



TECHNICAL SPECIFICATION.

Product Name

**First Response® Malaria Ag. *P. falciparum*
(HRP2/pLDH) Combo 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

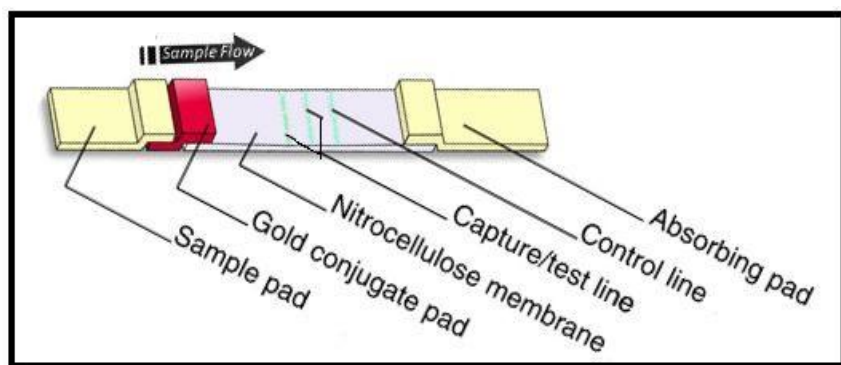
1	Product Name	:	First Response® Malaria Ag. <i>P. falciparum</i> (HRP2/pLDH) Combo Card Test
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	PI25FRC
4	Catalogue Number	:	PI25FRC05, PI25FRC10, PI25FRC25, PI25FRC30, PI25FRC10s, PI25FRC25s

Intended Use:

First Response® Malaria Ag. *P. falciparum* (HRP2/pLDH) Combo Card Test is intended to be performed by trained users (In either laboratory or point of care settings) as qualitative screening test for detection of histidine rich protein 2 (HRP2) antigen and plasmodium lactate dehydrogenase antigen (pLDH) from Malaria causing parasite *Plasmodium falciparum*. The test is intended for whole blood specimens (capillary or venous blood). Venous Blood with anti-coagulants heparin, EDTA, citrate or ACD do not affect the test results. However, not intended to be used for screening of blood donors. The test is not automated and does not require any additional instrument.

Assay Principle:

First Response® Malaria Ag. *P. falciparum* (HRP2/pLDH) Combo Card Test is based on principle of immunochromatography in which nitrocellulose membrane is pre-coated with two monoclonal antibodies as two separate lines. One monoclonal antibody (test line pLDH) is specific to lactate dehydrogenase (pLDH) of the *P. falciparum* and the other line (test line HRP2) consists of a monoclonal antibody specific to Histidine Rich Protein 2 (HRP2) of the *P. falciparum*. Control reagent is coated at control line (C). When the test sample along with assay buffer flows through the nitrocellulose membrane, monoclonal antibodies conjugated with colloidal gold, which are specific to *P. falciparum* pLDH and *P. falciparum* specific to HRP2 binds to Plasmodium antigens released from the lysed blood sample. These antigen-conjugated antibody complex moves through the nitrocellulose membrane and binds to corresponding immobilised antibody at test lines, which leads to the formation of color line / lines indicating reactive results. The control line will appear irrespective of reactive or non-reactive sample.

**Storage & Stability**

First Response® Malaria Ag. *P.falciparum* (HRP2/pLDH) Combo Card Test should be stored at 1-40 °C. Do not freeze the kit or components. Assay buffer & the unopened Test Device are stable until the expiry date printed on the label, when stored at room temperature 1-40 °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 assay buffer beyond the date of expiry.

Shelf Life:

First Response® Malaria Ag. *P.falciparum* (HRP2/pLDH) Combo Card Test has shelf life of 24 months.

Performance Characteristics:

First Response® Malaria Ag. *P.falciparum* (HRP2/pLDH) Combo Card Test were tested using an in-house panel of positive and negative clinical specimens characterized by malaria microscopy as the reference method. First Response® Malaria Ag. *P.falciparum* (HRP2/pLDH) Combo Card Test showed 100% sensitivity and 100% specificity. First Response® Malaria Ag. *P.falciparum* (HRP2/pLDH) Combo Card Test showed 100% agreement with the reference method.

Operational Characteristics:

Temperature range:

- First Response® Malaria Ag. *P.falciparum* (HRP2/pLDH) Combo Card Test is stable at temperature range of 1- 40°C.
- Operating Temperature range is room temperature.
- Test result interpretation time 20 minutes.

Certification:

- First Response® Malaria Ag. *P.falciparum* (HRP2/pLDH) Combo 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® Malaria Ag. *P.falciparum* (HRP2/pLDH) Combo Card Test contains:

- Test devices packed in aluminum pouch with desiccant.
- Specimen Transfer device.
- Sterile lancet.
- Alcohol swab.
- Instructions for use in English language.
- Assay buffer bottle.

Each single test kit of First Response® Malaria Ag. *P.falciparum* (HRP2/pLDH) Combo Card Test contains:

- Single test pack contents: Test device & desiccant, specimen transfer device, alcohol swab, sterile lancet, buffer vial & instructions for use
- Master instructions for use.