antibodies are detected, no line forms there. If the test procedure performed correctly, a line forms in the “C” area of result window, which is called the control line. No presence of control line 'C' in the result window (irrespective of the presence of test line) or a red background makes it impossible to read the test indicates an invalid result. The Invalid test results should be retested with a new test device.

Note :The control line provided in this assay is specimen addition control. No control line will appear if specimen is not added.

**Graphical presentation of test strip of First Response® HIV 1.2-O Card test (Self Test)**



## **Storage & Stability**

First Response® HIV 1-2.O 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® HIV 1-2.O Card Test (Self Test) has shelf life of 24 months.

## **Operational Characteristics:**

### **Temperature range:**

- First Response® HIV 1-2.O Card Test (Self 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.O 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® HIV 1-2.O 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