



TECHNICAL SPECIFICATION.

Product Name

**First Response® Malaria Ag.
P.f. (HRP2)/ *P.f.* (pLDH)/ *P.v.* (pLDH) Test**

**Manufacturer:
Premier Medical Corporation Private
Limited**

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

An ISO 13485 & EN ISO 13485 Certified Company

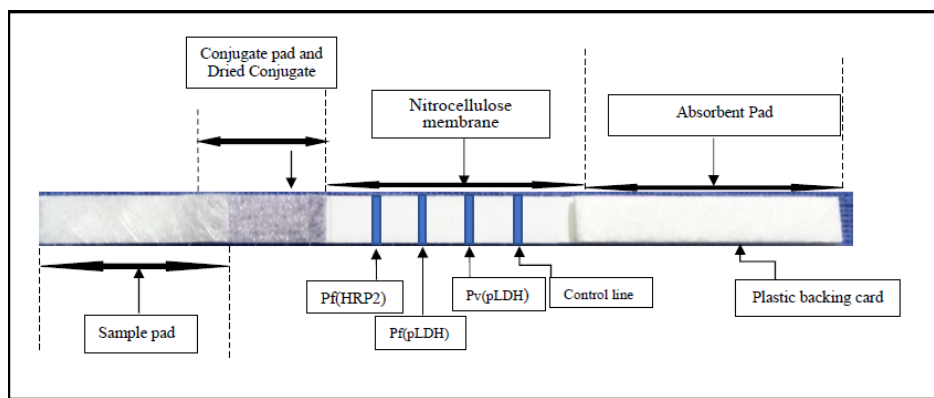
Product Details			
1	Product Name	:	First Response® Malaria Ag. <i>P.f.</i> (HRP2)/ <i>P.f.</i> (pLDH)/ <i>P.v.</i> (pLDH) Test
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	PI29FRC
4	Catalogue Number	:	PI29FRC05, PI29FRC10, PI29FRC25, PI29FRC30, PI29FRC10s, PI29FRC25s

Intended Use:

First Response® Malaria Ag. *P.f.* (HRP2)/*P.f.* (pLDH)/*P.v.* (pLDH) 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* and pLDH from malaria causing parasite *Plasmodium vivax* in human whole blood. The test is intended for whole blood specimens (capillary or venous blood). Venous Blood with anti-coagulants heparin, EDTA, Sodium citrate or ACD do not affect the test results. However, the test is 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.f.* (HRP2)/*P.f.* (pLDH)/*P.v.* (pLDH) Test is based on immunochromatography principle. First Response® Malaria Ag. *P.f.* (HRP2)/*P.f.* (pLDH)/*P.v.* (pLDH) Test kit contains nitrocellulose membrane strip coated with pLDH specific monoclonal antibody for *P. vivax*, pLDH specific monoclonal antibody for *P. falciparum* and HRP2 specific monoclonal antibody for *P. falciparum* at respective test region. Control reagent is coated at control line (C). When the *P.f.* (HRP2, pLDH) and *P.v.* (pLDH) reactive specimen flow through the membrane along with assay buffer, forms an immune complex with monoclonal antibody specific to *P.f.* HRP2 gold conjugate and monoclonal antibody specific to PAN (pLDH) gold conjugate. This immune complex moves further flows through the nitrocellulose membrane test region and bind with coated monoclonal antibodies specific to *P.f.* HRP2, *P.f.* pLDH and *P.v.* pLDH, leads to the formation of colored line in the respective test region, which confirms reactive test results. Absence of colored line in test region indicates non-reactive results. The control line will appear irrespective of reactive or non-reactive specimen, if test procedure is performed with specified instructions.



Storage & Stability

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

Performance Characteristics:

First Response® Malaria Ag. *P.f.* (HRP2)/*P.f.* (pLDH)/*P.v.* (pLDH) 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.f.* (HRP2)/*P.f.* (pLDH)/*P.v.* (pLDH) Test showed 100% sensitivity and 100% specificity.

Operational Characteristics:

Temperature range:

- First Response® Malaria Ag. *P.f.* (HRP2)/*P.f.* (pLDH)/*P.v.* (pLDH) 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.f.* (HRP2)/*P.f.* (pLDH)/*P.v.* (pLDH) 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.f.* (HRP2)/*P.f.* (pLDH)/*P.v.* (pLDH) 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.f.* (HRP2)/*P.f.* (pLDH)/*P.v.* (pLDH) 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.