WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag
WHO reference number: PQDx 0294-074-00

One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag with product codes **MFLRPD-05, MFLRPD-02**, **MFLRPD-03, MFLRPD-04, MFLRPD-06, MFLRPD-07, and MFLRPD-08** manufactured by **Meril Diagnostics Pvt. Ltd.**, **CE-mark regulatory version**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 09 November 2018.

Summary of WHO Prequalification Assessment for MERISCREEN Malaria Pf/Pv Ag

	Date	Outcome
Prequalification listing	9 November 2018	listed
Dossier assessment	13 September 2018	MR
Site inspection(s) of quality management system	19-21 June 2023	MR
Product performance evaluation	2016	MR

MR: Meets Requirements

Report amendments and 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 summarised in the following table, and details of each amendment are provided below.

Version	Summary of amendment	Date of report amendment
2.0	1. Fulfilling prequalification commitments and adding labels for sterile lancets and alcohol swabs. Addition of new pack sizes of 25 tests and 50 tests to the existing pack size of 30 tests. Product codes for these two new pack sizes are MFLRPD-03 (25T) and MFLRPD-04 (50T). 2. Change in regulatory version, i.e., RoW (Rest-of-World) version to CE mark version of product codes MFLRPD-02, MFLRPD-03, MFLRPD-04).	30 March 2020

3.0	1. Addition of pack size (10T) with product code MFLRPD-05 to serve the requirement of various tenders across the globe. 2. Change in Labels and Pack insert of MERISCREEN Malaria Pf/Pv Ag kit, i.e., incorporation of information of CE mark of lancets and alcohol swabs is made due to request from European Representative of Meril Diagnostics, i.e., Obelis S.A. Belgium.	24 May 2021
4.0	Changed the Manufacturer's telephone and fax numbers in the MERISCREEN Malaria Pf/Pv Ag labelling.	15 November 2021
5.0	Changed the specimen transfer device from the Sample loop to the Inverted cup.	24 July 2024.
6.0	Addition of new Point of Care Testing (POCT) pack sizes with product codes, MFLRPD-06 (1T/Kit), MFLRPD-07 (1T/Kit x 10 each) and MFLRPD-08 (1T/Kit x 25 each)	21 July 2025

Intended use:

According to the intended use claimed by the manufacturer, "*One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is an in vitro diagnostic immunochromatographic assay for the qualitative detection of infections with Plasmodium falciparum and P. vivax parasites causing malaria in human whole blood specimens. It does not assess parasite densities. It assists trained users (in either laboratory or point-of-care settings):*

- *in detecting Plasmodium falciparum and P. vivax infections*
- *to differentiate infection between Plasmodium falciparum histidine-rich protein II (Pf-HRP-II) and Plasmodium vivax Plasmodium lactate dehydrogenase (Pv-pLDH)*

The assay is intended for trained users and an initial screening as well as an aid to the diagnosis of malaria infection.
Note: Malaria RDTs can give positive results after successful anti-malarial treatment. Therefore, the One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is not recommended for monitoring response to anti-malarial treatment.
The assay is to be used in the diagnosis of malaria in symptomatic patients as well as asymptomatic patients i.e., pregnant women and children. Testing is not intended for blood donors".

Assay Description:

According to the manufacturer's claim, "*One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test utilizes the principle of immunochromatography in which nitrocellulose membrane is pre-coated with one monoclonal antibody (test line Pf) specific to Histidine-Rich Protein II (Pf-HRP-II) of the Plasmodium falciparum and one monoclonal antibody (test line Pv) specific to lactate dehydrogenase of Plasmodium vivax (Pv-pLDH). Thus, the following Plasmodium antigens are detected in this test:*

- *Histidine Rich Protein II specific for P. falciparum (Pf-HRP-II)*

- *Plasmodium lactate dehydrogenase to Plasmodium vivax (Pv-pLDH)*

The cassette contains a test strip pre-coated with capture antibodies.
The sequence of events is as follows:

1. *Whole blood is applied to the specimen well (labelled well "S").*
2. *Next, buffer is applied to the buffer well (labelled well "B").*
3. *Migration of the blood/buffer mixture starts towards the opposite end of the cassette.*
4. *The blood-buffer mixture passes the conjugate pad, which contains detection antibodies targeting Pf-HRP-II and Pv-pLDH. These detection antibodies are conjugated to colloidal gold. If present in the specimen, Plasmodium target antigens bind to this detection antibody-conjugate.*
5. *The antigen-antibody-conjugate complex migrates further and binds to the capture Plasmodium specific antibodies present on the test line. These capture antibodies bind to another site (epitope) of the Plasmodium target antigens.*
6. *The capture antibodies are applied on a narrow section of the test strip: as a result, the antibody conjugate with the colloidal gold will be concentrated and become visible as a pinkish-purple colored line.*
7. *The excess of the detection antibody-conjugate that was not bound by the Plasmodium target antigens and the capture antibodies moves further to absorbent pad.*
8. *At control zone Goat anti-chicken IgY (as blue coloured line) is immobilised and it binds to IgY colloidal gold conjugate to give a pinkish-purple colored control line. The visualization of the control line indicates* that the migration was successful. It does not confirm the presence of specimen".

Test kit contents

Component	**30 T/k (MFLRPD-02)**	**25 T/k (MFLRPD-03)**	**50 T/k (MFLRPD-04)**	**10 T/k (MFLRPD-05)**	**1 T/k (POCT) (MFLRPD-06)**	**10 T/k (POCT) (MFLRPD-07)**	**25 T/k (POCT) (MFLRPD-08)**
Cassette packaging, each containing 1 device and 1 desiccant	30	25	50	10	1	10	25
Assay buffer bottles (protein stabilizer, detergent, and	2 × 3.0 mL	2 × 3.0 mL	4 x 3.0mL	1 x 3.0mL	\	\	\

preservatives)							
Assay buffer ampoules	\	\	\	\	1	10	25
Pouches each containing one assay Buffer one specimen transfer device (5µL), one alcohol swab and one lancet	\	\	\	\	1	10	25
Specimen transfer device (inverted cups)-5µL.	30	25	50	10	\	\	\
Lancet	30	25	50	10	\	\	\
Alcohol swab	30	25	50	10	\	\	\
Instructions for Use (IFU)	1	1	1	1	1	1	1
Summarised IFU	\	\	\	\	\	10	25

Items required but not provided

- Disposable gloves
- Pen
- Timer
- Sharp box
- Non-sharp disposal container
- Venipuncture blood collection materials and precision pipette plus tips (if whole blood is collected by venipuncture)

Storage:

The test kit should be stored at 1-40 °C.

Shelf-life upon manufacture:

24 months.

Warnings/limitations:

Refer to the current version of the manufacturer's instructions for use.

Prioritisation for prequalification:

Based on the results of the WHO product testing of malaria RDTs for Round 7, MERISCREEN Malaria Pf /Pv Ag was given priority for WHO prequalification assessment.

Dossier assessment

Meril Diagnostics Pvt. Ltd. submitted a product dossier for One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag 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 13 September 2018.

Based on the product dossier screening and assessment findings, the product dossier for the One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag meets WHO prequalification requirements.

Manufacturing site inspection

A desk assessment of Meril Diagnostics Pvt. Ltd located on the second floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India, was conducted between 19-21 June 2023. At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of the product of consistent quality. Routine inspections of the Manufacturer will be conducted with copies of these WHO Public Inspection Reports (WHOPIRs) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. To note that a WHOPIR reflects the information on the most current inspection performed at a manufacturing site for in vitro diagnostic products and gives a summary of the inspection findings.

Information on the most current inspection can be found at:

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

All published WHOPIRs are with the agreement of the manufacturer.

Product performance evaluation

The seventh round of WHO product testing of RDTs for malaria antigen detection was completed in 2016. 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 (78.0% at 200 parasites/µl), *P. vivax* panel detection score (85.7% at 200 parasites/µl), false-positive rates (0.0% for clean negatives, 0.5% for *P. falciparum* at 200 parasites/µl, 0.7% for *P. vivax* at 200 parasites/µl, 0.0% for *P. falciparum* at 2000 to 5000 parasites/µl, x1.4% for *P. vivax* at 2000 to 5000 parasites/µl) and invalid rate (0.0%), One Step test for Malaria *Pf/Pv* Ag MERISCREEN Malaria *Pf/Pv* Ag 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*		
One Step test for Malaria *Pf/Pv* Ag MERISCREEN Malaria Pf/Pv Ag	78	85.7	0.5	0.7	0.0	0.0

Labelling

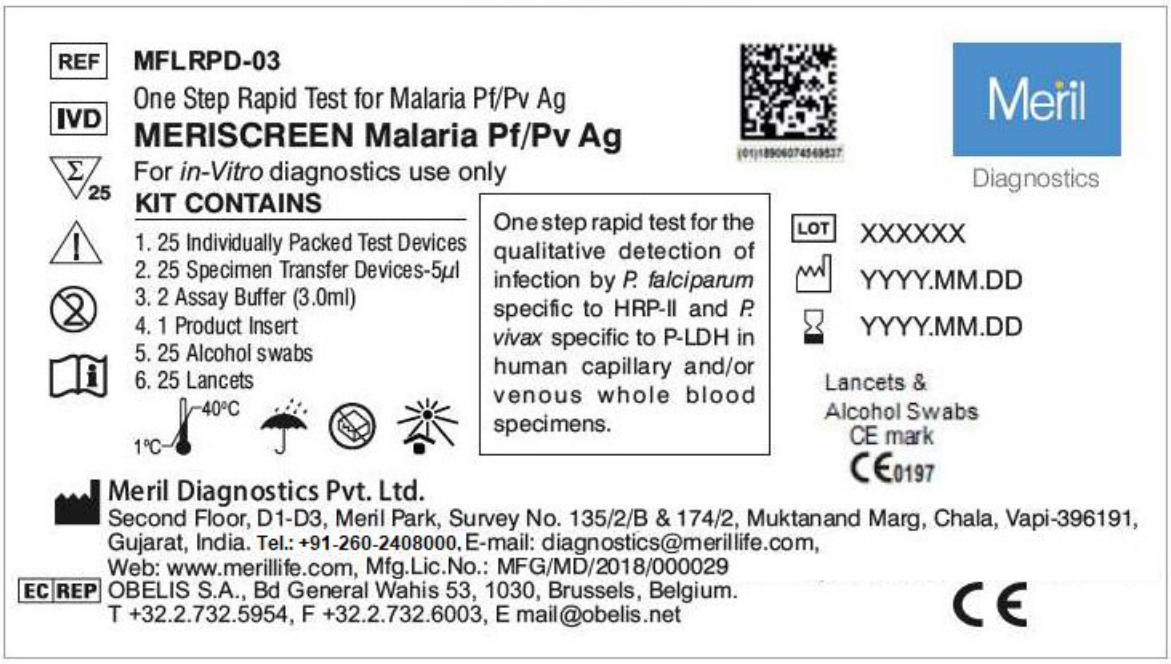
1. **Labels**
2. **Instructions for use**

1. Labels

1.1 MERISCREEN Malaria Pf/Pv Ag (MFLRPD-03)- 25 tests configuration

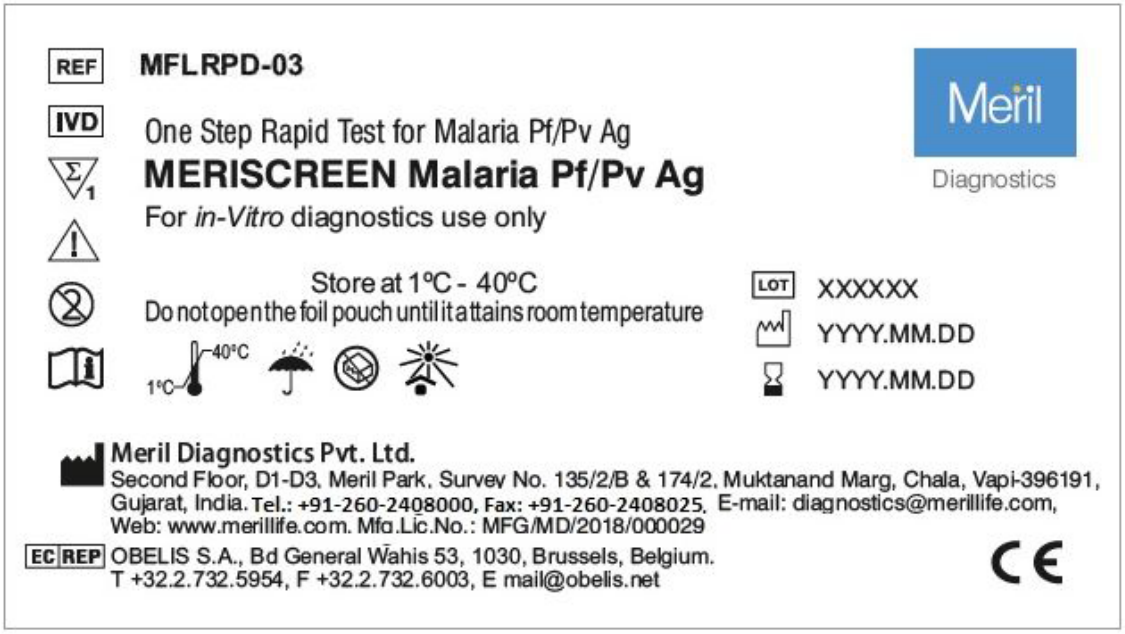
1.1.1 Kit label

Product Box Label



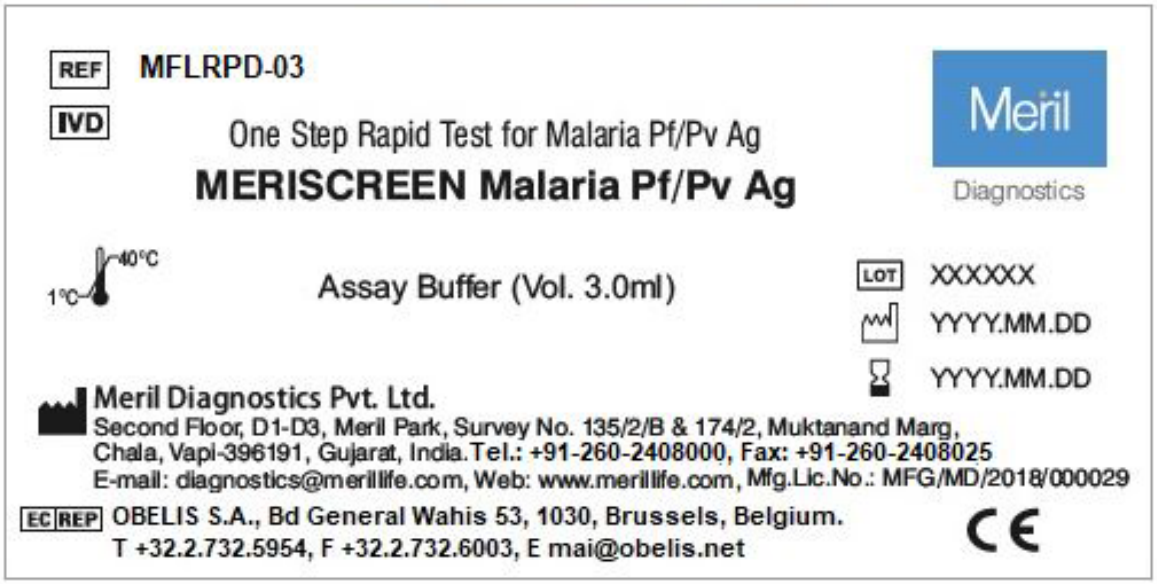
1.1.2 Aluminum pouch label

Aluminum Pouch Label



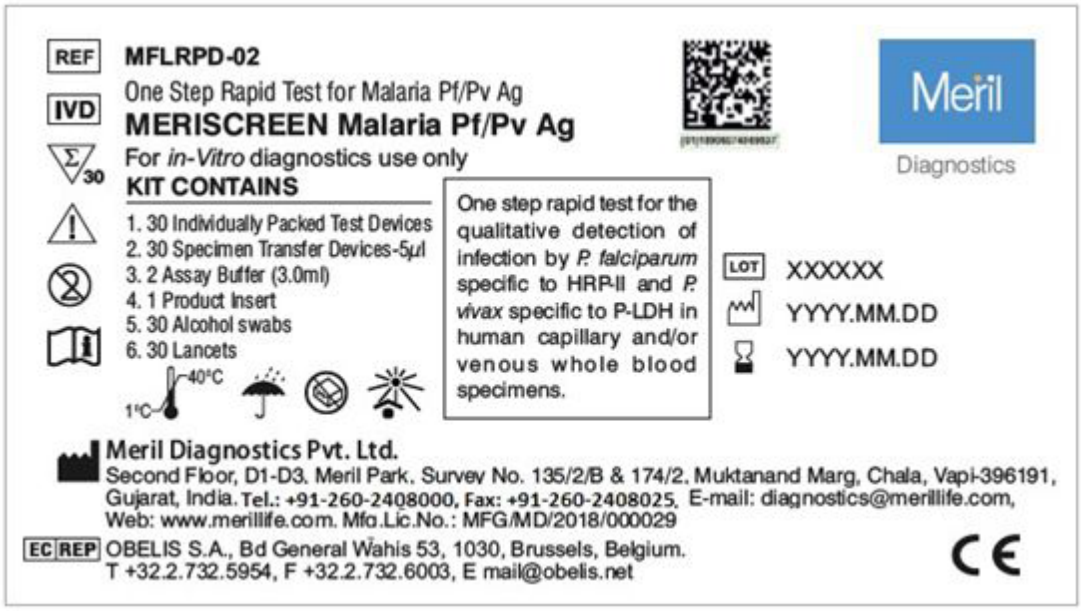
1.1.3 Assay buffer bottle label

Assay Buffer Bottle Label

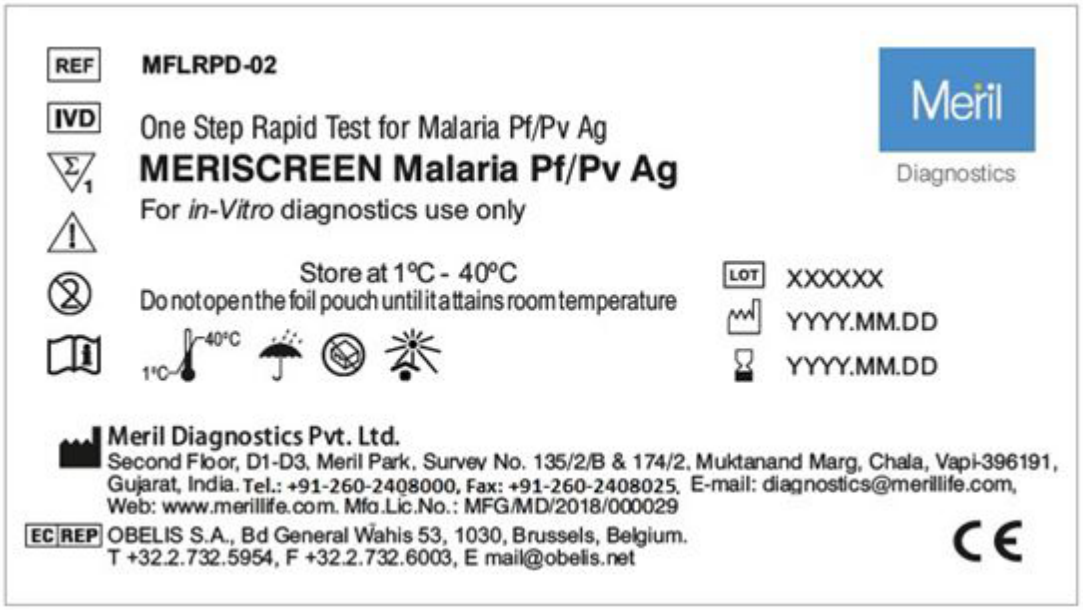


1.2 MERISCREEN Malaria Pf/Pv Ag (MFLRPD-02)-30 tests configuration

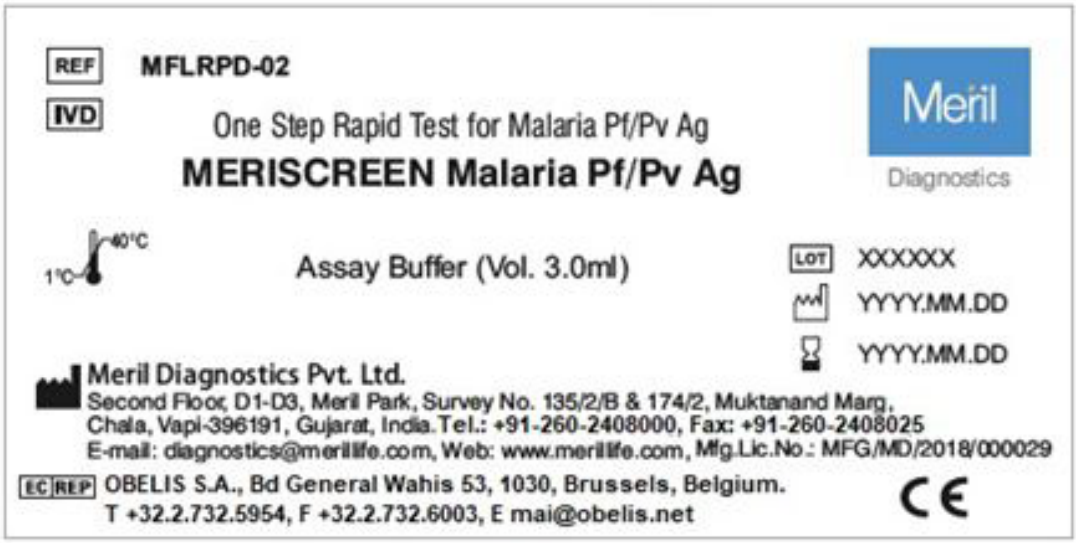
1.2.1 Kit label



1.2.2 Aluminum pouch label

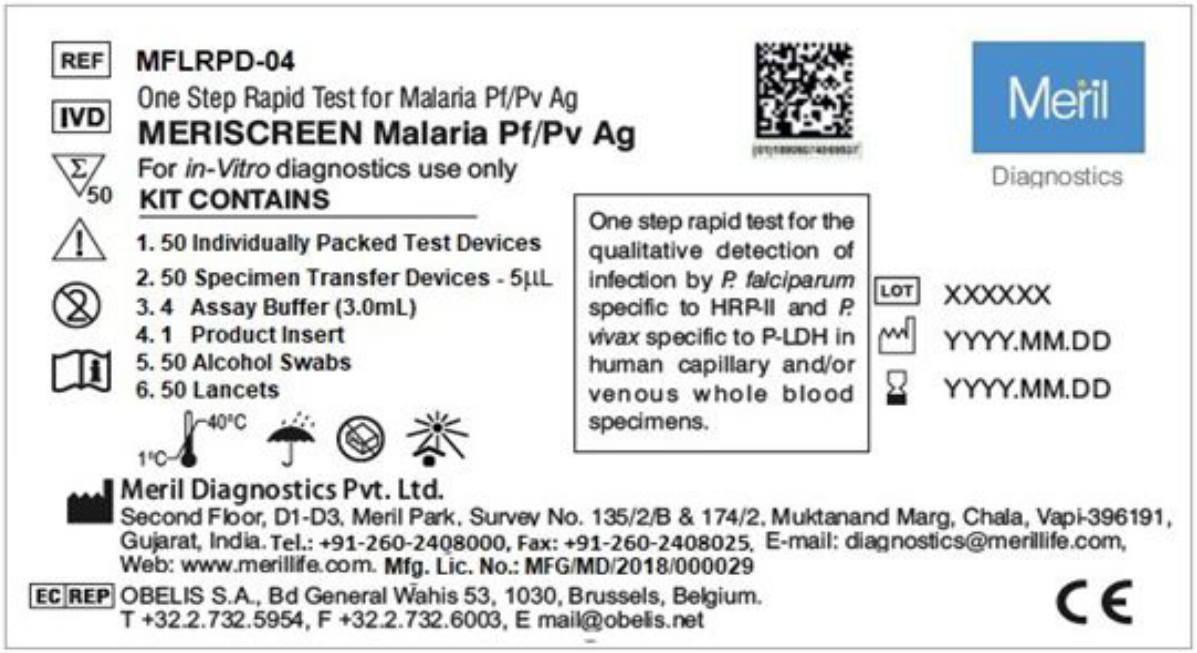


1.2.3 Assay buffer bottle label

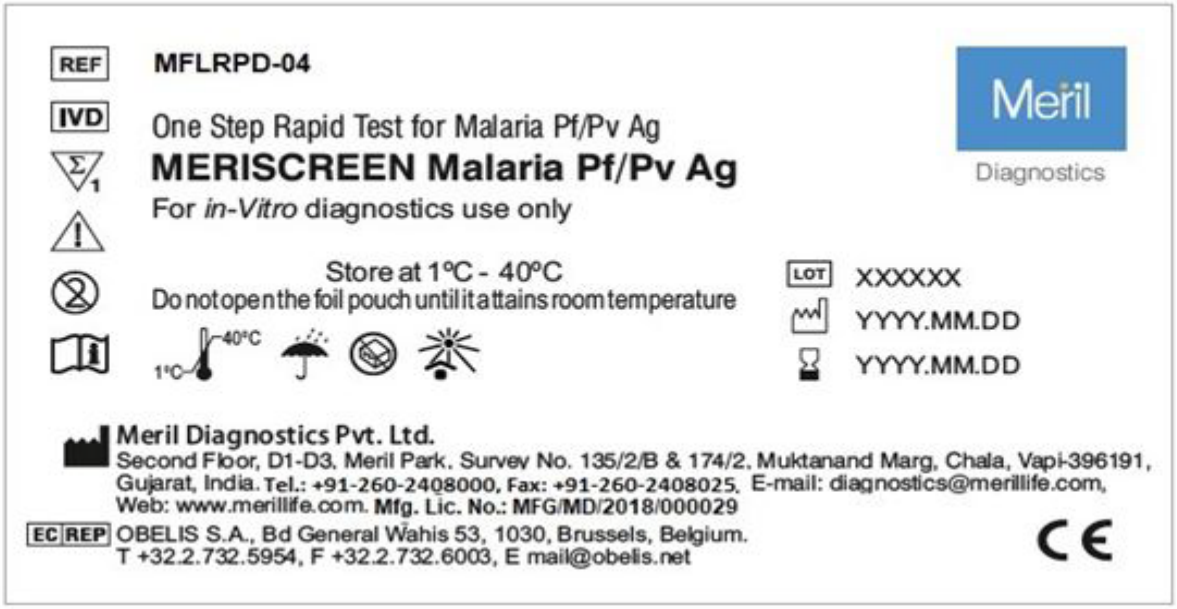


1.3 MERISCREEN Malaria Pf/Pv Ag (MFLRPD-04)-50 tests configuration

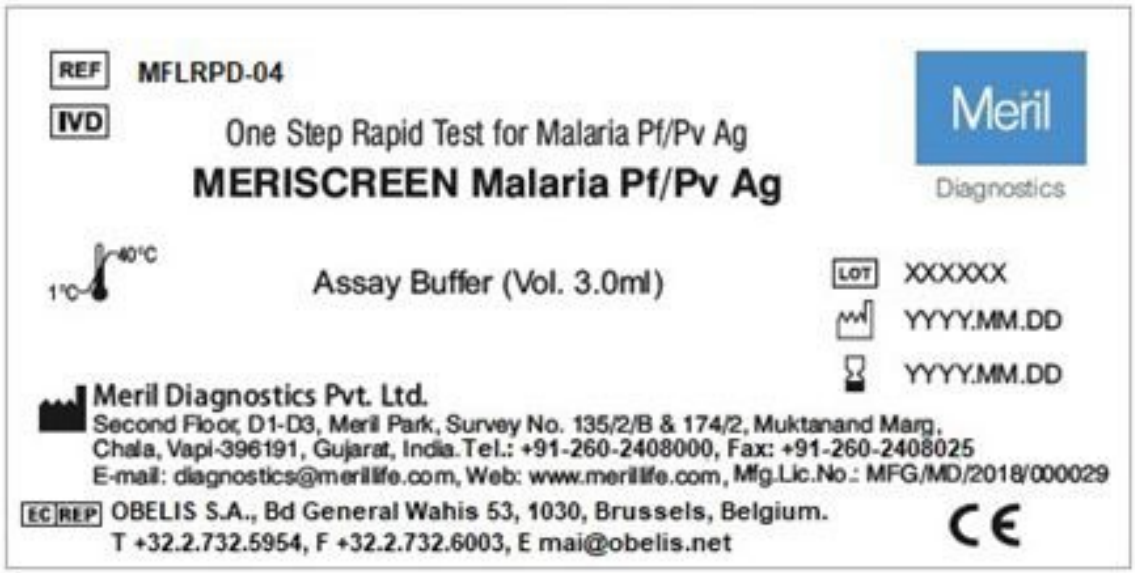
1.3.1 Kit label



1.3.2 Aluminum pouch label



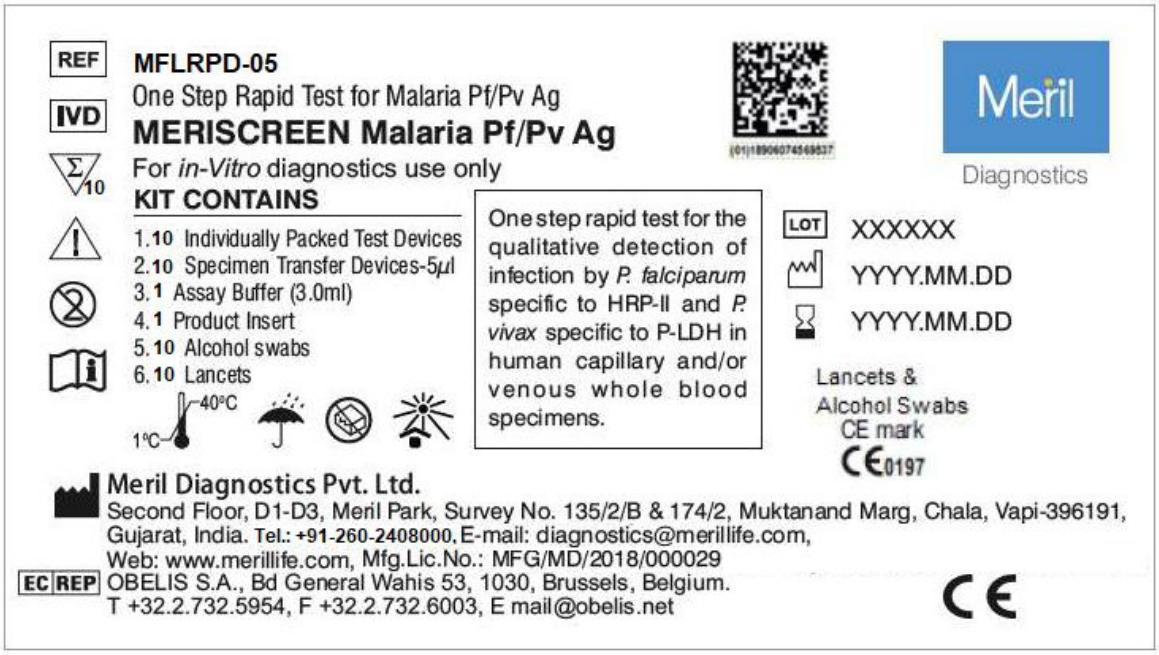
1.3.3 Assay buffer bottle label



1.4 MERISCREEN Malaria Pf/Pv Ag (MFLRPD-05)-10 tests configuration

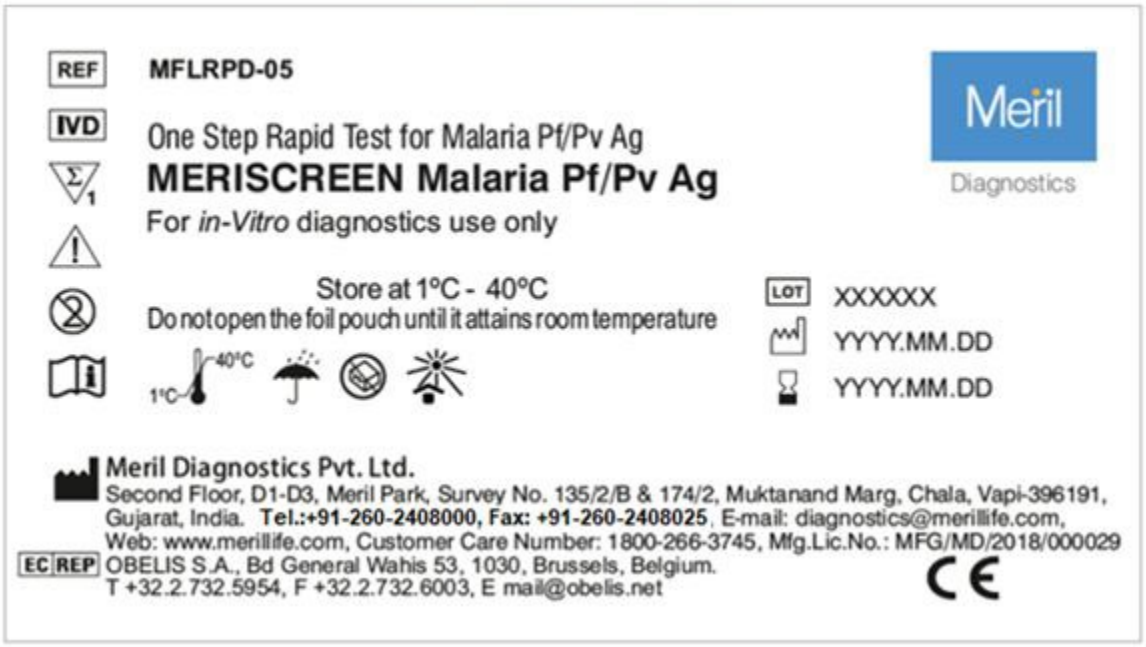
1.4.1 Kit label

Product Box Label

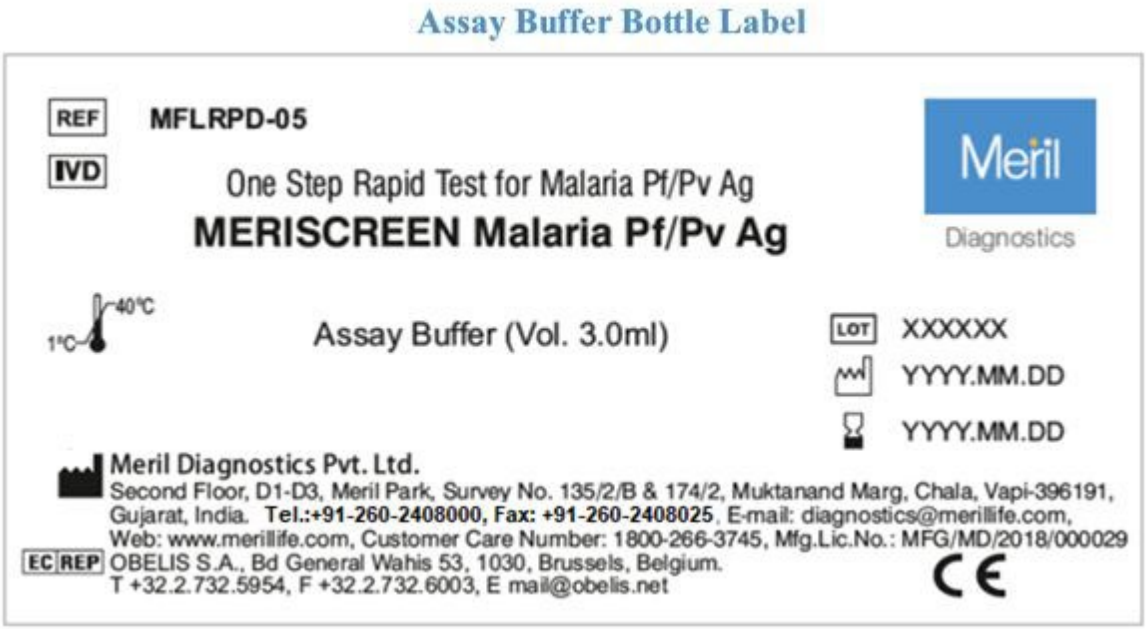


1.4.2 Aluminum pouch label

Aluminum Pouch Label



1.4.2 Assay buffer bottle label



1.5 MERISCREEN Malaria Pf/Pv Ag (MFLRPD-06)-1 T/k POCT configuration

Outer Pouch Label

One Step Rapid Test for Malaria Pf/Pv Ag

MERISCREEN Malaria Pf/Pv Ag

Meril
Diagnostics

CONTENTS:

Test Device, Assay Buffer, Specimen transfer device (5µL), Alcohol Swab, Lancet, Instructions for use

Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg,
Chala, Vapi-396191, Gujarat, India. Tel.:+91-260-2408000, Fax:+91-260-2408025,
E-mail: diagnostics@merillife.com, Web: www.merillife.com, Mfg.Lic.No.: MFG/MD/2018/000029

REF : XXXXXX-XX

LOT : XXXXXX

Mfg : YYYY.MM.DD

Exp : YYYY.MM.DD

Device Label

One Step Rapid Test for Malaria Pf/Pv Ag

MERISCREEN Malaria Pf/Pv Ag

For *in-vitro* diagnostics use only

Store at 1°C - 40°C

Do not open the foil pouch until it attains room temperature

Mfg.Lic.No.: MFG/MD/2018/000029

Meril Diagnostics

Meril Diagnostics Pvt. Ltd.,
Second Floor, D1 - D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396 191, Gujarat, India. Tel : +91 260 2408000 Fax : +91 260 2408025,Email: diagnostics@merillife.com, Web: www.merillife.com

REF : XXXXX-XX

LOT : XXXXXX

Mfg : YYYY.MM.DD

Exp : YYYY.MM.DD

1.6 MERISCREEN Malaria Pf/Pv Ag (MFLRPD-07)-1 x 10 T/k POCT configuration

KIT Box Label.1

REF **MFLRPD-07**

IVD One Step Rapid Test for malaria Pf/Pv Ag

MERISCREEN Malaria Pf/Pv Ag

Σ_{10} For *in vitro* diagnostics use only

KIT CONTAINS

1. 10 Individually packed Test Devices
2. 10 pouches each containing one assay Buffer
   one specimen transfer device (5µL),
   one alcohol swab and one lancet
3. 01 Product Insert
4. 10 Summarized Instruction for use

1°C – 40°C

One step rapid test for the qualitative detection of infection by *P.falciparum* specific to HRP-II and *P.vivax* specific to P-LDH in human capillary and/or venous whole blood specimens.

Meril
Diagnostics

LOT **XXXXXX**

YYYY.MM.DD

YYYY.MM.DD

Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg,
Chala, Vapi-396191, Gujarat, India. Tel.:+91-260-2408000, Fax:+91-260-2408025,
E-mail: diagnostics@merillife.com,Web: www.merillife.com, Mfg.Lic.No.: MFG/MD/2018/000029

Outer Pouch Label

One Step Rapid Test for Malaria Pf/Pv Ag

MERISCREEN Malaria Pf/Pv Ag

Meril
Diagnostics

CONTENTS:

Test Device, Assay Buffer, Specimen transfer device (5µL), Alcohol Swab, Lancet, Summarized Instruction for use

Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg,
Chala, Vapi-396191, Gujarat, India. Tel.:+91-260-2408000, Fax:+91-260-2408025,
E-mail: diagnostics@merillife.com, Web: www.merillife.com, Mfg.Lic.No.: MFG/MD/2018/000029

REF : XXXXXX-XX

LOT : XXXXXX

Mfg : YYYY.MM.DD

Exp : YYYY.MM.DD

Device Label

One Step Rapid Test for Malaria Pf/Pv Ag

MERISCREEN Malaria Pf/Pv Ag

For *in-vitro* diagnostics use only

Store at 1°C - 40°C

Do not open the foil pouch until it attains room temperature

Mfg.Lic.No.: MFG/MD/2018/000029

Meril Diagnostics

Meril Diagnostics Pvt. Ltd.,
Second Floor, D1 - D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396 191, Gujarat, India. Tel : +91 260 2408000 Fax : +91 260 2408025,Email: diagnostics@merillife.com, Web: www.merillife.com

REF : XXXXX-XX

LOT : XXXXXX

Mfg : YYYY.MM.DD

Exp : YYYY.MM.DD

1.7 MERISCREEN Malaria Pf/Pv Ag (MFLRPD-08)-1 x 25 T/k POCT configuration

KIT Box Label.1

REF **MFLRPD-08**

One Step Rapid Test for malaria Pf/Pv Ag

IVD **MERISCREEN Malaria Pf/Pv Ag**

Σ 25 For *in vitro* diagnostics use only

Meril Diagnostics

KIT CONTAINS

1. 25 Individually packed Test Devices
2. 25 pouches each containing one assay Buffer
   one specimen transfer device (5µL),
   one alcohol swab and one lancet
3. 01 Instructions for use
4. 25 Summarized Instructions for use

One step rapid test for the qualitative detection of infection by *P.falciparum* specific to HRP-II and *P.vivax* specific to P-LDH in human capillary and/or venous whole blood specimens.

LOT **XXXXXX**

YYYY.MM.DD

YYYY.MM.DD

1°C – 40°C

Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg,
Chala, Vapi-396191, Gujarat, India. Tel.:+91-260-2408000, Fax:+91-260-2408025,
E-mail: diagnostics@merillife.com,Web: www.merillife.com, Mfg.Lic.No.: MFG/MD/2018/000029

Device Label

One Step Rapid Test for Malaria Pf/Pv Ag

MERISCREEN Malaria Pf/Pv Ag

For *in-vitro* diagnostics use only

Store at 1°C - 40°C

Do not open the foil pouch until it attains room temperature

Mfg.Lic.No.: MFG/MD/2018/000029

Meril Diagnostics

Meril Diagnostics Pvt. Ltd.,
Second Floor, D1 - D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396 191, Gujarat, India. Tel : +91 260 2408000 Fax : +91 260 2408025,Email: diagnostics@merillife.com, Web: www.merillife.com

REF : XXXXX-XX

LOT : XXXXXX

Mfg : YYYY.MM.DD

Exp : YYYY.MM.DD

Outer Pouch Label

One Step Rapid Test for Malaria Pf/Pv Ag

MERISCREEN Malaria Pf/Pv Ag

Meril
Diagnostics

CONTENTS:

Test Device, Assay Buffer, Specimen transfer device (5µL), Alcohol Swab, Lancet, Summarized Instructions for use

Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg,
Chala, Vapi-396191, Gujarat, India. Tel.:+91-260-2408000, Fax:+91-260-2408025,
E-mail: diagnostics@merillife.com, Web: www.merillife.com, Mfg.Lic.No.: MFG/MD/2018/000029

REF : XXXXXX-XX

LOT : XXXXXX

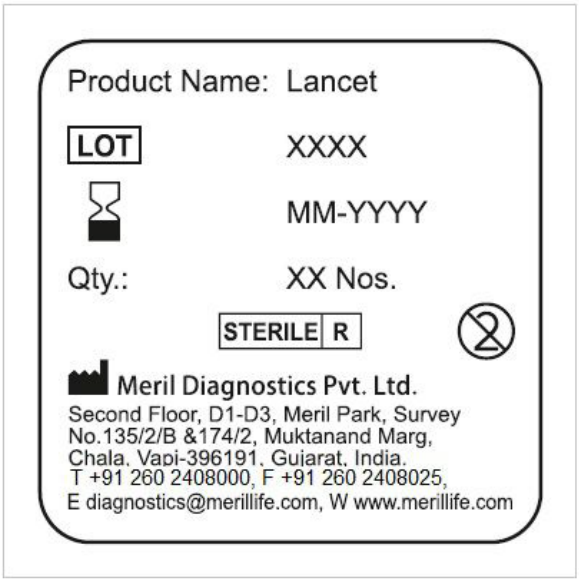
Mfg : YYYY.MM.DD

Exp : YYYY.MM.DD

1.8 Alcohol swabs label

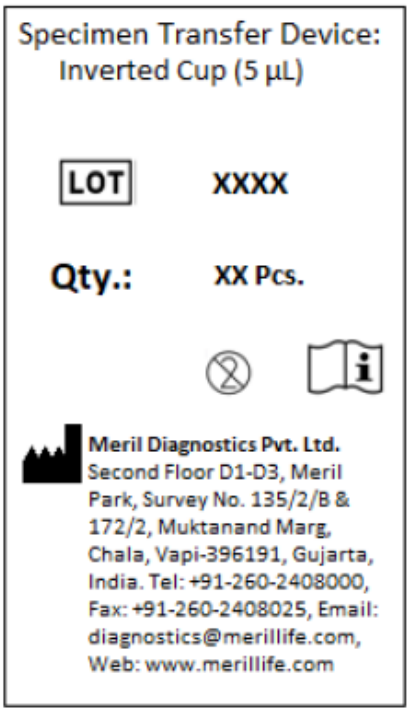
Size: 65mm x 65mm

1.9 Sterile lancet label



Size: 40mm x 40mm

1.10 Specimen transfer device label



2 Instructions for use[1]

[1] English version of the IFU was the one that the WHO assessed. The manufacturer is responsible for ensuring correct translation into other languages.

specimens, the haemolytic specimens, rheumatoid factors-contained specimens and lipaemic, icteric specimens were investigated. In this study, the performance of the One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is not affected by interfering substances such as, bilirubin (conjugated & unconjugated), triglyceride, acetaminophen, total protein, vitamin B12, sodium azide, thimerosol, alcohol/ethanol, hemoglobin, lipids, aspirin, cross reacting factors such as, Rheumatoid Arthritis, typhoid, pneumonia, diarrhea, filariasis, Hepatitis B, Hepatitis C, syphilis, HIV, dengue and cross reacting antibodies such as, Human Anti-Mouse Antibody (HAMA), Systemic Lupus Erythematous (SLE), Anti- Nuclear Antibodies (ANA).

D. Precision (Repeatability & reproducibility):

One P. falciparum positive of high parasite density i.e., 5634 parasites/µl, one P. vivax positive of high parasites density i.e., 6745 parasites/pl and three Plasmodium negative specimens were utilized for this study. These specimens are further diluted to make moderate and low positive samples. Testing was done by using these samples (high, moderate & low) in replicates of three by three different operators by using three different lots over five (05) days. Total of 1215 tests were generated and 1215 results were obtained. Out 1215, 405 results were generated for Pf, 405 results for Pv and 405 results for Plasmodium negative samples. The results have shown 100% agreement with the sample status when tested with Pf positive, Pv positive and Plasmodium negative samples by three operators, in replicates of three by using three lots over five days. The results & data analysis showed 100% sensitivity for Pf positive and Pv positive samples and 100% specificity for Plasmodium negative samples.

The test results have met the acceptance criteria of the study

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- World Health Organization, Geneva. (2004). Laboratory biosafety manual, third edition.

Product Disclaimer:

Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. The product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning:

The manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

IFU/MFLRPD02/05
Date:09/01/2023

Symbols used on Meril Diagnostics labels:

REF	Catalogue No.	LOT	Batch No.		For single use only do not reuse
	Manufacturer		Expiry date		Keep away from direct sunlight
	Manufacturing date		Keep dry		Do not use if box open or damaged
	Storage temperature	Σ	Sufficient for	CE	European health & safety product label
IVD	In Vitro Diagnostics		Caution	CE 0197	This CE mark concerns lancets and alcohol swabs
	Consult instruction for use	EC REP	Authorized European Representative in the European Community		

Manufacturer of Lancets and Alcohol swabs:
Beijing Ruicheng Medical Supplies Co. Ltd., No. 558 Zhangzikou, Yansong Town, Huairou District, 101400 Beijing, China.
Authorized Representative of Lancets and Alcohol swabs:
Lotus Global Co. Ltd., 1 Four Seasons Terrace West Drayton, Middlesex London, UB7 9GG United Kingdom

One Step test for Malaria Pf/Pv Ag

MERISCREEN Malaria Pf/Pv Ag

Product Code	Pack Size
MFLRPD-02	30 Tests
MFLRPD-03	25 Tests
MFLRPD-04	50 Tests
MFLRPD-05	10 Tests

Meril
Diagnostics

IVD For in vitro diagnostic use
Read this pack insert thoroughly before use

Intended use:

One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is an in vitro diagnostic immunochromatographic assay for the qualitative detection of infections with Plasmodium falciparum and P.vivax parasites causing malaria in human whole blood specimens. It does not assess parasite densities.

It assists trained users (in either laboratory or point-of-care settings)

- in detecting Plasmodium falciparum and P.vivax infections
- to differentiate infection between Plasmodium falciparum . histidine-rich protein II (Pf-HRP-II) and Plasmodium vivax Plasmodium lactate dehydrogenase (Pv-pLDH)

The assay is intended for trained users and for an initial screening as well as an aid to the diagnosis of malaria infection.

Note: Malaria RDTs can give positive results after successful anti-malarial treatment. Therefore, the One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is not recommended for monitoring response to anti-malarial treatment.

The assay is to be used in the diagnosis of malaria in symptomatic patients as well as asymptomatic patients i.e., pregnant women and children. Testing is not intended for blood donors.

PRINCIPLE:

One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test utilizes the principle of immunochromatography in which nitrocellulose membrane is pre-coated with one monoclonal antibody (test line Pf) specific to Histidine-Rich Protein II (Pf-HRP-II) of the Plasmodium falciparum and one monoclonal antibody (test line Pv) specific to lactate dehydrogenase of Plasmodium vivax (Pv-pLDH). Thus, the following Plasmodium antigens are detected in this test:

- Histidine Rich Protein II specific for P. falciparum (Pf-HRP-II)
- Plasmodium lactate dehydrogenase to Plasmodium vivax (Pv- PLDH)

The cassette contains a test strip pre-coated with capture antibodies.

THE SEQUENCE OF EVENTS IS AS FOLLOWS:

1. Whole blood is applied to the specimen well (labelled well "S").
2. Next, buffer is applied to the buffer well (labelled well "B").
3. Migration of the blood/buffer mixture starts towards the opposite end of the cassette.
4. The blood-buffer mixture passes the conjugate pad, which contains detection antibodies targeting Pf-HRP-II and Pv-pLDH. These detection antibodies are conjugated to colloidal gold. If present in the specimen, Plasmodium target antigens bind to this detection antibody-conjugate.
5. The antigen-antibody-conjugate complex migrates further and binds to the capture Plasmodium specific antibodies present on the test line. These capture antibodies bind to another site (epitope) of the Plasmodium target antigens.
6. The capture antibodies are applied on a narrow section of the test strip: as a result, the antibody conjugate with the colloidal gold will be concentrated and become visible as a pinkish-purple colored line.
7. The excess of the detection antibody-conjugate that was not bound by the Plasmodium target antigens and the capture antibodies moves further to absorbent pad.
8. At control zone Goat anti-chicken IgY (as blue coloured line) is immobilized and it binds to IgY colloidal gold conjugate to give a pinkish-purple colored control line. The visualization of the control line indicates that the migration was successful. It does not confirm the presence of specimen.

THE MAIN INGREDIENTS OF THE KIT ARE:

1. Test strip:

- Detection antibodies conjugated to colloidal gold:
  - o Mouse monoclonal antibodies specific to PF-HRP-II-gold Colloid
  - o Mouse monoclonal antibodies specific to Pv-pLDH-gold Colloid
  - o Chicken IgY - gold Colloid
- Capture antibodies:
  - o Test lines

Pfalciparum (Pf) line: Mouse monoclonal antibodies specific to Pf-HRP-II

P. vivax (Pv): Mouse monoclonal antibodies specific to pan-pLDH

- o Control line: Goat anti-Chicken IgY polyclonal antibodies (as blue coloured line)

2. Assay buffer:

- Protein stabilizers, detergent and preservatives

INTENDED USER:

The test must be performed by a trained user (in either laboratory or point- of-care settings).

SPECIMEN REQUIRED:

- Capillary blood or venous blood with the following anticoagulants: EDTA, Heparin, Citrate.
- Time between collection and analysis:

Capillary: immediately

Venous: If immediate testing is not possible, store the whole blood specimen at 2-8°C for maximum 72 hours (3 days).

WARNINGS AND PRECAUTIONS:

- For in vitro diagnostic use only.
- Read the instructions carefully before performing the test. The instruction must be followed exactly to get accurate results.
- Apply standard biosafety precautions for handling and disposal of potentially infective material.
  - o Handle all specimens as potentially infectious.
  - o Wear gloves while handling specimens and performing the test.
  - o Avoid splashing and aerosol formation.
  - o Clean up spills thoroughly using an appropriate disinfectant.
- The buffer contains sodium azide as a preservative which may be toxic if ingested. When disposed off through a sink, flush with large quantities of water.
- Do not use any other buffer than the buffer supplied within this kit.
- Do not use the RDT kit beyond the expiration date.
- Do not use if the packaging is damaged.
- Do not use any other specimen than whole blood.
- Do not use if the product has been exposed to excessive heat or humidity.
- Perform the test immediately after opening of the cassette packaging
- Do not re-use the test device.
- Do not touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
- Do not use the lancet if the seal is broken.
- Do not touch the tip of buffer bottle, it might contaminate buffer.
- Allow all reagents and specimen (s) to attain room temperature (18°C to 30°C) before use.
- Do not smoke, eat or drink while handling specimens and performing a test.
- Contamination of specimen transfer devices and/or reagents can lead to inaccurate results.

CE EC REP Meril Diagnostics Pvt. Ltd., Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396191, Gujarat, India. Tel.:+91-260-2408000, Fax:+91-260-2408025, E-mail: diagnostics@merillife.com, Web: www.merillife.com
Obelis s.a., Bd General Wahis 53, 1030, Brussels, Belgium. T +(32) 2 732-59-54, F +(32) 2 732-60-03, E mail@obelis.net

MATERIALS:

MATERIALS PROVIDED:

Kit Contents	MFLRPD-02	MFLRPD-03	MFLRPD-04	MFLRPD-05
Cassette packaging, each containing: 1 device1desiccant	30	25	50	10
Assay buffer bottle	2 x 3.0 ml	2 x 3.0 ml	4 x 3.0 ml	1 x 3.0 ml
Specimen transfer devices (Inverted cups) -5 µL	30	25	50	10
Lancets	30	25	50	10
Alcohol Swabs	30	25	50	10
Pack insert	1	1	1	1

MATERIALS REQUIRED BUT NOT PROVIDED:

- New pair of disposable gloves
- Pen
- Timer
- Sharp box
- Non-sharps disposal container
- Venipuncture blood collection materials and precision pipette plus tips (if whole blood is collected by venipuncture)

TEST KIT STORAGE AND STABILITY:

- Store the kit between 1-40°C
- Do not store the kit in the freezer.
- Protect the kit from excessive heat and humidity.
- The kit including assay buffer has a shelf life of 24 months from the date of manufacture. The test kit is stable until the expiration date marked on the kit box and/or the packaging of individual components when stored as specified.
- Once opened the Test Device, it gives accurate results within 24 hours, but it should be used immediately.

PROCEDURE:

BEFORE TESTING:

- Prepare all necessary materials:

o When stored in the refrigerator, bring the kit components to room temperature (18°C to 30°C) minimum 30 minutes before use.

o Prepare all the materials:

Materials Provided	Materials required but not provided
Test Device **Assay Buffer bottles** Specimen transfer device (Inverted cups) **Pack Insert** **Lancet** **Alcohol swabs**	**New pair of disposable gloves** **Pen** **Timer** **Sharp box** **Non-sharps disposal container** **Venipuncture blood collection materials and precision pipette plus tips (if whole blood is collected by venipuncture)**

- Check the expiration date of the test. If expired, do not use it but take another test from an unexpired kit.
- Check that the cassette packaging is not damaged. If damaged, discard the cassette packaging and use another test.
- Open the cassette packaging and check the desiccant. If there is a humidity indicator and it shows saturation (color changed from blue to pink/white), throw away the cassette and take another cassette packaging. If the color of the desiccant does not show any change, you can use the test. Throw away the desiccant in the non-sharps disposal container.
- Take the cassette and place it on a horizontal flat surface.

  You see:

  o a result window (marked with C, Pv, Pf)

  o a circle well marked "S" (for specimen)

  o a square well "B" (for buffer)
- Write the patient name or patient identification number on the cassette.
- Put on gloves. Use new gloves for each patient.

Note: Perform the test immediately after opening of the cassette packaging.

- Do not re-use the test device.

TEST PROCEDURE:

Capillary whole blood from finger prick:

1. Wear gloves.
2. Choose a finger for the finger prick:

   Do not choose a finger that is swollen, bruised or scarred.
3. Preferably choose the 3rd or 4th finger of the hand which the patient does not use to write.
4. Open the packaging of the alcohol swab. Take out the alcohol swab. Do not throw away the empty packaging (wrapper) but keep it aside.
5. Wipe the complete fingertip with the alcohol swab. Wait until the finger has completely dried (minimum 30 seconds).
6. Place the alcohol swab in the wrapper and set it aside (you will use it again to stop the bleeding after you collected the patient's blood). 7. Take the safety-seal lancet.
8. Detach the cap of the lancet. Puncture the side of the pulp (ball) of the finger with the lancet, perpendicular to the lines of the fingerprint. Dispose the lancet immediately into the sharps box.
9. Make sure a well-formed drop of blood is present on the tip of the finger.
10. If there is no well-formed drop of blood, repeat the finger prick. Use a new lancet and choose a different puncture site.
11. Take the specimen transfer devices and collect 5 µl of blood by dipping the circular end of the specimen transfer devices into the whole blood drop.
12. Place the circular end of the specimen transfer devices in the circle well/specimen well (marked "S") so that it touches the strip (pad at the bottom of the well). Press down lightly to transfer the whole blood to the strip. Put the used specimen transfer devices into the non-sharps disposal container.
13. Take the alcohol swab you put aside (step 5). Ask the patient to press it to the finger prick to stop the bleeding. After use, put the alcohol swab into the non-sharps disposal container.
14. Take the buffer bottle. Hold the open buffer bottle vertically above the square well/buffer well (marked "B"). Squeeze the buffer bottle gently and apply exactly four drops into the square well/buffer well (marked "B").

! Do not use any other buffer than the buffer supplied within this kit !	! Hold the buffer bottle vertically - this ensures that the drops contain the correct volume of buffer!

15. Remove your gloves and discard them into the non-sharps disposal container.
16. Write the time on the cassette or set countdown timer to the required reading time.
17. Read test results at 20 minutes but no later than 30 minutes.

    Use a good light source when reading the test results.

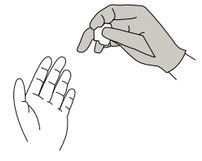
Note: Don't read test results after 30 minutes. Reading too late can give false results.

WHOLE BLOOD FROM VENIPUNCTURE:

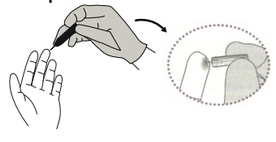
1. Wear gloves.
2. Collect blood by standard venipuncture procedure into a tube containing the correct anticoagulant (EDTA, heparin or Citrate).
3. Mix the tube gently.
4. Transfer 5 µl of whole blood using specimen transfer devices in the circle well (marked "S") of the cassette using a precision pipette.
5. Perform steps 14-17 of the previous section ("Capillary whole blood from finger prick")

Pictorial representation of procedure:

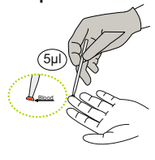
Step 1:



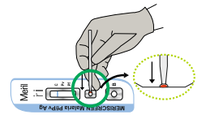
Step 2:



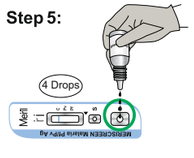
Step 3:



Step 4:



Step 5:



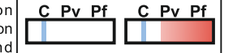
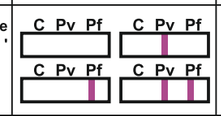
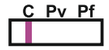
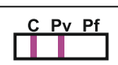
INTERPRETATION OF THE TEST RESULT:

1. At 20 but no later than 30 minutes: compare the test lines with the presentation in the table below.
2. Where possible, have the results confirmed by a second reader within this time frame.
3. Line intensities may vary from faint to strong intensity. Consider also a faint test line as a positive result.

Note: Test line of any Intensity (light to dark) should be considered positive.

4. Record the test results as noted in the table below. Consult the national guidelines for malaria case management to complement the table below.

Note: The faint blue line at "Control" position is always visible before testing. This faint blue line should not be interpreted as Control line during result interpretation.

Lines that you see	Picture / Drawing	Record the following result, take the following action
Faint Blue line at Control position even after addition of samples and assay buffer		Invalid. Take a new cassette packaging and repeat the test.
NO Pink Purple line at 'C' (=control)		Invalid. Take a new cassette packaging and repeat the test.
Pink Purple Line at 'C' and **NO** other line		Negative
Pink Purple Line at **'C'** AND at **'Pf'**		Positive for *P. falciparum*
Pink Purple Line at 'C', at 'Pf' AND at 'Pv'		Positive for *as* a mixed infection with *P. falciparum* and *P. vivax*
Pink Purple Line at 'C' AND at 'Pv'		Positive for *P. vivax*

LIMITATIONS OF THE PRODUCT, CAUSES OF FALSE-NEGATIVE AND FALSE- POSITIVE RESULTS:

- The test procedure, precautions and interpretation of result for this
- test must be followed when testing.
- The test kit is intended for an initial screening as well as an aid to the diagnosis of infection. Other clinically tests are required only if questionable results are obtained. As with all diagnostic tests, the test result must always be co-related with clinical findings.
- The performance of product may be degraded at an ambient temperature of 45°C.
- One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit was tested with interfering substances such as, bilirubin (conjugated & unconjugated), triglyceride, acetaminophen, total protein, vitamin B12, sodium azide, thimerosal, alcohol/ethanol, hemoglobin, lipids, aspirin, cross reacting samples such as, Rheumatoid Arthritis, typhoid, pneumonia, diarrhea, filariasis, Hepatitis B, Hepatitis C, syphilis, HIV, dengue and cross reacting antibodies such as, Human Anti-Mouse Antibody (HAMA), Systemic Lupus Erythematous (SLE), Anti-Nuclear Antibodies (ANA) and the performance of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit was not affected by these interfering and cross-reacting factors. Interfering substances, cross reacting factors other than these may affect the performance of the kit.
- False positive result can occur - amongst others in the following conditions:

  o Some viral infection other than hepatitis B or hepatitis C, HIV or dengue.

  o Parasitic infection (e.g. Schistosomiasis and Trypanosomiasis)
- Presence of heterophile antibodies in patient's sample other than Rheumatic diseases and autoimmune disorder may lead to false results.
- False negative result can occur in the following conditions:

  o Hook effect due to very high parasite densities i.e., ≥ 26,000 parasites/µl for P. falciparum and ≥ 22,000 parasites/µl for P.vivax. Repeat the test by using different dilutions of same sample.

  o If antigen concentration/parasite densities present in the specimen is below the detection limits of the assay or the analyte of interest that are detected are not present during the stage of disease in which a sample is collected.

  o Deletion in the HRP-II gene resulting in no production of HRP-II antigen
- A positive test should be carefully interpreted to distinguish between new infections and effectively treated old infections. This is due to the persistence of HRP II antigen in the blood for 1-3 weeks after effective treatment. Therefore, malaria RDTs are not recommended for monitoring treatment of malaria.
- This assay cannot be used for the diagnosis of infection by other type of malarial parasites (P.malariae, P.ovale or P.knowlesi).
- A negative result at any time does not preclude the possibility of exposure or infection.
- Repeat the test in case of very faint band or if have any doubt for test band.
- This kit is intended for initial screening of malaria infection as well as an aid to the diagnosis of infection. This test kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative results caused by various factors.
- Although the test is accurate in detecting HRP-II specific to P. falciparum or pLDH specific to P. vivax in blood specimens, low incidence of false results may occur. Other clinically available tests should be used if questionable results are obtained "Pv" band may turn negative after successful anti-malarial therapy.
- In few cases, HRP-II band appears in certain post treatment malaria, however, such observations are also observed in certain untreated malaria. In such cases, re-testing after 2 days is recommended.
- In P. falciparum malaria infection, HRP-II is not secreted in gametogony stage. Hence, in "Carriers", the HRP-II band may be absent.

Note: The presence of the pink-purple control line only means that migration of the test occurred. It does not guarantee that:

- The correct specimen has been used
- The specimen has been applied correctly
- The specimen and test have been correctly stored
- The test procedure was followed correctly

PERFORMANCE SPECIFICATIONS:

A. Sensitivity and specificity:

88 P. falciparum positive specimens, 89 P. vivax positive specimens including P. falciparum & P. vivax mixed infection positive specimens, P. falciparum and P. vivax positive specimens of pregnant women and children were tested with One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/PvAg to evaluate the diagnostic sensitivity of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/PvAg test kit. 1000 Plasmodium negative specimens, 107 Plasmodium negative blood donor specimens, 54 Plasmodium negative pregnant women specimens and 66 Plasmodium negative children specimens were tested with One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag to evaluate the Diagnostic Specificity of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit. The status of the specimen was determined by microscopic examination.

Types of Specimens	Sensitivity %	%CI
Sensitivity of *P. falciparum*	98.86%	95% CI value 93.83% to 99.97%
Sensitivity of *P. vivax*	96.63%	95% CI value 90.46% to 99.30%
Total Sensitivity	97.74%	95% CI value 94.32% to 99.38%
Types of Specimens	**Specificity %**	**%CI**
Specificity of *Plasmodium spp.* Negative samples	98.53%	95% CI value 97.69% to 99.13%

B. Analytical sensitivity (Limit of detection):

The sensitivity of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag for P. falciparum ("Pf" Band) is 250 parasites/µl and for P. vivax ("Pv" Band) is 2200 parasites/pl.

C. Analytical specificity (Cross reactivity):

To evaluate the interference of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit with known relevant interfering

Performance specifications:

A. Sensitivity and specificity:

88 *P.falciparum* positive specimens, 89 *P.vivax* positive specimens including *P.falciparum* & *P.vivax* mixed infection positive specimens, *P.falciparum* and *P.vivax* positive specimens of pregnant women and children were tested with One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag to evaluate the diagnostic sensitivity of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit. 1000 Plasmodium negative specimens, 107 Plasmodium negative blood donor specimens, 54 Plasmodium negative pregnant women specimens and 66 Plasmodium negative children specimens were tested with One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag to evaluate the Diagnostic Specificity of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit. The status of the specimen was determined by microscopic examination.

Types of Specimens	**Sensitivity %**	**%CI**
Sensitivity of *P.falciparum*	98.89%	95% CI value 93.83% to 99.97%
Sensitivity of *P.vivax*	96.63%	95% CI value 90.46% to 99.30%
Total Sensitivity	97.74%	95% CI value 94.32% to 99.38%
Types of Specimens	**Specificity %**	**%CI**
Specificity of *Plasmodium spp.* Negative samples	98.53%	95% CI value 97.69% to 99.13%

B. Analytical sensitivity (Limit of detection):

The sensitivity of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag for *P.falciparum* ("Pf" Band) is ≥50 parasites/µl and for *P.vivax* ("Pv" Band) is ≥200 parasites/pl.

C. Analytical specificity (Cross reactivity):

To evaluate the interference of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit with known relevant interfering specimens, the haemolytic specimens, rheumatoid factors-contained specimens and lipaemic, icteric specimens were investigated. In this study, the performance of the One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is not affected by interfering substances such as, bilirubin (conjugated & unconjugated), triglyceride, acetaminophen, total protein, vitamin B12, sodium azide, thimerosol, alcohol/ethanol, hemoglobin, lipids, aspirin, cross reacting factors such as, Rheumatoid Arthritis, typhoid, pneumonia, diarrhea, filariasis, Hepatitis B, Hepatitis C, syphilis, HIV, dengue and cross reacting antibodies such as, Human Anti-Mouse Antibody (HAMA), Systemic Lupus Erythematous (SLE), Anti- Nuclear Antibodies (ANA).

D. Precision (Repeatability & reproducibility):

One *P.falciparum* positive of high parasite density i.e., 5634 parasites/µl, one *P.vivax* positive of high parasites density i.e., 6745 parasites/µl and three Plasmodium negative specimens were utilized for this study. These specimens are further diluted to make moderate and low positive samples. Testing was done by using these samples (high, moderate & low) in replicates of three by three different operators by using three different lots over five (05) days. Total of 1215 tests were generated and 1215 results were obtained. Out 1215, 405 results were generated for Pf, 405 results for Pv and 405 results for Plasmodium negative samples. The results have shown 100% agreement with the sample status when tested with Pf positive, Pv positive and Plasmodium negative samples by three operators, in replicates of three by using three lots over five days. The results & data analysis showed 100% sensitivity for Pf positive and Pv positive samples and 100% specificity for Plasmodium negative samples.

The test results have met the acceptance criteria of the study

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Product disclaimer:

Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. The product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning:

The manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

IFU/MFLRPD06/00
Date:14/10/2024

Symbols used on Meril Diagnostics labels:

REF *Catalogue number*
IVD In vitro diagnostic *medical device*
Contains sufficient for <n> tests
Keep away from sunlight
Manufacturer
LOT *Batch code*
Caution
Do not use if package is damaged and consult *instructions for use*
Date of manufacture
Use-by date
Consult *instructions for use*
Temperature limit
Keep dry
Do not re-use

One Step test for Malaria Pf/Pv Ag

MERISCREEN Malaria Pf/Pv Ag

Product Code	Pack Size
MFLRPD-06	(1T/kit)
MFLRPD-07	(1T/kit x 10 each)
MFLRPD-08	(1T/kit x 25 each)

Meril Diagnostics

IVD For in vitro diagnostic use
Please read this leaflet carefully before use

Intended use:

One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is an *in vitro* diagnostic immunochromatographic assay for the qualitative detection of infections with Plasmodium *falciparum* and *P.vivax* parasites causing malaria in human whole blood specimens. It does not assess parasite densities.

It assists trained users (in either laboratory or point-of-care settings)

- in detecting Plasmodium falciparum and P. vivax infections
- to differentiate infection between Plasmodium falciparum histidine-rich protein II (Pf-HRP-II) and Plasmodium vivax Plasmodium lactate dehydrogenase (Pv-pLDH)

The assay is intended for trained users and for an initial screening as well as an aid to the diagnosis of malaria infection.

Note: Malaria RDTs can give positive results after successful anti-malarial treatment. Therefore, the One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit is not recommended for monitoring response to anti-malarial treatment.

The assay is to be used in the diagnosis of malaria in symptomatic patients as well as asymptomatic patients i.e., pregnant women and children. Testing is not intended for blood donors.

Principle:

One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test utilizes the principle of immunochromatography in which nitrocellulose membrane is pre-coated with one monoclonal antibody (test line Pf) specific to Histidine-Rich Protein II (Pf-HRP-II) of the Plasmodium *falciparum* and one monoclonal antibody (test line Pv) specific to lactate dehydrogenase of Plasmodium vivax (Pv-pLDH). Thus, the following Plasmodium antigens are detected in this test:

- Histidine Rich Protein II specific for *P.falciparum* (Pf-HRP-II)
- Plasmodium lactate dehydrogenase to Plasmodium vivax (Pv-PLDH)

The cassette contains a test strip pre-coated with capture antibodies.

The sequence of events is as follows:

1. Whole blood is applied to the specimen well (labelled well "S").
2. Next, buffer is applied to the buffer well (labelled well "B").
3. Migration of the blood/buffer mixture starts towards the opposite end of the cassette.
4. The blood-buffer mixture passes the conjugate pad, which contains detection antibodies targeting Pf-HRP-II and Pv-pLDH. These detection antibodies are conjugated to colloidal gold. If present in the specimen, Plasmodium target antigens bind to this detection antibody-conjugate.
5. The antigen-antibody-conjugate complex migrates further and binds to the capture Plasmodium specific antibodies present on the test line.
6. These capture antibodies bind to another site (epitope) of the Plasmodium target antigens. The capture antibodies are applied on a narrow section of the test strip: as a result, the antibody conjugate with the colloidal gold will be concentrated and become visible as a pinkish-purple colored line.
7. The excess of the detection antibody-conjugate that was not bound by the Plasmodium target antigens and the capture antibodies moves further to absorbent pad.
8. At control zone Goat anti-chicken IgY (as blue coloured line) is immobilized and it binds to IgY colloidal gold conjugate to give a pinkish-purple colored control line. The visualization of the control line indicates that the migration was successful. It does not confirm the presence of specimen.

The main ingredients of the kit are:

1. Test strip:

- Detection antibodies conjugated to colloidal gold:
- Mouse monoclonal antibodies specific to Pf-HRP-II-gold Colloid
- Mouse monoclonal antibodies specific to Pv-pLDH-gold Colloid
- Chicken IgY-gold Colloid
- Capture antibodies:
- Test lines
  P.falciparum (Pf) line: Mouse monoclonal antibodies specific to Pf HRP-II
  P. vivax (Pv): Mouse monoclonal antibodies specific to pan-pLDH
- Control line: Goat anti-Chicken IgY polyclonal antibodies (as blue coloured line)

2. Assay buffer:

- Protein stabilizers, detergent and preservatives

Intended user:

The test must be performed by a trained user (in either laboratory or point- of-care settings).

Specimen required:

- Capillary blood or venous blood with the following anticoagulants: EDTA, Heparin, Citrate.
- Time between collection and analysis:
  Capillary: immediately
  Venous: If immediate testing is not possible, store the whole blood specimen at 2-8°C for maximum 72 hours (3 days).

Warnings and precautions:

- For *in vitro* diagnostic use only.
- Read the instructions carefully before performing the test. The instruction must be followed exactly to get accurate results.
- Apply standard biosafety precautions for handling and disposal of potentially infective material.
  - Handle all specimens as potentially infectious.
  - Wear gloves while handling specimens and performing the test.
  - Avoid splashing and aerosol formation.
  - Clean up spills thoroughly using an appropriate disinfectant.
- The buffer contains sodium azide as a preservative which may be toxic if ingested. When disposed off through a sink, flush with large quantities of water.
- Do not use any other buffer than the buffer supplied within this kit.
- Do not use the RDT kit beyond the expiration date. Do not use if the packaging is damaged.
- Do not use any other specimen than whole blood.
- Do not use if the product has been exposed to excessive heat or humidity.
- Perform the test immediately after opening of the cassette packaging.
- Do not re-use the test device.
- Do not touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.

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- Do not use the lancet if the seal is broken. Do not touch the tip of assay buffer ampoule, it might contaminate buffer.
- Allow all reagents and specimen (s) to attain room temperature (18°C to 30°C) before use.
- Do not smoke, eat or drink while handling specimens and performing a test.
- Contamination of specimen transfer devices and/or reagents can lead to inaccurate results.

Materials:
Materials provided:

Kit Contents	MFLRPD-06 (1T/kit)	MFLRPD-07 (1T/kit x 10 each)	MFLRPD-08 (1T/kit x 25 each)
Test cassettes individually packed in foil pouch with a desiccant	1 test device	10x1 test device	25x1 test device
Assay diluent dispensed in Ampoule	1 pouch containing: 1 assay diluent (400µl), 1 specimen transfer device (5µl), 1 lancet, 1 alcohol swab	10 pouches each containing: 1 assay diluent (400µl), 1 specimen transfer device (5µl), 1 lancet, 1 alcohol swab	25 pouches each containing: 1 assay diluent (400µl), 1 specimen transfer device (5µl), 1 lancet, 1 alcohol swab
Specimen transfer devices (Inverted Cup) (5 µL)			
Lancets			
Alcohol swabs			
Instructions for use	1 No.	1 No.	1 No.
Summarized instructions for use	-	10 Nos.	25 Nos.

Materials required but not provided:
- New pair of disposable gloves
- Pen
- Timer
- Sharp box
- Non-sharps disposal container
- Venipuncture blood collection materials and precision pipette plus tips (if whole blood is collected by venipuncture)

Test kit storage and stability:
- Store the kit between 1-40 °C
- Do not store the kit in the freezer.
- Protect the kit from excessive heat and humidity.
- The kit including assay buffer has a shelf life of 24 months from the date of manufacture. The test kit is stable until the expiration date marked on the kit box and/or the packaging of individual components when stored as specified.
- Once opened the Test Device, it gives accurate results within 24 hours, but it should be used immediately.

Procedure:
Before testing:
- Prepare all necessary materials:
- When stored in the refrigerator, bring the kit components to room temperature (18°C to 30°C) minimum 30 minutes before use.
- Prepare all the materials:

Materials Provided	Materials required but not provided
Test Device	New pair of disposable gloves
Assay buffer ampoule	Pen
Lancets	Timer
Alcohol swabs	Sharp box
Specimen transfer devices (Inverted cups)	Non-sharps disposal container
Pack Insert	Venipuncture blood collection materials and precision pipette plus tips (if whole blood is collected by venipuncture)

- Check the expiration date of the test. If expired, do not use it but take another test from an unexpired kit.
- Check that the cassette packaging is not damaged. If damaged, discard the cassette packaging and use another test.
- Open the cassette packaging and check the desiccant. If there is a humidity indicator and it shows saturation (color changed from blue to pink/white), throw away the cassette and take another cassette packaging. If the color of the desiccant does not show any change, you can use the test. Throw away the desiccant in the non-sharps disposal container.
- Take the cassette and place it on a horizontal flat surface.

You see:
- a result window (marked with C, Pv, Pf)
- a circle well marked "S" (for specimen)
- a square well "B" (for buffer)

- Write the patient name or patient identification number on the cassette.
- Put on gloves. Use new gloves for each patient.

Note: Perform the test immediately after opening of the cassette packaging.
- Do not re-use the test device.

Test procedure:
Capillary whole blood from finger prick:
1. Wear gloves.
2. Choose a finger for the finger prick: Do not choose a finger that is swollen, bruised or scarred.
3. Preferably choose the 3rd or 4th finger of the hand which the patient does not use to write.
4. Open the packaging of the alcohol swab. Take out the alcohol swab. Do not throw away the empty packaging (wrapper) but keep it aside.
5. Wipe the complete fingertip with the alcohol swab. Wait until the finger has completely dried (minimum 30 seconds).
6. Place the alcohol swab in the wrapper and set it aside (you will use it again to stop the bleeding after you collected the patient's blood).
7. Take the safety-seal lancet.
8. Detach the cap of the lancet. Puncture the side of the pulp (ball) of the finger with the lancet, perpendicular to the lines of the fingerprint. Dispose the lancet immediately into the sharps box.
9. Make sure a well-formed drop of blood is present on the tip of the finger.
10. If there is no well-formed drop of blood, repeat the finger prick. Use a new lancet and choose a different puncture site.
11. Take the specimen transfer devices and collect 5 µl of blood by dipping the circular end of the specimen transfer devices into the whole blood drop.
12. Place the circular end of the specimen transfer devices in the circle well/specimen well (marked "S") so that it touches the strip (pad at the bottom of the well). Press down lightly to transfer the whole blood to the strip. Put the used specimen transfer devices into the non-sharps disposal container.
13. Take the alcohol swab you put aside (step 5). Ask the patient to press it to the finger prick to stop the bleeding. After use, put the alcohol swab into the non-sharps disposal container.
14. Take the assay buffer ampoule. Hold the open assay buffer ampoule vertically above the square well/buffer well (marked "B"). Squeeze the assay buffer ampoule gently and apply exactly four drops into the square well/buffer well (marked "B").

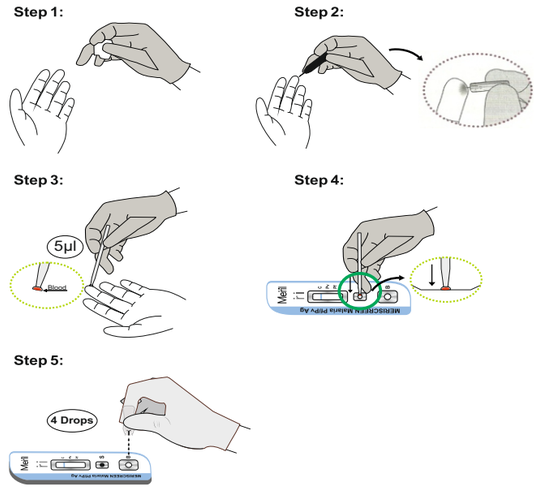
! Do not use any other buffer than the buffer supplied within this kit. !	! Hold the assay buffer ampoule vertically this ensures that the drops contain the correct volume of buffer !

15. Remove your gloves and discard them into the non-sharps disposal container.
16. Write the time on the cassette or set a countdown timer to the required reading time.
17. Read test results at 20 minutes but no later than 30 minutes. Use a good light source when reading the test results.

Note: Don't read test results after 30 minutes. Reading too late can give false results.

Whole blood from venipuncture:
1. Wear gloves.
2. Collect blood by standard venipuncture procedure into a tube containing the correct anticoagulant (EDTA, heparin or Citrate).
3. Mix the tube gently.
4. Transfer 5 µl of whole blood using specimen transfer devices in the circle well (marked "S") of the cassette using a precision pipette.
5. Perform steps 14-17 of the previous section ("Capillary whole blood from finger prick")

Pictorial representation of procedure:



Interpretation of the test result:
1. At 20 but no later than 30 minutes: compare the test lines with the presentation in the table below.
2. Where possible, have the results confirmed by a second reader within this time frame.
3. Line intensities may vary from faint to strong intensity. Consider also a faint test line as a positive result.

Note: Test line of any Intensity (light to dark) should be considered positive.
4. Record the test results as noted in the table below. Consult the national guidelines for malaria case management to complement the table below.

Note: The faint blue line at "Control" position is always visible before testing. This faint blue line should not be interpreted as Control line during result interpretation.

Lines that you see	Picture / Drawing	Record the following result, take the following action
Faint Blue line at Control position even after addition of samples and assay buffer	C Pv Pf C Pv Pf	Invalid. Take a new cassette packaging and repeat the test.
NO Pink Purple line at 'C' (=control)	C Pv Pf C Pv Pf C Pv Pf C Pv Pf	Invalid. Take a new cassette packaging and repeat the test.
Pink Purple Line at 'C' and **NO** other line	C Pv Pf	Negative
Pink Purple Line at **'C'** AND at **'Pf'**	C Pv Pf	Positive for *P. falciparum*
Pink Purple Line at 'C', at 'Pf' AND at 'Pv'	C Pv Pf	Positive for *as* a mixed infection with *P. falciparum* and *P. vivax*
Pink Purple Line at 'C' AND at 'Pv'	C Pv Pf	Positive for *P. vivax*

Limitations of the product, causes of false-negative and false-positive results:
- The test procedure, precautions and interpretation of result for this test must be followed when testing.
- The test kit is intended for an initial screening as well as an aid to the diagnosis of infection. Other clinically tests are required only if questionable results are obtained. As with all diagnostic tests, the test result must always be co-related with clinical findings.
- The performance of product may be degraded at an ambient temperature of 45°C.
- One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit was tested with interfering substances such as, bilirubin (conjugated & unconjugated), triglyceride, acetaminophen, total protein, vitamin B12, sodium azide, thimerosal, alcohol/ethanol, hemoglobin, lipids, aspirin, cross reacting samples such as, Rheumatoid Arthritis, typhoid, pneumonia, diarrhea, filariasis, Hepatitis B, Hepatitis C, syphilis, HIV, dengue and cross reacting antibodies such as, Human Anti-Mouse Antibody (HAMA), Systemic Lupus Erythematous (SLE). Anti-Nuclear Antibodies (ANA) and the performance of One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag test kit was not affected by these interfering and cross-reacting factors. Interfering substances, cross reacting factors other than these may affect the performance of the kit.
- False positive result can occur amongst others in the following conditions:
  - Some viral infection other than hepatitis B or hepatitis C, HIV or dengue.
  - Parasitic infection (e.g. Schistosomiasis and *Trypanosomiasis*)
- Presence of heterophile antibodies in patient's sample other than Rheumatic diseases and autoimmune disorder may lead to false results
- False negative result can occur in the following conditions:
  - Hook effect due to very high parasite densities i.e., ≥ 26,000 parasites/ul for *P.falciparum* and 2 22,000 parasites/pl for *P.vivax*. Repeat the test by using different dilutions of same sample.
  - If antigen concentration/parasite densities present in the specimen is below the detection limits of the assay or the analyte of interest that are detected are not present during the stage of disease in which a sample is collected.
  - Deletion in the HRP-II gene resulting in no production of HRP-II antigen
- A positive test should be carefully interpreted to distinguish between new infections and effectively treated old infections. This is due to the persistence of HRP II antigen in the blood for 1-3 weeks after effective treatment. Therefore, malaria RDTs are not recommended for monitoring treatment of malaria.
- This assay cannot be used for the diagnosis of infection by other type of malarial parasites (*P.malariae, Povale* or *P.knowlesi*).
- A negative result at any time does not preclude the possibility of exposure or infection.
- Repeat the test in case of very faint band or if have any doubt for test band.
- This kit is intended for initial screening of malaria infection as well as an aid to the diagnosis of infection. This test kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative results caused by various factors.
- Although the test is accurate in detecting HRP-II specific to *P. falciparum* or pLDH specific to *P.vivax* in blood specimens, low incidence of false results may occur. Other clinically available tests should be used if questionable results are obtained "Pv" band may turn negative after successful anti-malarial therapy.
- In few cases, HRP-II band appears in certain post treatment malaria, however, such observations are also observed in certain untreated malaria. In such cases, re-testing after 2 days is recommended.
- In *P.falciparum* malaria infection, HRP-II is not secreted in gametogony stage. Hence, in “Carriers”, the HRP-II band may be absent.

Note: The presence of the pink-purple control line only means that migration of the test occurred. It does not guarantee that:
- The correct specimen has been used
- The specimen has been applied correctly
- The specimen and test have been correctly stored
- The test procedure was followed correctly

MERISCREEN
Malaria Pf/Pv Ag

Meril
Diagnostics

One Step Rapid Test for Malaria Pf/Pv Ag

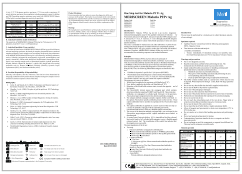
REF MFLRPD-06, MFLRPD-07, MFLRPD-08

PREPARATION

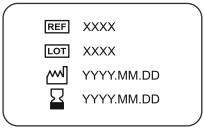
1 **Kit Contents**

1. Test device with desiccant in individual foil pouch
2. Assay diluent dispensed in Ampoule
3. Inverted Cup (5 µL)
4. Lancet
5. Alcohol swab
6. Instructions for use
7. Summarized Instruction for use

2 First, read carefully the instruction on how to use the MERISCREEN Malaria Pf/Pv Ag test kit.

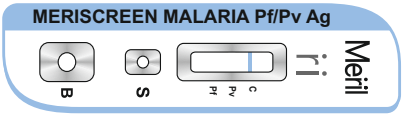


3 Look at the expiration date at the back of the foil pouch. If the expiration date has passed, use another kit.



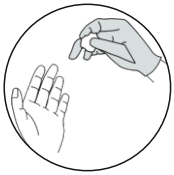
4 **Open the foil pouch and look for the following in Test Device:**

1. Result window
2. Circle well (Marked “S”)
3. Square well (Marked “B”)

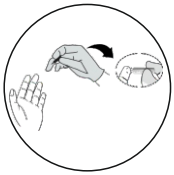


TEST PROCEDURE

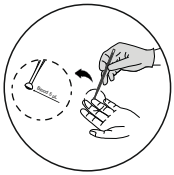
1. Label the test device with patient identification number / name.



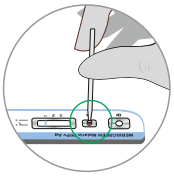
2. Open the packaging of the alcohol swab. Wipe the complete fingertip. Wait until the finger has completely dried.



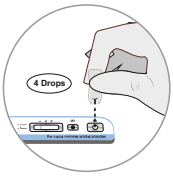
3. Take the safety-seal lancet. Detach the cap of the lancet. Puncture the side of the pulp (ball) of the finger with the lancet, perpendicular to the lines of the fingerprint.



4.Take specimen transfer device and collect 5 µL of blood by dipping the circular end of the specimen transfer device into the whole blood drop.



5. Place the circular end of the specimen transfer device in the circle well (marked “S”) so that it touches the strip (pad at the bottom of the well).



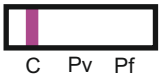
6. Take the assay buffer ampoule. Hold the open buffer ampoule vertically above the square well (marked "B"). Squeeze the buffer ampoule gently and apply exactly four drops into the square well (marked "B").

7. Interpret the test results at 20 minutes. Do not read the results after 30 minutes.

8. Place the test device, lancet, alcohol swab, Prefilled assay buffer ampoule, Inverted Cup in a waste bin.

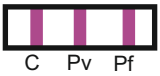
INTERPRETATION

Non-Reactive

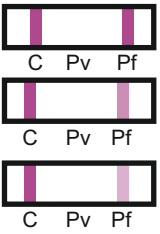


Reactive

Mixed Infection



Positive for *P.falciparum*

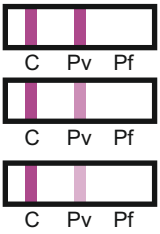


Strong

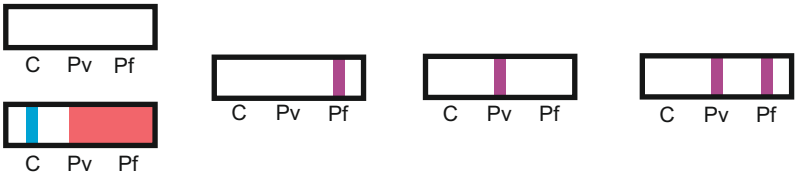
Medium

Weak

Positive for *P.vivax*



Invalid



QRI/MFLRPD07/02
Date: 09/04/2025

Manufactured By:
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