



TECHNICAL SPECIFICATION.

Product Name

First Response® Sickle Cell Detection Card Test

Manufacturer:

**Premier Medical Corporation Private
Limited**

**A1-302, GIDC, Sarigam-396155. Dist. Valsad,
Gujarat, INDIA.**

An ISO 13485 & EN ISO 13485 Certified Company

Product Details

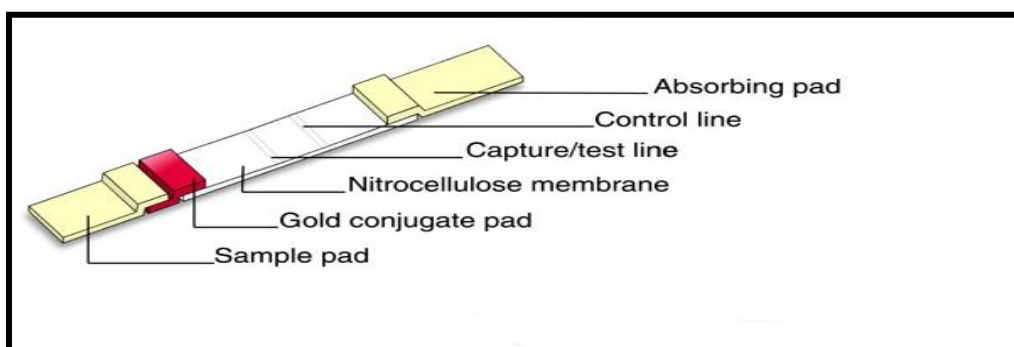
1	Product Name	:	First Response® Sickle Cell Detection Card Test
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	PI27FRC
4	Catalogue Number	:	PI27FRC05, PI27FRC10, PI27FRC25

Intended Use:

First Response® Sickle Cell Detection Card Test is a lateral flow immunochromatographic qualitative immunoassay for detection of hemoglobins variants Type-A and Type-S using finger prick capillary and venous whole blood specimens. The test is intended to be performed by trained users (In either laboratory or point of care settings) as qualitative screening test. Whole Blood Specimen with anti-coagulants heparin, EDTA, or citrate do not affect the test results. The test is not automated and does not require any additional instrument.

Assay Principle:

First Response® Sickle Cell Detection Card Test is a rapid, qualitative lateral flow assay based on principle of immunochromatography for identification of sickle cell disorder of hemoglobins A and S. Nitrocellulose membrane is coated with Anti-Hemoglobin A and Anti-Hemoglobin S monoclonal antibody in test region(s). Control reagent is coated at control line (C). When the test sample along with extraction buffer flows through Nitrocellulose membrane, anti-hemoglobin antibody conjugated colloidal gold conjugate forms antigen-antibody complex that migrates through the membrane and gets captured at tests region(s), which leads to the formation of color line indicating reactive results. The control line will appear irrespective of reactive or non-reactive specimen and act as a procedural control serves to validate the test result.

**Storage & Stability**

First Response® Sickle Cell Detection Card Test should be stored at 4-30°C. Do not freeze the kit or components. Extraction buffer & the unopened Test Device are stable until the expiry date printed on the label, when stored at 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 extraction buffer beyond the date of expiry.

Shelf Life:

First Response® Sickle Cell Detection Card Test has shelf life of 24 months.

Performance Characteristics:

First Response® Sickle Cell Detection Card Test were tested using an in-house panel. Performance comparison with reference method (High Performance Liquid Chromatography (HPLC)). First Response® Sickle Cell Detection Card Test showed >99% sensitivity and >99% specificity.

Operational Characteristics:**Temperature range:**

- First Response® Sickle Cell Detection Card Test is stable at temperature range of 4- 30°C.
- Operating Temperature range is room temperature.
- Test result interpretation time 5-10 minutes.

Certification:

- First Response® Sickle Cell Detection 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® Sickle Cell Detection Card Test contains:

- Test devices packed in aluminum pouch with desiccant.
- Specimen Transfer device.
- Sterile lancet.
- Alcohol swab.
- Instructions for use in English language.
- Prefilled Reaction Buffer Vial.
- Nozzle