TECHNICAL SPECIFICATION.

Product Name

First Response® HIV 1-2.O Card Test (Version 2.0)

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

Digitally signed by Chirtoacă Iurie
Date: 2022.10.28 17:20:51 EEST
Reason: MoldSign Signature
Location: Moldova

Product Details			
1	Product Name	:	First Response® HIV 1-2.O Card Test (Version 2.0)
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	PI05FRC

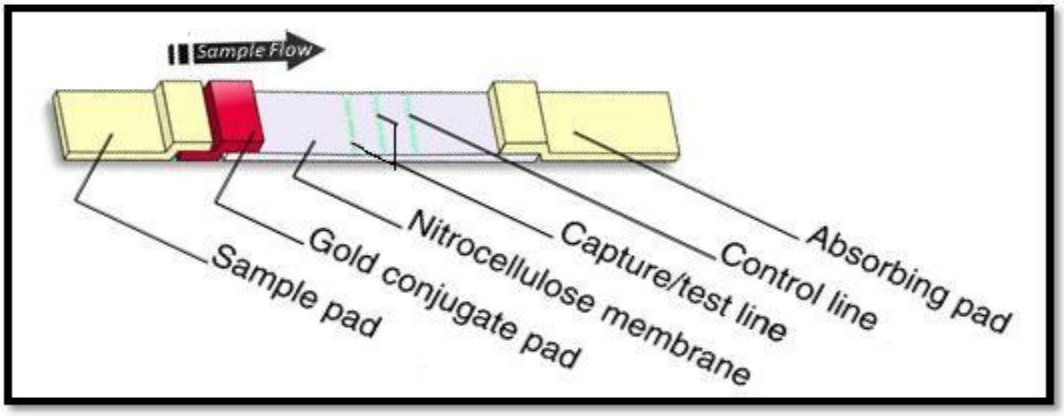
Intended Use:

First Response® HIV 1-2.O Card Test (Ver. 2.0) is intended for use by healthcare professionals and qualified laboratory personnel. It is a rapid, qualitative screening, in vitro diagnostic test for detection of antibodies specific to HIV-1 (including Group O) and HIV-2 in human serum, plasma or venous and capillary whole blood. The test can be used as an aid in the diagnosis of HIV-1 and HIV-2. The product can be used for symptomatic, asymptomatic and pregnant women populations. The test kit is not automated and does not require any additional instrument. Reactive specimens should be confirmed by supplemental testing. The product is not intended for blood donor screening.

Assay Principle

First Response® HIV 1-2.O Card Test (Ver.2.0) is based on the principle of immunochromatography for the qualitative detection of antibodies specific for HIV-1 and HIV-2. The nitrocellulose membrane is coated with recombinant HIV-1 capture antigens (gp41 including Group O) on test line “1” region and with recombinant HIV-2 capture antigen (gp36) on test line “2" region and control reagent coated at control line “C”. When serum or plasma or whole blood specimen is applied followed by assay buffer addition to the specimen well of the test device, the recombinant HIV-1 and 2 antigens (gp41 and gp36) conjugated with colloidal gold particles(CGC) bind to HIV-1 and 2 antibodies present in the test specimen. This conjugated antigen-antibody complex moves through the nitrocellulose membrane and bind to the corresponding immobilized HIV-1 antigen and HIV-2 antigen (Test Lines) leading to the formation of purple colored visible line as the capture antigen-antibody-conjugated antigen complex, indicating reactive results. Purple colored control line will appear irrespective of the reactive or non-reactive specimen. The control line is a procedural control, serves to demonstrate functional reagents and correct migration of fluid.

Graphical presentation of test strip of First Response® HIV 1.2-O Card test (Version 2.0)



Storage & Stability

First Response® HIV 1-2.O Card Test (Ver. 2.0) kit should be stored at 4-30°C. Do not freeze the kit or components. The kit is sensitive to humidity and heat. Do not store the kit at temperatures above 30°C and in humid conditions. Assay buffer (opened and unopened) and unopened test device are stable until the expiry date printed on the label when stored at 4-30°C.
Perform the test immediately after removing the test device from the aluminium pouch. If desiccant color has changed from orange to green, do not use the test device. Test device is stable until the printed expiry date on the pouch/external secondary packaging.

Shelf Life:

First Response® HIV 1-2.O Card Test (Version 2.0) has shelf life of 24 months.

Performance Characteristics:

First Response® HIV 1-2. O Card Test (Version 2.0) has the final sensitivity 100 % & specificity 100 % as per WHO Prequalification of In vitro diagnostic Programme.

Operational Characteristics:

Temperature range:

- First Response® HIV 1-2.O 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.O Card Test (Version 2.0) is WHO Pre-qualified.
- First Response® HIV 1-2.O Card Test (Version 2.0) is CE certified product.

- First Response® HIV 1-2.O 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.O Card Test (Version 2.0) 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.