



TECHNICAL SPECIFICATION.

Product Name

Sure Status® HIV-1 Rapid Recency 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	:	Sure Status® HIV-1 Rapid Recency Card Test
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	SS01P25

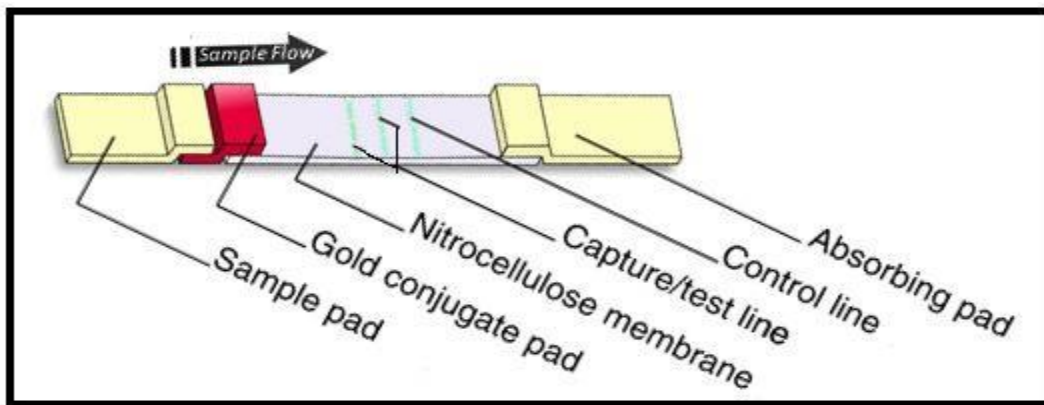
Intended Use:

Sure Status® HIV-1 Rapid Recency Card Test is a single-use rapid in vitro immunoassay that distinguishes HIV-1 infections on the basis of recency of infection. The assay is intended for use with whole blood, serum or plasma specimens as either a laboratory or point-of-collection test to detect HIV antibodies and recency of HIV-1 infection at the same time. This product is for research and evaluation use only and not for professional use.

Assay Principle

Sure Status® HIV-1 Rapid Recency Card Test is a 3rd generation lateral flow chromatographic immunoassay. The test cassette consists of 1) a red-colored conjugate pad containing HIV-1 specific recombinant antigens (gp41 including Group O,) and control protein conjugated with colloidal gold particles; and 2) a nitrocellulose membrane strip containing two test lines (T and LT) and a control line (C). Test line 'T' is pre-coated with HIV-1 recombinant antigens (gp41 including Group O) for the detection of antibodies to HIV-1. The test line 'LT' is pre-coated with rIDR-M recombinant antigen for the detection of Highly reactive antibodies to HIV. The Control line is pre-coated with a control line protein. When an adequate volume of the test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the strip. HIV-1 antibodies, if present in the specimen, migrate through the conjugate pad where they bind to the HIV-1 conjugates. The immune-complex is then captured on the membrane by the pre-coated HIV-1 antigen forming a red-colored line at test line "T", indicating an HIV-1 antibody positive or reactive test result. Lack of color development on test line "T" suggests an HIV-1 antibody-negative or non-reactive result. Highly reactive antibodies (Long term Infection), if present in the specimen, migrate through the conjugate pad where they bind to the HIV-1 conjugates. The immune-complex is then captured on the membrane by the pre-coated rIDR-M antigen forming a red-colored line at the test line "LT", indicating a Highly antibody positive or high reactive test result. Lack of color development on test line "LT" suggests the Lowest antibody (Initially infection) in specimens or non-reactive results. The test contains an internal control line ("C"), which should exhibit a red-colored line of the immune-complex of the control proteins regardless of color development on the test lines. If the "C" line does not develop, the test result is invalid and the specimen must be retested with another device. The control line in a test device is not a specimen addition control.

Graphical presentation of test strip of Sure Status® HIV-1 Rapid Recency Card Test



Storage & Stability

- 1) Sure Status® HIV-1 Rapid Recency Card Test kit should be stored at 4-30°C.
 - 2) Do not freeze the kit or components.
 - 3) The kit is sensitive to humidity and heat.
 - 4) Assay buffer (opened & unopened) & the unopened test device are stable until the expiry date printed on the label, when stored at 4-30°C.
 - 5) Perform the test immediately after removing the test device from the aluminium pouch.
- The shelf life of the kit is as indicated on the outer package.

Shelf Life:

Sure Status® HIV-1 Rapid Recency Card Test has shelf life of 24 months.

Performance Characteristics:

IN-HOUSE EVALUATION				
REFERENCE EIA ASSAY				
Visual Interpretation		Recent	Long Term	Total
	Recent	138	5	143
	Long Term	0	40	40
	Total	138	45	183

%agreement observed 97.27% Kappa: 0.923 (0.857 to 0.989)

Operational Characteristics:

Temperature range:

- Sure Status® HIV-1 Rapid Recency Card Test is stable at temperature range of 4-30°C.
- Operating Temperature range is room temperature.
- Test result interpretation time 20 minutes.

Certification:

- Sure Status® HIV-1 Rapid Recency Card Test is Approved for Export Only by CDSCO.
- Sure Status® HIV-1 Rapid Recency Card Test is manufactured by Premier Medical Corporation Private Limited, is ISO 13485 & EN ISO 13485 certified company.

Kit components:

Each kit of Sure Status® HIV-1 Rapid Recency 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.