



TECHNICAL SPECIFICATION.

Product Name

**First Response Malaria Antigen *P.falciparum*(HRP2)
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 Antigen <i>P.falciparum</i> (HRP2) Card Test
2	Product Family	:	Rapid Diagnostic Tests
3	Product Code	:	PI13FRC

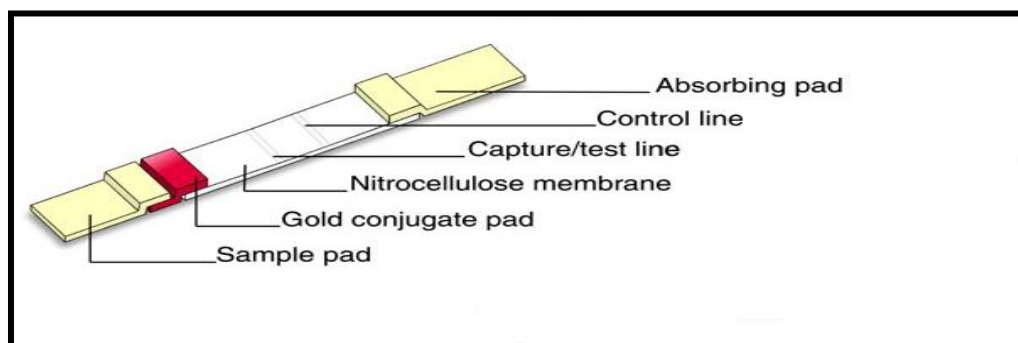
Intended Use:

First Response® Malaria Antigen. *P. falciparum* (HRP2) Card Test is intended for use by healthcare professionals and as qualitative screening *in vitro* diagnostic test for detection of *P. falciparum* specific HRP2 antigens. The test is intended for use with whole blood. The test is not automated and does not require any additional instrument. Reactive samples should be confirmed by additional tests such as Microscopic examination.

Assay Principle

First Response® Malaria Antigen. *P. falciparum* (HRP2) Card Test is based on principle of immunochromatography. In which nitrocellulose membrane is pre-coated with one monoclonal antibody (test line P.f.) specific to Histidine-Rich Protein 2 (HRP2) of the Plasmodium falciparum species. When the test sample along with assay diluent flows through the nitrocellulose membrane, monoclonal antibodies conjugated with colloidal gold, which is specific to HRP2 binds to antigens released from the lysed blood sample. This antigen conjugated antibody complex moves through the nitrocellulose membrane and binds to the immobilized antibody at the test line, which leads to the formation of color band indicating reactive results. The control band will appear irrespective of reactive or non reactive sample. So, First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test is designed for the diagnosis of Plasmodium falciparum.

General Presentation of test strip of First Response® Malaria Antigen .*P. falciparum* (HRP2) Card Test



Storage & Stability

First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test should be stored at 1-40 °C. Do not freeze the kit or components. Buffer (opened & unopened) & 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 Buffer beyond the date of expiry.

Shelf Life:

First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test has shelf life of 24 months.

Performance Characteristics:

Based on the demonstrated *P. falciparum* panel detection score (91.0% at 200 parasites/μl), false-positive rates (1.0% for clean negatives, 0.0% for *P. vivax* at 200 parasites/μl, 0.0% for *P. vivax* at 2000 to 5000 parasites/μl) and invalid rate (0.0%).

Operational Characteristics:

Temperature range:

- First Response® Malaria Antigen *P. falciparum* (HRP2) 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 Antigen *P. falciparum* (HRP2) Card Test is WHO pre-qualified product.
- First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test is CE certified product.
- First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test is manufactured by Premier Medical Corporation Private Limited, an ISO 13485 & EN ISO 13485 certified company.

Kit components:

Each kit of First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test contains:

- Individually pouched test device with desiccant.
- Specimen Transfer device.
- Sterile lancet.
- Alcohol swab.
- Instructions for use in English language.
- Assay buffer bottle.