

## WHO Prequalification of In Vitro Diagnostics PUBLIC ASSESSMENT REPORT

### Product: First Response Malaria Ag. pLDH/HRP2 Combo Card Test WHO reference number: PQDx 0285-010-00

First Response Malaria Ag. pLDH/HRP2 Combo Card Test with product codes PI16FRC10s, PI16FRC25s, PI16FRC25, PI16FRC30, PI16FRC05, and PI16FRC10 manufactured by Premier Medical Corporation Private Limited, rest-of-world regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 04 December 2018.

### Summary of the WHO prequalification assessment for the First Response Malaria Ag. pLDH/HRP2 Combo Card Test

	Date	Outcome
<b>Prequalification listing</b>	04 December 2018	listed
<b>Dossier assessment</b>	07 September 2018	MR
<b>Product performance evaluation</b>	2015	MR

MR: Meets Requirements

### Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendments and change request reference where applicable.	Date of report amendment
2.0	Introducing new suppliers for Alcohol Swab and Twist Lancet resulted in the change of labels.	11 March 2025
3.0	1. Change in the regulatory certification and labelling of the supplier for sterile lancet "Shandong Lianfa Medical Plastic Products Co., Ltd." 2. Change in the label of the alcohol swab supplied by Medtrue Enterprises Co., Limited.	4 June 2025
4.0	Addition of pack sizes of 05 and 10 tests/pack.	12 September 2025

5.0	Changes to the assay buffer bottle supplied with the IVD for the First Response product line. There are no changes to the assay buffer itself (PQC-IVD-2025-0015).	9 January 2026
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### Intended use

According to the claim of the manufacturer *"First Response Malaria Ag. pLDH/HRP2 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 P. falciparum, P. vivax, P. ovale and P. malariae. The test is intended for use with whole blood specimens (capillary or venous blood). Venous blood with the anti-coagulants heparin, EDTA or citrate do not affect the results. This kit is not intended to be used for screening of blood donors. The test is not automated and does not require any additional instrument."*

### Test kit contents

Description	Configuration	
<b>Each single test pack contains:</b> <ul style="list-style-type: none"> <li>1 × Test device &amp; desiccant</li> <li>1 × Specimen Transfer device</li> <li>1 × Alcohol swab</li> <li>1 × Sterile lancet</li> <li>1 × Buffer vial</li> <li>1 × Instructions for use</li> </ul>	10 × single test (product code PI16FRC10s)	1 × Master Instructions for Use
	25 × single test (product code PI16FRC25s)	1 × Master Instructions for Use
<ul style="list-style-type: none"> <li>Test device with desiccant</li> <li>Specimen Transfer device</li> <li>Buffer Bottle</li> <li>Sterile Lancet</li> <li>Alcohol swabs</li> <li>Instructions for use</li> </ul>	25 × Bulk test (product code PI16FRC25)	n/a
	30 × Bulk test (product code PI16FRC30)	n/a
	05 × Bulk test (product code PI16FRC05)	n/a
	10 × Bulk test (product code PI16FRC10)	n/a

### Items required but not provided

- New pair of disposable gloves
- Permanent marker pen
- Timer
- Extra lancets and alcohol swabs, if needed
- Sharp disposable box and biohazardous waste container
- Venipuncture blood collection materials and precision pipette plus tip (if whole blood is collected by venipuncture)
- Bio-hazardous waste container

**Storage**

The test kit must be stored between 1 and 40 °C.

**Shelf-life upon manufacture<sup>1</sup>**

24 months.

**Dossier assessment**

Premier Medical Corporation Private Limited submitted a product dossier for First Response Malaria Ag. pLDH/HRP2 Combo Card Test as per the *“Instructions for compilation of a product dossier”* (PQDx\_018 v1). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 07 September 2018.

Based on the product dossier screening and assessment findings, the product dossier for First Response Malaria Ag. pLDH/HRP2 Combo Card Test meets WHO prequalification requirements.

**Manufacturing site inspection**

The inspection of the manufacturing site(s) was conducted to assess whether the manufacturer's quality management system (QMS) and manufacturing practices are in alignment with:

- (i) applicable international standards, such as ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes);
- (ii) the manufacturer's own documented procedures and quality requirements; and
- (iii) other relevant international standards and guidelines applicable to in vitro diagnostic (IVD) medical devices. The WHO's Public Inspection Reports are accessible at:

<https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports>

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<sup>1</sup> The assigned device shelf-life is based on stability data generated from the date of manufacture. The finished goods shelf-life, calculated from the date of packaging completion, may be shorter depending on the time elapsed between manufacture and final packaging of the device.

## Product performance evaluation

The sixth round of WHO product testing of RDTs for malaria antigen detection was completed in 2015. The product was evaluated against a *Plasmodium falciparum* cultured line panel, *P. falciparum* wild type parasite panel, *P. vivax* wild type parasite panel and a *Plasmodium spp.* negative panel. Thermal stability was assessed after 2 months of storage at elevated temperature and humidity, and a descriptive ease of use assessment was recorded.

Based on the demonstrated *P. falciparum* panel detection score (82% at 200 parasites/μl), *P. vivax* panel detection score (91.4% at 200 parasites/μl), false-positive rates (1.9% for clean negatives, 1.5% for *P. falciparum* at 200 parasites/μl, 0.0% for *P. vivax* at 200 parasites/μl, 0.0% for *P. falciparum* at 2000 to 5000 parasites/μl, 0.0% for *P. vivax* at 2000 to 5000 parasites/μl) and invalid rate (0.1%), **First Response Malaria Ag. pLDH/HRP2 Combo Card Test** meets the current laboratory evaluation requirements for prequalification.

Summary performance characteristics	Panel detection score (%)		False positive rate (%)			Invalid rate (%)
	200 parasites/μl		200 parasites/μl		Clean negatives	
	Pf	Pv	Pf	Pv		
<b>First Response Malaria Ag. pLDH/HRP2 Combo Card Test</b>	82.0	91.4	1.5	0.0	1.9	0.1

## Labelling review

The labelling submitted for the First Response Malaria Ag. pLDH/HRP2 Combo Card Test was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

The table below provides traceability of the labelling documents reviewed during the assessment, including document titles, version numbers, approval dates, and control identifiers.

**Controlled Labelling References**

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
<b>Outer box artwork</b>	Carton – 10 Single Tests	AB	2024-10	FM-QA-40
	Carton – 25 Single Tests	AD	2022-05	FM-QA-40
	Carton – 25 Tests	AD	2020-10	FM-QA-40
	Carton – 30 Tests	AB	2024-10	FM-QA-40
	Carton – 5 Tests	AA	2025-01	FM-QA-40
	Carton – 10 Tests	AA	2025-01	FM-QA-40
<b>Pouch / Device label</b>	Aluminium Pouch	01	2024-08-23	FM-QA-40
<b>Reagent bottle labels</b>	Assay Buffer Bottle Label - DBS-027	01	2024-08-23	FM-QA-40
	Assay Buffer Bottle Label - DBS-041	01	2024-08-23	FM-QA-40
<b>Accessory labeling (e.g., pipettes, buffer caps)</b>	Alcohol Swab (Medtrue)	02	2025-11-25	FM-QA-40
	Alcohol Swab (Phoenix)	01	2024-08-23	FM-QA-40
	Sterile Twist Lancet – (LAN-007)	01	2024-08-23	FM-QA-40
	Sterile Twist Lancet – (LAN-008)	01	2024-08-23	FM-QA-40
	Sterile Twist Lancet – (LAN-012)	01	2024-08-23	FM-QA-40
	Sterile Twist Lancet – (LAN-013)	01	2024-08-23	FM-QA-40
	Specimen Transfer device - (25 Nos.) PMD - (IC-002)	02	2025-06-23	FM-QA-40
	Specimen Transfer device - (30 Nos.) PMD - (IC-003)	02	2025-06-23	FM-QA-40
	Specimen Transfer device - (5 Nos.) PMD	02	2025-06-23	FM-QA-40
	Specimen Transfer device - (10 Nos.) PMD	02	2025-06-23	FM-QA-40
	Specimen Transfer device - (25 Nos.) KPI-(IC-002)	01	2024-08-23	FM-QA-40
	Specimen Transfer	01	2024-08-23	FM-QA-40

	device - (30 Nos.) KPI-(IC-003)			
	Specimen Transfer device - (5 Nos.) KPI	01	2025-01-02	FM-QA-40
	Specimen Transfer device - (10 Nos.) KPI	01	2025-01-02	FM-QA-40
<b>Instructions for Use (IFU)</b>	(S)PI16-INS-001	AD	2025-09-21	FM-QA-40
	(S)PI16-INS-002	AD	2025-09-21	FM-QA-40
	(S)PI16-INS-003	AD	2025-09-21	FM-QA-40

### Labels

Carton – 10 Single Tests

For *in vitro* Diagnostic Use Only.

Malaria Ag. pLDH/HRP2  
Combo Card Test  
(Whole Blood)



REF PI16FRC10s  
10 Tests/kit

One Step Malaria Ag. P.f. / Pan Combo



IVD



REF PI16FRC10s  
10 Tests/kit

One Step Malaria Ag. P.f. / Pan Combo



Mfg. Lic. No.: MFG/MD/2018/000064

LOT

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- Material Provided:**
- 10 Single Test Pack
  - Each single test pack contents:  
(Test device & desiccant, Specimen Transfer Device, Alcohol swab, Sterile lancet, Buffer Vial & Instructions for use.)
  - Master Instruction for use : 1 No.

Rev.: AB, 2024-10



Malaria Ag. pLDH/HRP2  
Combo Card Test  
(Whole Blood)



For Professional Use.



**Premier Medical Corporation Private Limited**  
A1 - 302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA  
Customer support email : [info@premiermedcorp.com](mailto:info@premiermedcorp.com)  
Tel.: +91 260 2780112/113, [www.premiermedcorp.com](http://www.premiermedcorp.com)



Malaria Ag. pLDH/HRP2  
Combo Card Test  
(Whole Blood)



Carton – 25 Single Tests

For *in vitro* Diagnostic Use Only.

**Malaria Ag. pLDH/HRP2**  
**Combo Card Test**  
**(Whole Blood)**

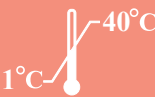


FIRTS  
RESPONSE



**REF** P116FRC25s  
Σ 25 Tests/kit

## One Step Malaria Ag. P.f. / Pan Combo



**1** **FIRST**  
**RESPONSE**®

# Malaria Ag. pLDH/HRP2 Combo Card Test (Whole Blood)



IVD



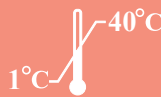
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**Premier Medical Corporation Private Limited**  
A1 - 302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA  
Customer support email : [info@premiermedcorp.com](mailto:info@premiermedcorp.com)  
Tel.: +91 260 2780112/113, [www.premiermedcorp.com](http://www.premiermedcorp.com)

**REF** PI16FRC25s  
Σ 25 Tests/kit

## One Step Malaria Ag. P.f. / Pan Combo



**FIRST<sup>®</sup>**  
RESPONSE

## Malaria Ag. pLDH/HRP2 Combo Card Test (Whole Blood)



Mfg. Lic. No. : MFG/MD/2018/000064

LOT



### Materials Provided :

- 25 Single Test Pack  
Each single test pack contents:  
(Test device & desiccant, Specimen transfer device, Alcohol swab, Sterile lancet, Buffer vial & Instructions for use.)
- Master Instructions for use: 1 No.

Rev.: AD, 2022-05

#### Carton –25 Tests

For *in vitro* Diagnostic Use Only.

**Malaria Ag. pLDH/HRP2**  
**Combo Card Test**  
**(Whole Blood)**



**REF** PI16FRC25  
Σ 25 Tests/kit

## One Step Malaria Ag. P.f. / Pan Combo



Mfg. Lic. No.: MFG/MD/2018/000064

LOT



## Contents:

- Individually pouched test devices with desiccant : 25 Nos.
- Specimen Transfer Device : 25 Nos.
- Sterile Lancets : 25 Nos.
- Alcohol Swabs : 25 Nos.
- Assay Buffer Bottle : 1 No.
- Instructions for use : 1 No.

Rev.: AD, 2020-10

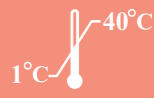
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**REF** **PI16FRC25**  
 $\Sigma$  25 Tests/kit

## One Step Malaria Ag. P.f. / Pan Combo



# FIRST RESPONSE®

## Malaria Ag. pLDH/HRP2 Combo Card Test (Whole Blood)



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		<div>REF P116FRC25 Σ 30 Tests/kit</div>	
		One Step Malaria Ag. P.f. / Pan Combo	
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		<div>i</div>	

Carton – 5 Tests

<div><div><div>1° C-40° C</div><div></div></div><div><div>Malaria Ag. pLDH/HRP2</div><div>Combo Card Test</div><div>(Whole Blood)</div></div><div><div>For <i>in vitro</i> Diagnostic Use Only.</div></div></div>		<div><div><div>1° C-40° C</div><div></div></div><div><div>Malaria Ag. pLDH/HRP2</div><div>Combo Card Test</div><div>(Whole Blood)</div></div><div><div>For <i>in vitro</i> Diagnostic Use Only.</div></div></div>	
<div><div><div>REF P116FRC05</div><div>▽ 05 Tests/kit</div></div><div><div>One Step Malaria Ag. P.f./PAN Combo</div></div><div><div>1° C-40° C</div><div></div></div></div>		<div><div><div>REF P116FRC05</div><div>▽ 05 Tests/kit</div></div><div><div>One Step Malaria Ag. P.f./PAN Combo</div></div><div><div>1° C-40° C</div><div></div></div></div>	
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<div><div><div>REF P116FRC05</div><div>▽ 05 Tests/kit</div></div><div><div>One Step Malaria Ag. P.f./PAN Combo</div></div><div><div>1° C-40° C</div><div></div></div></div>		<div><div><div>REF P116FRC05</div><div>▽ 05 Tests/kit</div></div><div><div>One Step Malaria Ag. P.f./PAN Combo</div></div><div><div>1° C-40° C</div><div></div></div></div>	

Carton –10 Tests

<div>Mfg. Lic. No.: MFG/MD/2018/000064</div> <div><div>LOT</div><div></div><div></div><div></div></div> <div><div>Contents:</div><div><div>Individually pouched test devices with desiccant</div><div>: 10 Nos.</div></div><div><div>Specimen Transfer Device</div><div>: 10 Nos.</div></div><div><div>Sterile Lancets</div><div>: 10 Nos.</div></div><div><div>Alcohol Swabs</div><div>: 10 Nos.</div></div><div><div>Assay Buffer Bottle</div><div>: 01 No.</div></div><div><div>Instructions for use</div><div>: 01 No.</div></div></div> <div>Rev.: AA, 2025-01</div>		<div><div>REF</div><div>PI16FRC10</div><div>Σ</div><div>10 Tests/Kit</div></div> <div>One Step Malaria Ag. P.f./PAN Combo</div> <div><div>1°C</div><div>40°C</div></div>	<div><div>REF</div><div>PI16FRC10</div><div>Σ</div><div>10 Tests/Kit</div></div> <div>One Step Malaria Ag. P.f./PAN Combo</div> <div><div>1°C</div><div>40°C</div></div>
<div><div>1</div><div>FIRST</div><div>RESPONSE</div></div> <div>Malaria Ag. pLDH/HRP2 Combo Card Test (Whole Blood)</div> <div></div>		<div>For Professional Use.</div> <div><div></div><div>Premier Medical Corporation Private Limited</div><div>A1 - 302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA</div><div>Customer support email : info@premiermedcorp.com</div><div>Tel.: +91 260 2780112/113, www.premiermedcorp.com</div></div>	<div><div>1</div><div>FIRST</div><div>RESPONSE</div></div> <div>Malaria Ag. pLDH/HRP2 Combo Card Test (Whole Blood)</div> <div></div>

For *in vitro* Diagnostic Use Only.

Malaria Ag. pLDH/HRP2  
Combo Card Test  
(Whole Blood)

FIRST  
RESPONSE



## Aluminium Pouch



**MALARIA Ag. pLDH / HRP2 COMBO CARD TEST**  
**P.f. AND PAN DETECTION RAPID CARD TEST**



**Premier Medical Corporation Private Limited**  
A1 - 302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA  
[www.premiermedcorp.com](http://www.premiermedcorp.com)

**Mfg. Lic. No.: MFG/MD/2018/000064**

**LOT** :



:

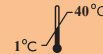


:

**REF**

**PI16FRC**

**IVD**



# Assay Buffer Label



**Malaria Ag. pLDH/HRP2  
Combo Card Test**

Assay Buffer 2.5 ml/vial



Premier Medical Corporation Pvt. Ltd.





Lic.No.: MFG/MD/2018/000064


**REF : PI16FRC**




**LOT :**


**EXP :**

# Assay Buffer Label - 3.0 ml

    Lic.No.: MFG/MD/2018/000064

 **FIRST**  
**RESPONSE**  
Malaria Ag. pLDH/HRP2  
Combo Card Test  
Assay Buffer 3.0 ml/vial

 : PI16FRC  
 :  
 :

 Premier Medical Corporation Pvt. Ltd.



MEDTRUE<sup>®</sup>

# Alcohol Swabs



CODE:MT59010102

LOT LOT NO. : XXXXXX

MFG. DATE : YYYYMMDD

EXP. DATE : YYYYMMDD

For External Use Only

CONTAIN:One pad saturated  
with 70% Isopropyl Alcohol.

DIRECTION:Cleaning the  
required area.

Discard after single use.



MEDTRUE ENTERPRISE CO., LTD  
Room No.301-302, Hongpujiezuo Mansion  
186-1 Jiangdongzhonglu Road, 210019 Nanjing, China



EC REP RIOMAVIX SOCIEDAD LIMITADA  
Calle de Almansa 55, 1D, Madrid 28039 Spain

TEAR HERE

PHX2006-NS



# Alcohol Prep Pad

70% v/v Isopropyl Alcohol

**\*For External Use Only\***

**1 Pad**

Medium

## **\*Discard Prep Pad After Single Use\***

### **Directions:**

Apply topically as needed to cleanse intended area

Phoenix Innovative Healthcare Manufacturers Pvt. Ltd.  
EL-209, Shil Mahape Road, Electronic Zone,  
MIDC, TTC Industrial Area, Mahape,  
Navi Mumbai - 400 710 MH | India  
Customer Care : 022-61075501  
Email : [customercare@phoenix-hs.com](mailto:customercare@phoenix-hs.com)  
NCE-MH/DRUGS/25-MH/101592



Advena Ltd.,  
Tower Business Centre,  
2nd Flr, Tower Street,  
Swatar, BKR 4013, Malta



XXXXXXXXXX



YYYY-MM



YYYY-MM

Rev.00

# Blood Lancets (Sterile Lancet)

Model / Specification : I / 28G

UDI

LOT

LOT NO. : XXXXXXXXXXXX



MFG. DATE : YYYY-MM-DD



EXP. DATE : YYYY-MM-DD

QTY : 25pcs



(01)06949517007109(11)YYMMDD  
(17)YYMMDD(10)XXXXXXXXXX



STERILE



MD

STERILE

R



-20°C

40°C

0%



80%



CE 0197

EC

REP

**Linkfar Healthcare GmbH**

Niederrheinstraße 71, 40474 Düsseldorf, Germany

TEL: +49-21138530888



**Shandong Lianfa Medical Plastic Products Co., Ltd.**

No.1 Shuangshan Sanjian Road, Zhangqiu, Jinan City, 250200, Shandong P. R. China

# Blood Lancets (Sterile Lancet)

Model / Specification : I / 28G UDI

LOT LOT NO. : XXXXXXXXXXXX

 MFG. DATE : YYYY-MM-DD

 EXP. DATE : YYYY-MM-DD

QTY : 30pcs



(01)06949517007116(11)YYMMDD  
(17)YYMMDD(10)XXXXXXXXXX



STERILE



MD

STERILE

R



-20°C

40°C

0%

80%



C E 0197

EC

REP

**Linkfar Healthcare GmbH**

Niederrheinstraße 71, 40474 Düsseldorf, Germany




TEL: +49-21138530888



**Shandong Lianfa Medical Plastic Products Co., Ltd.**

No.1 Shuangshan Sanjian Road, Zhangqiu, Jinan City, 250200, Shandong P. R. China

# Blood Lancets (Sterile Lancet)

Model / Specification : I / 28G  
 LOT NO. : XXXXXXXX  
 MFG. DATE : XXXX-XX-XX  
 EXP. DATE : XXXX-XX-XX  
QTY : 5pcs

UDI



(01)06949517008892(11)XXXXXX  
(17)XXXXXX(10)XXXXXXXXX



STERILE



MD

STERILE R



40°C

0%



80%



CE 0197

EC

REP

**Linkfar Healthcare GmbH**

Niederrheinstraße 71, 40474 Düsseldorf, Germany




TEL: +49-21138530888



**Shandong Lianfa Medical Plastic Products Co., Ltd.**

No.1 Shuangshan Sanjian Road, Zhangqiu, Jinan City, 250200, Shandong P. R. China

# Blood Lancets (Sterile Lancet)

Model / Specification : I / 28G  
 LOT NO. : XXXXXXXX  
 MFG. DATE : XXXX-XX-XX  
 EXP. DATE : XXXX-XX-XX  
QTY : 10pcs

UDI



(01)06949517008908(11)XXXXXX  
(17)XXXXXX(10)XXXXXXXXX



STERILE



MD

STERILE R



40°C

0%



80%



CE 0197

EC

REP

**Linkfar Healthcare GmbH**

Niederrheinstraße 71, 40474 Düsseldorf, Germany

TEL: +49-21138530888



**Shandong Lianfa Medical Plastic Products Co., Ltd.**

No.1 Shuangshan Sanjian Road, Zhangqiu, Jinan City, 250200, Shandong P. R. China

**Product: Specimen Transfer Device**

**Lot No. : IC/NN/YY-YY**

**Mfg. Date : DD/MM/YYYY**

**Expiry Date : DD/MM/YYYY**

**Qty : 25 Nos**



**Precision Medical Device Industries**

Ground Floor, Survey No. 1044, Kumbharwadi,

Opp. Bhilosa Industries, Village Naroli,

Dadra & Nagar Haveli and Daman & Diu - 396235.

**Product: Specimen Transfer Device**

**Lot No. : IC/NN/YY-YY**

**Mfg. Date : DD/MM/YYYY**

**Expiry Date : DD/MM/YYYY**

**Qty : 25 Nos**



**Krishna Plastic Industries**

Gala No.-117 First Floor, Pragati Industrial Estate,  
Opp-66 KVA Road, Amli, Silvassa 396230

**Product: Specimen Transfer Device**

**Lot No. : IC/NN/YY-YY**

**Mfg. Date : DD/MM/YYYY**

**Expiry Date : DD/MM/YYYY**

**Qty : 30 Nos**



**Precision Medical Device Industries**

Ground Floor, Survey No. 1044, Kumbharwadi,

Opp. Bhilosa Industries, Village Naroli,

Dadra & Nagar Haveli and Daman & Diu - 396235.

**Product: Specimen Transfer Device**

**Lot No. : IC/NN/YY-YY**

**Mfg. Date : DD/MM/YYYY**

**Expiry Date : DD/MM/YYYY**

**Qty : 30 Nos**



**Krishna Plastic Industries**

Gala No.-117 First Floor, Pragati Industrial Estate,  
Opp-66 KVA Road, Amli, Silvassa 396230

**Product: Specimen Transfer Device**

**Lot No. : IC/NN/YY-YY**

**Mfg. Date : DD/MM/YYYY**

**Expiry Date : DD/MM/YYYY**

**Qty : 5 Nos**



**Precision Medical Device Industries**

Ground Floor, Survey No. 1044, Kumbharwadi,

Opp. Bhilosa Industries, Village Naroli,

Dadra & Nagar Haveli and Daman & Diu - 396235.

**Product: Specimen Transfer Device**

**Lot No. : IC/NN/YY-YY**

**Mfg. Date : DD/MM/YYYY**

**Expiry Date : DD/MM/YYYY**

**Qty : 5 Nos**



**Krishna Plastic Industries**

Gala No.-117 First Floor, Pragati Industrial Estate,  
Opp-66 KVA Road, Amli, Silvassa 396230

**Product: Specimen Transfer Device**

**Lot No. : IC/NN/YY-YY**

**Mfg. Date : DD/MM/YYYY**

**Expiry Date : DD/MM/YYYY**

**Qty : 10 Nos**



**Precision Medical Device Industries**

Ground Floor, Survey No. 1044, Kumbharwadi,

Opp. Bhilosa Industries, Village Naroli,

Dadra & Nagar Haveli and Daman & Diu - 396235.

**Product: Specimen Transfer Device**

**Lot No. : IC/NN/YY-YY**

**Mfg. Date : DD/MM/YYYY**

**Expiry Date : DD/MM/YYYY**

**Qty : 10 Nos**



**Krishna Plastic Industries**

Gala No.-117 First Floor, Pragati Industrial Estate,  
Opp-66 KVA Road, Amli, Silvassa 396230

**Instructions for use<sup>2</sup>**


---

<sup>2</sup> English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

- ## Specimen collection and storage
- ### [Collection by venipuncture]
- 1) Collect the whole blood into the collection tube (containing EDTA/sodium citrate/heparin) by venipuncture.
  - 2) If specimens are not immediately tested (within 1 hour) should be stored at 2-8 °C maximum upto 72 hours (3 days). Using the specimen more than three days can cause non-specific reaction.



- Wear gloves, massaging the fingertip gently. It will help to obtain a round drop of blood.

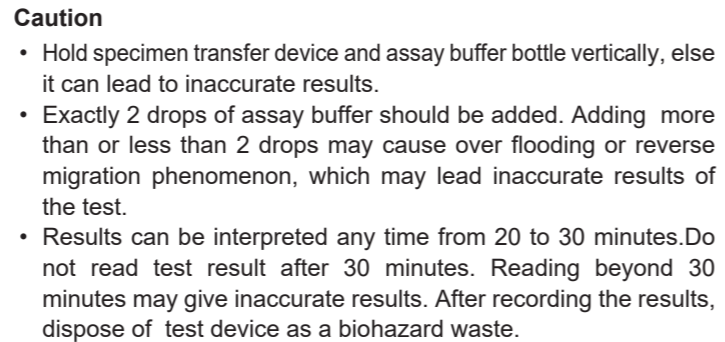
- 
- Detach the protective cap of the lancet and pierce the end of finger tip with the sterile lancet provided.

- After completion of specimen collection, take the used alcohol swab of same patient and press it on the finger to stop the bleeding.

- Do not share used lancets with another person. To prevent possible infection, a used lancet should not be touched by another person.
- Do not use expired lancet. The use of an expired lancet may cause any infection at the punctured skin due to cease to exist its sterility.
- Use new lancet and choose a different puncture site, if repeat the finger prick.
- Do not share used alcohol swab.

1) Whole blood specimen may be used for testing immediately (within 1 hour) or may be stored at 2-8°C for maximum up to 72 hours (3 days). Do not use blood specimen stored for more than 3 days. It can cause non-specific reaction.

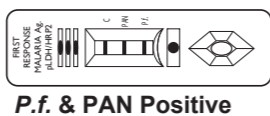
- 1) Bring the First Response® Malaria Ag. pLDH/HRP2 Combo Card Test kit components to room temperature (15 - 40°C) prior to 15 minutes of testing.
- 2) Remove the Test Device and the Specimen transfer Device from the kit and place it on a flat, dry surface and label the Test Device with specimen identification number/name.
- 3) Slowly add 5 µl of whole blood to the specimen well using the Specimen Transfer Device. Dispose the used Specimen transfer device as biohazard waste immediately after use.
- 4) Add two drops of the Assay buffer to the buffer well.
- 5) Observe for development of colored bands in the Results Window.
- 6) Interpret test results at 20 minutes. (After recording the results, dispose of test device as a biohazardous waste).
- 7) Do not interpret after 30 minutes.



The visualization of the control line in First Response® Malaria Ag. pLDH/HRP2 Combo Card Test indicates that active ingredient of the strips are functional and the migration is successful. The control line in First Response® Malaria Ag. pLDH/HRP2 Combo Card Test is not meant for specimen addition monitoring.

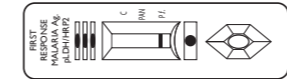
If only one color line appear, at control line 'C' as in the figure, the specimen is negative.

**P.f. Positive**

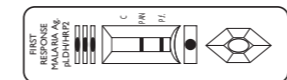


**FIRST RESPONSE**  
**TESTING**  
**CONDUIT**  
  
  


No presence of control line 'C' in the result window (irrespective of presence of test lines) indicates an invalid result.



The Invalid test results should be retested with new test device.



First Response® Malaria Ag. pLDH/HRP2 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. pLDH/HRP2 Combo Card Test showed 100% sensitivity and 100% specificity. First Response® Malaria Ag. pLDH/HRP2 Combo Card Test showed 100% agreement with the reference method.

Specimen details	Reference Method (Microscopy)		First Response® Malaria Ag. pLDH/HRP2 Combo Card Test		
	Positive	Negative	Positive	Negative	Total
<i>P. falciparum</i> Positive Whole blood specimen	231	0	231	0	231
<i>P. vivax</i> Positive Whole blood specimen	243	0	243	0	243
Malaria Negative Whole blood specimen	0	1287	0	1287	1287
Total	474	1287	474	1287	1761

Reference Method	Specimen details		First Response® Malaria Ag. pLDH/HRP2 Combo Card Test			
Microscopy	Clinical Status	Parameter	Positive	Negative	Total Result	95% Confidence Interval
	<i>P. falciparum</i> Positive	Sensitivity	231	00	231	(97.96%-100%)
	<i>P. Vivax</i> Positive	Sensitivity	243	00	243	(98.06%-100%)
	Malaria Negative	Specificity	00	1287	1287	(99.63%-100%)

Note: The product was not been fully assessed with *P.ovale* & *P.malariae* and the sensitivity is expected to be low (<50 %)

The analytical sensitivity of the First Response® Malaria Ag. pLDH/HRP2 Combo Card Test was carried out by testing WHO worldwide performance panel. Total 10 specimens were tested in-house. The First Response® Malaria Ag.pLDH/HRP2 Combo Card Test showed 100% Sensitivity.

Analytical Sensitivity : In-House Evaluation			
Total Specimens		First Response® Malaria Ag.pLDH/HRP2 Combo Card Test	
		Positive	Negative
05	200 p/μl	05	00
05	2000 p/μl	05	00

First Response® Malaria Ag. pLDH/HRP2 Combo Card Test was tested with specimen reactive for other diseases/conditions (mentioned in following table), which may interfere with performance of the test. The First Response® Malaria Ag. pLDH/HRP2 Combo Card Test tested with mentioned specimen for cross reactivity study as well as same diseased/condition specimens<sup>#</sup> were also used for spiking of malaria positive specimens<sup>#</sup> to determine effect on sensitivity of the test. None of the specimens interfere with the test results of First Response® Malaria Ag.pLDH/HRP2 Combo Card Test, and showed no cross reactivity with 100% sensitivity.

Specimens tested	<i>P. falciparum</i> positive specimens	<i>P. vivax</i> positive specimens	Malaria negative specimens	Specimens tested	<i>P. falciparum</i> positive specimens	<i>P. vivax</i> positive specimens	Malaria negative specimens
Syphilis Positive <sup>a</sup>	06	06	10	HSV 1/2 Positive <sup>a</sup>	05	05	05
HIV Positive <sup>a</sup>	03	03	05	HTLV- I Ab Positive <sup>a</sup>	07	07	07
Dengue NS1 Positive <sup>a</sup>	05	05	05	HTLV- II Ab Positive <sup>a</sup>	09	09	09
Multipara (Pregnant Woman)	08	04	72	HSV - I IgG Positive <sup>a</sup>	08	08	08
CMV Positive <sup>a</sup>	03	03	03	Rubella IgG & IgM Positive <sup>a</sup>	15	15	15
ANA Positive <sup>a</sup>	04	04	04	HBsAg Positive <sup>a</sup>	03	03	05
HAV Positive <sup>a</sup>	04	04	04	Chikungunya Positive <sup>a</sup>	05	05	05
EBV Positive <sup>a</sup>	02	02	02	Anti-malarial drug medication	02	02	Not tested
HCV Positive <sup>a</sup>	03	03	05	Anti-TB drug medication <sup>a</sup>	03	03	03
Yellow fever virus <sup>a</sup> post immunization	03	03	04	Influenza A and B <sup>a</sup>	03	03	06
Measles <sup>a</sup>	03	03	04	Visceral leishmaniasis <sup>a</sup>	03	03	05
Leptospirosis <sup>a</sup>	03	03	05	Bilirubin <sup>a</sup>	03	03	05
Cholesterol <sup>a</sup> Triglycerides	03	03	05	Chagas	03	03	05
Influenza vaccine <sup>a</sup> recipient	03	03	05	Sickle cell	03	03	05
Leishmaniasis <sup>a</sup>	03	03	05	Acute hepatitis A infection <sup>a</sup>	03	03	05
Schistosomiasis <sup>a</sup>	03	03	05	Toxoplasmosis <sup>a</sup>	03	03	05

The interfering substances that may affect performance of the First Response® Malaria Ag.pLDH/HRP2 Combo Card Test are mentioned in following table. The First Response® Malaria Ag.pLDH/HRP2 Combo Card Test showed no reactivity with any of mentioned specimens and showed 100% specificity. The same specimens<sup>#</sup> were spiked in malaria positive specimens respectively and tested. First Response® Malaria Ag.pLDH/HRP2 Combo Card Test showed 100% sensitivity with spiked specimens.

Specimens tested	<i>P. falciparum</i> positive specimens	<i>P. vivax</i> positive specimens	Malaria negative specimens	Specimens tested	<i>P. falciparum</i> positive specimens	<i>P. vivax</i> positive specimens	Malaria negative specimens
Lipemic specimen <sup>a</sup>	05	05	05	Low Hematocrit specimens	Not tested	Not tested	05
Icteric specimens <sup>a</sup>	05	05	05	Whole blood specimen in ACD anticoagulant	03	03	182
Hemolytic specimens	01	01	05	RF Ab Positive <sup>d</sup>	04	04	09
High Hematocrit specimens	Not tested	Not tested	05	dsDNA Antibody Positive <sup>d</sup>	01	01	01
Recipient of multiple blood transfusion	03	03	05				

- a) Within run, precision was determined by using 225 replicates of 9 different specimens containing different malaria parasitic count. Within run, precision was observed 100%.
- b) Between run, precision was determined by using the 9 different specimens containing different malaria parasitic count in 5 different replicates with 3 different lots of test devices X 5 different days X 3 different sites tested. Between run, precision was observed 100%.

External Evaluation Report							
Place of Evaluation	Year	Sensitivity				Specificity	
		PAN		P.f.		PAN	P.f.
		200 p/μl	2000 p/μl	200 p/μl	2000 p/μl		
WHO Evaluation Round 6	2014 - 2015	91.4%	100%	82%	100%	100%	100%
Ministry of Health & Children Care Zimbabwe	2014	92.5%		95.5%		98.78%	98.38%
National Public Health & Reference Lab, Ghana	2015	96%		100%		100%	100%

#### Potential interference drug substances

The details of interference drug molecules are mentioned in the following table. Each interfering drug molecule substance was spiked at the final concentration of 250μg/ml in malaria positive specimens as well as negative specimens, respectively. No false positive or false negative results were observed with any drug molecules, when tested with First Response® Malaria Ag. pLDH/HRP2 Combo Card Test.

Diclofenac	Acetaminophen	Aspirin
Folic acid	Pyrazinamide	Ampicillin Sodium salt
Abacavir	Cholecalciferol	Nevirapine
Magnesium sulphate	Ritonavir	Ibuprofen
Daruvir	Rifampicin	Ascorbic Acid
Naproxen IP	Metformin	Hydrochlorothiazide
Pantoprazole	Isoniazid	Ferrous Ascorbate
Ergocalciferol	Iron Chloride	Penicillin G Benzathine
Cyclobenzaprine Hydrochloride		

#### Limitation

- 1) The test procedure, precautions and interpretation of results for this test must be followed when testing.
- 2) The following anticoagulants have been validated for use with this test: heparin, EDTA & sodium citrate.
- 3) Interfering specimens like hemolytic (hemoglobin containing) samples, icteric (bilirubin containing) samples and lipemic samples do not affect the test results.
- 4) Do not mix reagent from different lots.
- 5) Interpret faint line as a reactive line. Repeat the test in case of very faint test line or if have any doubt for test line.
- 6) Although the test is very accurate in detecting HRP2 and /or pLDH, a low incidence of false results can occur. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- 7) False negative results may arise due to very low parasite density (for instance <100 p/μl), very high parasite density (prozone/hook effect), mutations in the HRP2 gene with deletion of HRP2 antigen, damage by heat, freezing or humidity, application of insufficient volume of blood on the device and use of wrong buffer.
- 8) False positive results can occur due to various conditions such as rheumatoid factors, antinuclear antibodies, chronic viral infection (hepatitis B or C), parasitic infection (schistosomiasis and trypanosomiasis) and use of wrong buffer.

#### References

- 1) Clinical and Laboratory Standards Institute. Procedures and devices for the collection of diagnostic capillary blood specimens; approved standard, fifth edition. CLSI H04-A6, Vol. 28, No. 25, 2008.
- 2) <http://vassarstats.net/clin1.html#def> , Richard Lowry.
- 3) Clinical and Laboratory Standards Institute. Procedures for the collection of diagnostic blood specimens by venipuncture; approved standard, sixth edition. CLSI H03-A6, Vol. 27, No. 26, 2007

- 4) World Health Organization: Laboratory biosafety manual, third edition. Geneva: WHO; 2004. <http://www.who.int/csr/resources/publications/biosafety/Bio-safety7.pdf>
- 5) WHO (2024). World malaria report, World Health Organization, Geneva, Switzerland. <https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2024>
- 6) Malaria rapid diagnostic test performance: results of WHO product testing of malaria RDTs: round 8 (2016-2018).
- 7) Gillet P, Scheirlinck A, Stokx J, De Weggeleire A, Chauque H, Canhanga O, Tadeu B, Mosse C, Tiago A, Mabunda S, Brugge-man C, Bottieau E, Jacobs J: Prozone in malaria rapid diagnos-tics tests: how many cases are missed? Malar J 2011, 10:166. <http://www.malariajournal.com/content/10/1/166>
- 8) Gillet P, Mori M, Van Den Ende J, Jacobs J: Buffer substitution in malaria rapid diagnostic tests causes false positive results. Malar J 2010, 9:215 <http://www.malariajournal.com/con-tent/9/1/215>
- 9) Maltha J, Gillet P, Cnops L, Van Den Ende J, Van Esbroeck M, Jacobs J: Malaria rapid diagnostic tests: Plasmodium falciparum infections with high parasite densities may generate false positive Plasmodium vivax pLDH lines. Malar J 2010, 9:198. <http://www.malariajournal.com/content/9/1/198>
- 10) Gamboa D, Ho M, Bendezu J, Torres K, Chiadini P, Barnwell J, Incardona S, Perkins M, Bell D, McCarthy J, Cheng Q: A large proportion of P. falciparum isolates in the Amazon region of Peru lack pfhrp2 and pfhrp3: implications for malaria rapid diagnostic tests. PLoS One 2010, 5:e8091. <http://www.plosone.org/article/i fo%3Adoi%2F10.1371%2Fjour-nal.pone.0008091>


SYMBOL LEGENDS			
Symbol	Explanation of symbol	Symbol	Explanation of symbol
	Consult instructions for use		Contains sufficient for < n > tests
	Non Sterile		Product Code
	In vitro diagnostic medical device		Lot Number
	Store at 1-40 °C		Manufacturer
	Caution		Date of manufacture (YYYY-MM)
	Keep dry		Expiration Date (YYYY-MM)
	Do not reuse		Do not use if package is damaged
	Keep away from sunlight		

#### Product Disclaimer and Warnings

Every warnings and precaution should be taken in to consideration before using the test. Failure to consider “Precaution, Warning and Limitations” may not ensure the diagnostic ability and accuracy of this product. The test result may accordingly be affected by environmental factors and / or user error outside of the control of the Manufacturer and Distributor.

A definitive clinical diagnosis should not be based on the results of a single test, but it should be made by physician after all clinical and laboratory findings have been evaluated.

“In no event shall our company or its distributor be liable for any direct, indirect, punitive, unforeseen, incidental, special consequential damages, to property or life, whatsoever arising out of or connected with an incorrect diagnosis, whether positive or negative, in the use or misuse of this product”.

 Manufactured by

**Premier Medical Corporation Private Limited**  
A1-302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA.  
Customer support E-mail : [info@premiermedcorp.com](mailto:info@premiermedcorp.com)  
Tel.: +91 2602780112/113 •Website : [www.premiermedcorp.com](http://www.premiermedcorp.com)

• ISO 13485 & EN ISO 13485 Certified Company

Part No.(S)PI16-INS-001, Rev.: AD, Date:2025-09-21      ENGLISH

Note : Instructions for use will be printed in local language of the country using the test, if required.



## FIRST RESPONSE® MALARIA Ag. pLDH/HRP2 COMBO CARD TEST

A rapid test for the detection of Malaria pLDH and HRP2 in human whole blood.

**[REF] PI16FRC05, PI16FRC10, PI16FRC25, PI16FRC30**

#### Intended Use

First Response® Malaria Ag. pLDH/HRP2 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 *P. falciparum*, *P. vivax*, *P. ovale* and *P. malariae*. The test is intended for use with whole blood specimens (capillary or venous blood). Venous blood with the anti-coagulants heparin, EDTA or citrate do not affect the test results. This kit is not intended to be used for screening of blood donors. The test is not automated and does not require any additional instrument.

#### Introduction

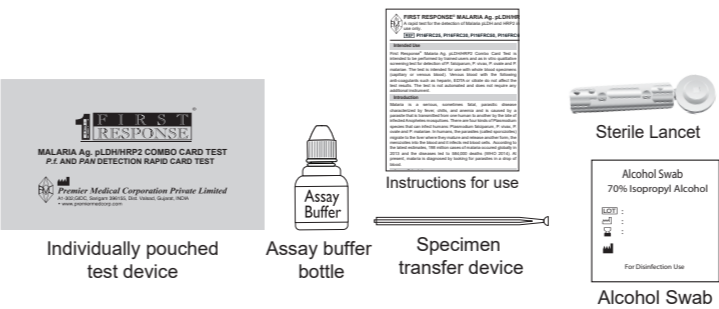
Malaria is a serious, sometimes fatal, parasitic disease characterized by fever, chills, and anemia and is caused by four species of plasmodium parasites that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four Plasmodium species that can infect humans: *Plasmodium falciparum*, *P. vivax*, *P. ovale* and *P. malariae*. In humans, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites into the blood which infect red blood cells. According to the latest estimates, 263 million cases of malaria occurred globally, and the diseases led to 0.6 million deaths (WHO 2024). At present, malaria is diagnosed by looking for parasites in a drop of blood.

#### Assay Principle

First Response® Malaria Ag. pLDH/HRP2 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 PAN) is PAN specific to lactate dehydrogenase (pLDH) of the *Plasmodium species (Plasmodium falciparum, P. vivax, P. ovale and P. malariae.)* and the other line (test line P.f.) consists of a monoclonal antibody specific to Histidine Rich Protein 2 (HRP2) of the *Plasmodium falciparum*. When the test sample along with assay Buffer flows through the nitrocellulose membrane, monoclonal antibodies conjugated with colloidal gold, which are PAN specific to 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 colour line / lines indicating reactive results. The control line will appear irrespective of reactive or non reactive sample.

So, the First Response® Malaria Ag. pLDH/HRP2 Combo Card Test is “of additional value” in the differential diagnosis of *Plasmodium falciparum* and other Plasmodium species.

#### Materials Provided



Materials Provided	PI16FRC05	PI16FRC10	PI16FRC25	PI16FRC30
Test Device Pouch Containing: 1 test Device, 1 desiccant	05 Nos.	10 Nos.	25 Nos.	30 Nos.
Specimen transfer device	05 Nos.	10 Nos.	25 Nos.	30 Nos.
Assay buffer bottle	1 No.	1 No.	1 No.	1 No.
Sterile lancet	05 Nos.	10 Nos.	25 Nos.	30 Nos.
Alcohol swab	05 Nos.	10 Nos.	25 Nos.	30 Nos.
Instructions for use	1 No.	1 No.	1 No.	1 No.

#### Materials Required but Not Provided

- New pair of disposable gloves.
- Permanent marker pen and timer .
- Extra lancets and alcohol swabs, if needed.
- Sharp disposable box and biohazardous waste container.
- Venipuncture blood collection kit (if whole blood is collected by venipuncture).

#### Storage and Stability

- 1) First Response® Malaria Ag. pLDH/HRP2 Combo Card Test should be stored at 1 - 40°C.
- 2) Do not freeze the kit or components.
- 3) Assay buffer (opened & unopened) & the unopened test device are stable until the expiry date printed on the label, when stored at 1 - 40°C.
- 4) Test device is sensitive to humidity and heat if remained opened for longer period hence perform the test immediately after removing the test device from the foil pouch.
- 5) The shelf life of the kit is as indicated on the outer package.

#### Precautions

- 1) Wear protective gloves while handling specimens.
- 2) Dispose of used gloves as biohazardous waste. Wash hands thoroughly afterwards.
- 3) Avoid splashing or aerosol formation.
- 4) Clean up spills thoroughly using an appropriate disinfectant.
- 5) Decontaminate and dispose of all used specimens, test devices, alcohol swabs and specimen transfer device as an infectious waste, in a biohazardous waste container. Dispose of used lancets in a sharp box.

#### Warnings

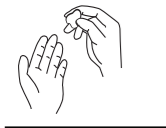

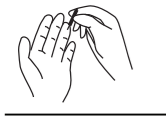


- 1) For *in vitro* diagnostic use only.
- 2) Read the instructions carefully before performing the test, deviation will invalidate the test results.
- 3) Apply standard biosafety precautions for handling and disposal of potentially infective material.
- 4) Assay buffer contains sodium azide as preservative which may be toxic if ingested. When disposed of through sink, flush with large quantity of water.
- 5) Devices and assay buffer of different lot must not be used.
- 6) Do not use the test device if the pouch is not intact.
- 7) Do not use the lancet if the seal is broken.
- 8) Do not use the test device if the dessicant is missing or if found saturated (orange colour has turned green).
- 9) Do not smoke, eat or drink while handling specimens and performing a test.
- 10) Do not re-use the test device, alcohol swab, lancet and specimen transfer device as are intended for single use only.
- 11) Perform the test by using kit assay buffer, any other buffer or fluid will invalidate the test results.
- 12) Do not allow the tip of assay buffer bottle to touch specimen well, it contaminate assay buffer.
- 13) Do not use test device and assay buffer beyond the date of expiry.

14) Do not use any other specimen other than human whole blood.  
Do not mix and interchange different specimens.

Specimen collection and storage

- [Collection by venipuncture]
- 1) Collect the whole blood into the collection tube (containing EDTA/sodium citrate/heparin) by venipuncture.
  - 2) If specimens are not immediately tested (within 1 hour) should be stored at 2-8 °C maximum upto 72 hours (3 days). Using the specimen more than three days can cause non-specific reaction.

Capillary blood specimen collection:

- 
  - Wear gloves, massaging the fingertip gently. It will help to obtain a round drop of blood.
- 
  - Wipe the complete finger tip with the alcohol swab. Wait untill the finger tip dried completely.
- 
  - Detach the protective cap of the lancet and pierce the end of finger tip with the sterile lancet provided.
- 
  - Gently squeeze the area until you get enough blood specimen.
- 
  - After completion of specimen collection, take the used alcohol swab of same patient and press it on the finger to stop the bleeding.
- Note :** The lancet should only be used once. Dispose of used lancets in sharp box and used alcohol swab in biohazardous waste container.

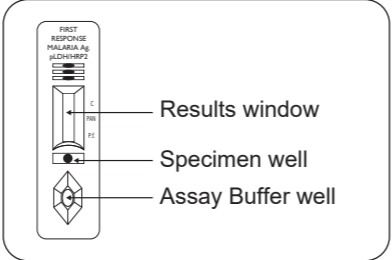
- Do not share used lancets with another person. To prevent possible infection, a used lancet should not be touched by another person.
- Do not use expired lancet. The use of an expired lancet may cause any infection at the punctured skin due to cease to exist its sterility.
- Use new lancet and choose a different puncture site, if repeat the finger prick.
- Do not share used alcohol swab.

Specimen storage

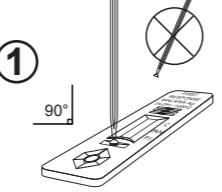
- 1) Whole blood specimen may be used for testing immediately (within 1 hour) or may be stored at 2-8°C for maximum up to 72 hours (3 days). Do not use blood specimen stored for more than 3 days, It can cause non-specific reaction.

Test Procedure

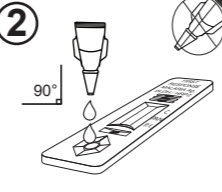
- 1) Bring the First Response® Malaria Ag. pLDH/HRP2 Combo Card Test kit components to room temperature (15 - 40°C) prior to 15 minutes of testing.
- 2) Remove the Test Device and the Specimen transfer Device from the kit and place it on a flat, dry surface and Label the Test Device with specimen identification number/name.
- 3) Slowly add 5 µl of whole blood to the specimen well using the Specimen Transfer Device. Dispose the used Specimen transfer device as biohazard waste immediately after use.
- 4) Add two drops of the Assay buffer to the buffer well.
- 5) Observe for development of colored bands in the Results Window.
- 6) Interpret test results at 20 minutes. (After recording the results, dispose of test device as a biohazardous waste).
- 7) Do not interpret after 30 minutes.




Results window  
Specimen well  
Assay Buffer well



① Do not tilt.  
Add 5 µl of whole blood to the specimen well.



② Do not tilt.  
Add two drops of the Assay buffer to the buffer well.



③ Interpret the test result at 20 minutes after adding assay buffer. Do not read test results after 30 minutes.  
**Results at 20-30 min.**

Caution

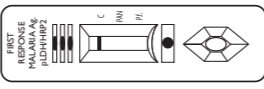
- Hold specimen transfer device and assay buffer vial vertically, else it can lead to inaccurate results.
- Exactly 2 drops of assay buffer should be added. Adding more than or less than 2 drops may cause over flooding or reverse migration phenomenon, which may lead inaccurate results of the test.
- Results can be interpreted any time from 20 to 30 minutes. Do not read test result after 30 minutes. Reading beyond 30 minutes may give inaccurate results. After recording the results, dispose of test device as a biohazard waste.

Internal Quality Control

The visualization of the control line in First Response® Malaria Ag. pLDH/HRP2 Combo Card Test indicates that active ingredient of the strips are functional and the migration is successful. The control line in First Response® Malaria Ag. pLDH/HRP2 Combo Card Test is not meant for specimen addition monitoring.

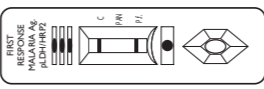
How to Interpret test results

Negative Results



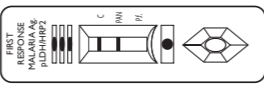
If only one color line appear, at control line 'C' as in the figure, the specimen is negative.

Positive Results



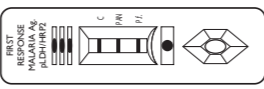
**P.f. Positive**

If two color lines appears, one at control line 'C' and other at test line *P.f.* as in the figure, the specimen is reactive for antigens to *P.f.* Interpret faint line as reactive line.



**PAN Positive**

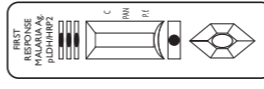
If two color lines appears, one at control line 'C' and other at test line PAN as in the figure, the specimen is reactive for antigens to PAN. Interpret faint line as reactive line.



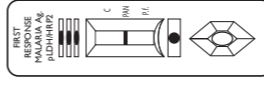
**P.f. & PAN Positive**

If all three color lines appears, one at control line 'C' and other two at test lines *P.f.* and PAN as in the figure, the specimen is reactive for antigens to *P.f.* and PAN. Interpret faint line as reactive line.

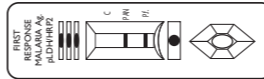
Invalid Results



No presence of control line 'C' in the result window (irrespective of presence of test lines) indicates an invalid result.



The directions may not have been followed correctly or the test may have deteriorated.



The Invalid test results should be retested with new test device.

Performance Characteristics

First Response® Malaria Ag.pLDH/HRP2 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. pLDH/HRP2 Combo Card Test showed 100% sensitivity and 100% specificity. First Response® Malaria Ag. pLDH/HRP2 Combo Card Test showed 100% agreement with the reference method.

Specimen details	Reference Method (Microscopy)		First Response® Malaria Ag. pLDH/HRP2 Combo Card Test		
	Positive	Negative	Positive	Negative	Total
<i>P. falciparum</i> Positive Whole blood specimen	231	0	231	0	231
<i>P. vivax</i> Positive Whole blood specimen	243	0	243	0	243
Malaria Negative Whole blood specimen	0	1287	0	1287	1287
Total	474	1287	474	1287	1761

Reference Method	Specimen details		First Response® Malaria Ag. pLDH/HRP2 Combo Card Test			
Microscopy	Clinical Status	Parameter	Positive	Negative	Total Result	95% Confidence Interval
	<i>P. falciparum</i> Positive	Sensitivity	231	00	231	(97.96%-100%)
	<i>P. Vivax</i> Positive	Sensitivity	243	00	243	(98.06%-100%)
	Malaria Negative	Specificity	00	1287	1287	(99.63%-100%)

Note: The product was not been fully assessed with *P. ovale* & *P. malariae* and the sensitivity is expected to be low (<50%)

Worldwide Performance Panel

The analytical sensitivity of the First Response® Malaria Ag.pLDH/HRP2 Combo Card Test was carried out by testing WHO worldwide performance panel. Total 10 specimens were tested in-house.The First Response® Malaria Ag.pLDH/HRP2 Combo Card Test showed 100% Sensitivity.

Analytical Sensitivity : In-House Evaluation					
Total Specimens		First Response® Malaria Ag.pLDH/HRP2 Combo Card Test			
		Positive		Negative	
05	200 p/µl	05		00	
05	2000 p/µl	05		00	

Cross Reactivity Study

First Response® Malaria Ag.pLDH/HRP2 Combo Card Test was tested with specimen reactive for other diseases/conditions (mentioned in following table), which may interfere with performance of the test.The First Response® Malaria Ag.pLDH/HRP2 Combo Card Test tested with mentioned specimen for cross reactivity study as well as same diseases/condition specimens# were also used for spiking of malaria positive specimens# to determine effect on sensitivity of the test. None of the specimens interfere with the test results of First Response® Malaria Ag.pLDH/HRP2 Combo Card Test, and showed no cross reactivity with 100% sensitivity.

Specimens tested	<i>P. falciparum</i> positive specimens	<i>P. vivax</i> positive specimens	Malaria negative specimens	Specimens tested	<i>P. falciparum</i> positive specimens	<i>P. vivax</i> positive specimens	Malaria negative specimens
Syphilis Positive <sup>#</sup>	06	06	10	HSV 1/2 Positive <sup>#</sup>	05	05	05
HIV Positive <sup>#</sup>	03	03	05	HTLV- I Ab Positive <sup>#</sup>	07	07	07
Dengue NS1 Positive <sup>#</sup>	05	05	05	HTLV- II Ab Positive <sup>#</sup>	09	09	09
Multipara (Pregnant Woman)	08	04	72	HSV - I IgG Positive <sup>#</sup>	08	08	08
CMV Positive <sup>#</sup>	03	03	03	Rubella IgG & IgM Positive <sup>#</sup>	15	15	15
ANA Positive <sup>#</sup>	04	04	04	HBsAg Positive <sup>#</sup>	03	03	05
HAV Positive <sup>#</sup>	04	04	04	Chikungunya Positive <sup>#</sup>	05	05	05
EBV Positive <sup>#</sup>	02	02	02	Anti-malarial drug medication	02	02	Not tested
HCV Positive <sup>#</sup>	03	03	05	Anti-TB drug medication <sup>#</sup>	03	03	03
Yellow fever virus <sup>#</sup> post immunization	03	03	04	Influenza A and B <sup>#</sup>	03	03	06
Measles <sup>#</sup>	03	03	04	Visceral leishmaniasis <sup>#</sup>	03	03	05
Leptospirosis <sup>#</sup>	03	03	05	Bilirubin <sup>#</sup>	03	03	05
Cholesterol <sup>#</sup> Triglycerides	03	03	05	Chagas	03	03	05
Influenza vaccine <sup>#</sup> recipient	03	03	05	Sickle cell	03	03	05
Leishmaniasis <sup>#</sup>	03	03	05	Acute hepatitis A infection <sup>#</sup>	03	03	05
Schistosomiasis <sup>#</sup>	03	03	05	Toxoplasmosis <sup>#</sup>	03	03	05

Potential interference substances

The interfering substances that may affect performance of the First Response® Malaria Ag.pLDH/HRP2 Combo Card Test are mentioned in following table. The First Response® Malaria Ag.pLDH/HRP2 Combo Card Test showed no reactivity with any of mentioned specimens and showed 100% specificity. The same specimens<sup>#</sup> were spiked in malaria positive specimens respectively and tested.First Response® Malaria Ag.pLDH/HRP2 Combo Card Test showed 100% sensitivity with spiked specimens.

Specimens tested	<i>P. falciparum</i> positive specimens	<i>P. vivax</i> positive specimens	Malaria negative specimens	Specimens tested	<i>P. falciparum</i> positive specimens	<i>P. vivax</i> positive specimens	Malaria negative specimens
Lipemic specimen <sup>#</sup>	05	05	05	Low Hematocrit specimens	Not tested	Not tested	05
Icteric specimens <sup>#</sup>	05	05	05	Whole blood specimen in ACD anticoagulant	03	03	182
Hemolytic specimens	01	01	05	RF Ab Positive <sup>#</sup>	04	04	09
High Hematocrit specimens	Not tested	Not tested	05	dsDNA Antibody Positive <sup>#</sup>	01	01	01
Recipient of multiple blood transfusion	03	03	05				

Precision

- a) Within run, precision was determined by using 225 replicates of 9 different specimens containing different malaria parasitic count. Within run, precision was observed 100%.
- b) Between run, precision was determined by using the 9 different specimens containing different malaria parasitic count in 5 different replicates with 3 different lots of test devices X 5 different days X 3 different sites tested. Between run, precision was observed 100%.

External Evaluation Report							
Place of Evaluation	Year	Sensitivity				Specificity	
		PAN		P.f.		PAN	P.f.
		200 p/μl	2000 p/μl	200 p/μl	2000 p/μl		
WHO Evaluation Round 6	2014 - 2015	91.4%	100%	82%	100%	100%	100%
Ministry of Health & Children Care Zimbabwe	2014	92.5%		95.5%		98.78%	98.38%
National Public Health & Reference Lab, Ghana	2015	96%		100%		100%	100%

#### Potential interference drug substances

The details of interference drug molecules are mentioned in the following table. Each interfering drug molecule substance was spiked at the final concentration of 250μg/ml in malaria positive specimens as well as negative specimens, respectively. No false positive or false negative results were observed with any drug molecules, when tested with First Response® Malaria Ag. pLDH/HRP2 Combo Card Test.

Diclofenac	Acetaminophen	Aspirin
Folic acid	Pyrazinamide	Ampicillin Sodium salt
Abacavir	Cholecalciferol	Nevirapine
Magnesium sulphate	Ritonavir	Ibuprofen
Daruvir	Rifampicin	Ascorbic Acid
Naproxen IP	Metformin	Hydrochlorothiazide
Pantoprazole	Isoniazid	Ferrous Ascorbate
Ergocalciferol	Iron Chloride	Penicillin G Benzathine
Cyclobenzaprine Hydrochloride		

#### Limitation

- 1) The test procedure, precautions and interpretation of results for this test must be followed when testing.
- 2) The following anticoagulants have been validated for use with this test: heparin, EDTA & sodium citrate.
- 3) Interfering specimens like hemolytic (hemoglobin containing) samples, icteric (bilirubin containing) samples and lipaemic samples do not affect the test results.
- 4) Do not mix reagent from different lots.
- 5) Interpret faint line as a reactive line. Repeat the test in case of very faint test line or if have any doubt for test line.
- 6) Although the test is very accurate in detecting HRP2 and /or pLDH, a low incidence of false results can occur. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- 7) False negative results may arise due to very low parasite density (for instance <100 p/μl), very high parasite density (prozone/hook effect), mutations in the HRP2 gene with deletion of HRP2 antigen, damage by heat, freezing or humidity, application of insufficient volume of blood on the device and use of wrong buffer.
- 8) False positive results can occur due to various conditions such as rheumatoid factors, antinuclear antibodies, chronic viral infection (hepatitis B or C), parasitic infection (schistosomiasis and trypanosomiasis) and use of wrong buffer.

#### References

- 1) Clinical and Laboratory Standards Institute. Procedures and devices for the collection of diagnostic capillary blood specimens; approved standard, fifth edition. CLSI H04-A6, Vol. 28, No. 25, 2008.
- 2) <http://vassarstats.net/clin1.html#def> , Richard Lowry.
- 3) Clinical and Laboratory Standards Institute. Procedures for the collection of diagnostic blood specimens by venipuncture; approved standard, sixth edition. CLSI H03-A6, Vol. 27, No. 26, 2007

- 4) World Health Organization: Laboratory biosafety manual, third edition. Geneva: WHO; 2004. <http://www.who.int/csr/resources/publications/biosafety/Bio-safety7.pdf>
- 5) WHO (2024). World malaria report, World Health Organization, Geneva, Switzerland. <https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2024>
- 6) Malaria rapid diagnostic test performance: results of WHO product testing of malaria RDTs: round 8 (2016-2018).
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- 8) Gillet P, Mori M, Van Den Ende J, Jacobs J: Buffer substitution in malaria rapid diagnostic tests causes false positive results. Malar J 2010, 9:215 <http://www.malariajournal.com/con-tent/9/1/215>
- 9) Maltha J, Gillet P, Cnops L, Van Den Ende J, Van Esbroeck M, Jacobs J: Malaria rapid diagnostic tests: Plasmodium falciparum infections with high parasite densities may generate false positive Plasmodium vivax pLDH lines. Malar J 2010, 9:198. <http://www.malariajournal.com/content/9/1/198>
- 10) Gamboa D, Ho M, Bendezu J, Torres K, Chiodini P, Barnwell J, Incardona S, Perkins M, Bell D, McCarthy J, Cheng Q: A large proportion of P. falciparum isolates in the Amazon region of Peru lack pfhrp2 and pfhrp3: implications for malaria rapid diagnostic tests. PLoS One 2010, 5:e8091. <http://www.plosone.org/article/i fo%3Adoi%2F10.1371%2Fjournal.pone.0008091>


SYMBOL LEGENDS			
Symbol	Explanation of symbol	Symbol	Explanation of symbol
	Consult instructions for use		Contains sufficient for < n > tests
	Non Sterile		Product Code
	In vitro diagnostic medical device		Lot Number
	Store at 1-40 °C		Manufacturer
	Caution		Date of manufacture (YYYY-MM)
	Keep dry		Expiration Date (YYYY-MM)
	Do not reuse		Do not use if package is damaged
	Keep away from sunlight		

#### Product Disclaimer and Warnings

Every warning and precaution should be taken in to consideration before using the test. Failure to consider “Precaution, warning and Limitations” may not ensure the diagnostic ability and accuracy of this product. The test result may accordingly be affected by environmental factor and / or user error outside of the control of the Manufacturer and Distributor.

A definitive clinical diagnosis should not be based on the results of a single test, but it should be made by physician after all clinical and laboratory findings have been evaluated.

“In no event shall our comapny or its distributor be liable for any direct, indirect, punitive, unforeseen, incidental, special consequential damages, to property or life, whatsoever arising out of or connected with an incorrect diagnosis, whether positive or negative, in the use or misuse of this product”.

 Manufactured by

**Premier Medical Corporation Private Limited**  
A1-302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA.  
Customer support E-mail : [info@premiermedcorp.com](mailto:info@premiermedcorp.com)  
Tel.: +91 2602780112/113 •Website : [www.premiermedcorp.com](http://www.premiermedcorp.com)  
• ISO 13485 & EN ISO 13485 Certified Company

Part No.(S)PI16-INS-003, Rev.: AD, Date:2025-09-21 ENGLISH  
Note : Instructions for use will be printed in local language of the country using the test, if required.



## FIRST RESPONSE® MALARIA Ag. pLDH/HRP2 COMBO CARD TEST

A rapid test for the detection of Malaria pLDH and HRP2 in human whole blood.

**[REF] PI16FRC10s & PI16FRC25s**

#### Intended Use

First Response® Malaria Ag. pLDH/HRP2 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 P. falciparum, P. vivax, P. ovale and P. malariae. The test is intended for use with whole blood specimens (capillary or venous blood). Venous blood with the anti-coagulants heparin, EDTA or citrate do not affect the test results. This kit is not intended to be used for screening of blood donors. The test is not automated and does not require any additional instrument.

#### Introduction

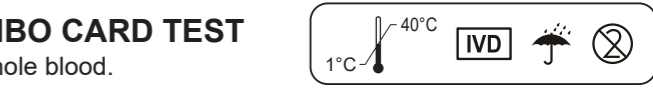
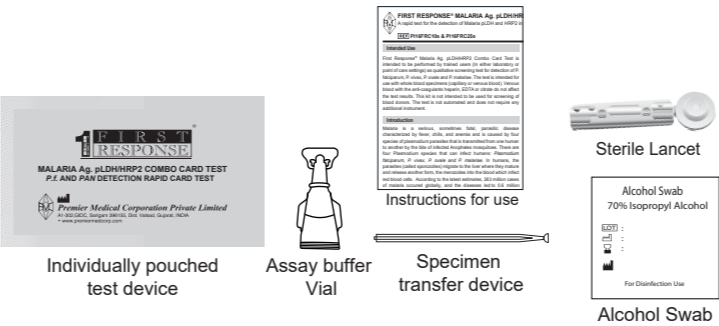
Malaria is a serious, sometimes fatal, parasitic disease characterized by fever, chills, and anemia and is caused by four species of plasmodium parasites that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four Plasmodium species that can infect humans: *Plasmodium falciparum*, *P. vivax*, *P. ovale* and *P. malariae*. In humans, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites into the blood which infect red blood cells. According to the latest estimates, 263 million cases of malaria ocurred globally, and the diseases led to 0.6 million deaths (WHO 2024). At present, malaria is diagnosed by looking for parasites in a drop of blood.

#### Assay Principle

First Response® Malaria Ag. pLDH/HRP2 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 PAN) is PAN specific to Lactate dehydrogenase (pLDH) of the *Plasmodium species (Plasmodium falciparum, P. vivax, P. ovale and P. malariae.)* and the other line (test line P.f.) consists of a monoclonal antibody specific to Histidine Rich Protein 2 (HRP2) of the *Plasmodium falciparum*. When the test sample along with assay Buffer flows through the nitrocellulose membrane, monoclonal antibodies conjugated with colloidal gold, which are PAN specific to 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 colour line / lines indicating reactive results. The control line will appear irrespective of reactive or non reactive sample.

So, the First Response® Malaria Ag. pLDH/HRP2 Combo Card Test is “of additional value” in the differential diagnosis of *Plasmodium falciparum* and other Plasmodium species.

#### Materials Provided



Materials Provided	PI16FRC10s	PI16FRC25s
Each single test pack contents: (Test device with desiccant, specimen transfer device) alcohol swab,sterile lancet, buffer vial & condensed instructions for use)	10 Nos.	25 Nos.
Master instructions for use	1 No.	1 No.

#### Materials Required but Not Provided

- New pair of disposable gloves.
- Permanent marker pen and timer .
- Extra lancets and alcohol swabs, if needed.
- Sharp disposable box and biohazardous waste container.
- Venipuncture blood collection kit (if whole blood is collected by venipuncture).

#### Storage and Stability

- 1) First Response® Malaria Ag. pLDH/HRP2 Combo Card Test should be stored at 1 - 40°C.
- 2) Do not freeze the kit or components.
- 3) Unopened test device & single use buffer vial are stable until the expiry date printed on the label, when stored at 1 - 40°C.
- 4) The device is sensitive to humidity and heat if remained opened for longer period hence perform the test immediately after removing the test device from the foil pouch.
- 5) The shelf life of the kit is as indicated on the outer package.

#### Precautions

- 1) Wear protective gloves while handling specimens.
- 2) Dispose of used gloves as biohazardous waste. Wash hands thoroughly afterwards.
- 3) Avoid splashing or aerosol formation.
- 4) Clean up spills thoroughly using an appropriate disinfectant.
- 5) Decontaminate and dispose of all used specimens, test devices, alcohol swabs and specimen transfer device as an infectious waste, in a biohazardous waste container. Dispose of used lancets in a sharp box.

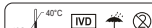
#### Warnings

- 1) For in vitro diagnostic use only.
- 2) Read the instructions carefully before performing the test, deviation will invalidate the test results.
- 3) Apply standard biosafety precautions for handling and disposal of potentially infective material.
- 4) Assay buffer contains sodium azide as preservative which may be toxic if ingested. When disposed of through sink, flush with large quantity of water.
- 5) Devices and assay buffer of different lot must not be used.
- 6) Do not use the test device if the pouch is not intact.
- 7) Do not use the lancet if the seal is broken.
- 8) Do not use the test device if the desiccant is missing or if found saturated (orange colour has turned green).
- 9) Do not smoke, eat or drink while handling specimens and performing a test.
- 10) Do not re-use the test device, alcohol swab, lancet and specimen transfer device as are intended for single use only.
- 11) Perform the test by using kit assay buffer, any other buffer or fluid will invalidate the test results.
- 12) Do not use test device and assay buffer beyond the date of expiry.
- 13) Do not eat the desiccant.



## First Response® Malaria Ag. pLDH / HRP2 Combo Card Test

Rapid One Step Malaria Ag.pLDH and HRP2 detection in human whole blood



[REF] P116FRC10s & P116FRC25s

### Intended Use :

First Response® Malaria Ag. pLDH/HRP2 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 *P. falciparum*, *P. vivax*, *P. ovale* and *P. malariae*. The test is intended to be used with whole blood specimens (capillary or venous blood). Venous blood with the anti-coagulants heparin, EDTA or Citrate do not affect the test results. This kit is not intended to be used for screening of blood donors. The test is not automated and does not require any additional instrument.

### Materials provided :

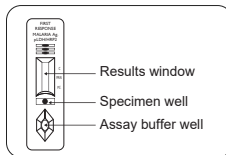
Test device with desiccant, specimen transfer device, assay buffer vial, sterile lancet, alcohol swab, instruction for use

### Storage & stability :

- 1) First Response® Malaria Ag. pLDH/HRP2 Combo Card Test should be stored at 1°C - 40°C.
- 2) Test device is sensitive to humidity and heat if remained opened for longer period hence perform the test immediately after removing the test device from the foil pouch.
- 3) The shelf life of the kit is as indicated on the outer package.

### Precautions & warnings:

- 1) Wear protective gloves while handling specimens.
- 2) Apply standard biosafety precautions for handling and disposal of potentially infective material.
- 3) Assay buffer contains sodium azide as preservative which may be toxic if ingested. When disposed of through sink, flush with large quantity of water.
- 4) Do not use the test device if the pouch is not intact.
- 5) Do not use the lancet if the seal is broken.
- 6) Do not use the test device if the desiccant is missing or if found saturated (orange colour has turned green).
- 7) Do not re-use the test device, alcohol swab, lancet and specimen transfer device as are intended for single use only.
- 8) Perform the test by using kit assay buffer, any other buffer or fluid will invalidate the test results.
- 9) Do not eat the desiccant.
- 10) Do not use any other specimen other than human whole blood & do not mix and interchange different specimens.



### Test Procedure :

- 1) Bring the First Response® Malaria Ag. pLDH/HRP2 Combo Card Test kit components to room temperature (15 - 40°C) prior to 15 minutes of testing.
- 2) Remove the test Device and the specimen transfer device from the kit and place it on a flat, dry surface and label the test device with specimen identification number/name.
- 3) Slowly add 5 µl of whole blood to the specimen well using the specimen transfer device. Dispose the used Specimen transfer device as biohazardous waste immediately after use.
- 4) Add two drops of the assay buffer to the assay buffer well.
- 5) Observe for development of colored bands in the Results Window.
- 6) Interpret test results at 20 minutes. (After recording the results, dispose of test device as a biohazardous waste).
- 7) Do not interpret after 30 minutes.

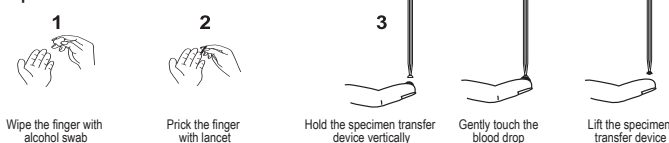
### Assay buffer vial opening process



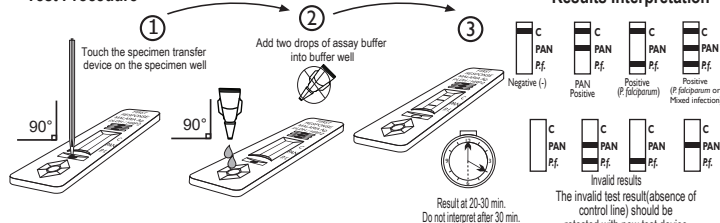
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## Specimen Collection , Test Procedure & Result Interpretation

### Specimen Collection



### Test Procedure



Manufactured by

**Premier Medical Corporation Private Limited**

A1-302, GIDC, Sarigam 396155, Dist. Valsad, Gujarat, INDIA. Customer support E-mail : [info@premiermedcorp.com](mailto:info@premiermedcorp.com)

Tel.: +91 2602780112/113 • Website : [www.premiermedcorp.com](http://www.premiermedcorp.com)

Part No.: (S)P116-INS-002, Rev.: AD, Date: 2025-09-21

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