WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3)
WHO reference number: PQDx 0321-024-00

Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3) with product codes[1] **302030005, 302030010, 302030025, 302030100, and 302030025(1T)** manufactured by **Orchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd**, **CE-Mark**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 14 September 2020.

Summary of WHO prequalification assessment for Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3)

	Date	Outcome
Prequalification listing	14 September 2020	listed
Dossier assessment	19 August 2020	MR
Site inspection(s) of the quality management system	21-25 January 2019	MR
Product performance evaluation	2018	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 the 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. Changed the specimen applicator from sample loops to Inverted cups. 2. Changed the lancets from stainless steel sterile blood lancets to blood lancets plastic (twist off). 3. Addition of pack size, i.e. single tests in a pack of 25 tests.	12 May 2023

[1] Product code 302030001 was not assessed for prequalification. However, it is included in the IFU attached in the labelling section of this public report.

3.0	Inverted cups and blood lancets plastic (twist-off) accessories were removed from the prequalified product due to the rejection of the change request initially granted provisional approval.	16 June 2023
4.0	Inclusion of the job aid that was omitted in version 3 of the public report.	16 May 2024

Intended use

According to the claim of intended use from Orchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd, "*paracheck Pf **[-Rapid Test for P. Falciparum Malaria Device (Ver. 3)]** is an invitro, rapid, qualitative, two site sandwich immunoassay for the determination of P. falciparum specific histidine-rich protein - 2 (Pf. HRP-2) in whole blood (capillary or venous) for the diagnosis of falciparum malaria in individuals with signs and symptoms consistent with malaria infection. The test is intended for healthcare professionals at the clinical setup and point of care sites*".

Assay description

According to the claim of assay description from Orchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd, "*paracheck Pf **[- Rapid Test for P. Falciparum Malaria Device (Ver. 3)]** utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immunochromatography format along with use of nano gold particles as agglutination revealing agent. As the test specimen flows through the membrane assembly of the device after addition of the clearing buffer, the colored Agglutinating Sera for HRP-2-colloidal gold conjugate complexes the HRP-2 in the lysed specimen. This complex moves further on the membrane to the test region where it is immobilized by the Agglutinating Sera for HRP-2 coated on the membrane leading to the formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any, move further on the membrane and are subsequently immobilized by the Agglutinating Sera for Rabbit globulin coated on the membrane at the control region, forming a colored band. The control band formation is based on the 'Rabbit globulin / Agglutinating Sera for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test performance."*

Test kit contents

Component	5 tests (product code 302030005)	10 tests (product code 302030010)	25 tests (product code 302030025)	100 tests (product code 302030100)	Single tests in a pack of 25 tests (product code 302030025(1T)
Individual pouches, each containing: a. Test device. b. Desiccant pouch. c.Disposable pipette.	\	\	\	\	25
Pouch sealed test with dessicant and specimen transfer device	5	10	25	100	\
Assay buffer bottle(s)	1 bottle (total volume 1.5 ml)	1 bottle (total volume 3.0 ml)	1 bottle (total volume 4.0 ml)	4 bottles (total volume 16.0 ml)	25 single-use vials
Alcohol swabs	5	10	25	100	25
Sterile lancets	5	10	25	100	25
Instructions for use	1	1	1	1	1
Pictorial instructions for use	1	1	1	1	1

Items required but not provided

Item	Description
Consumables: Disposable micropipette tips Venipuncture blood collection kit Additional alcohol swabs Additional sterile lancets	NA
Durables: Biohazard waste container	NA
Equipment: Calibrated micropipette Timer	Micropipette should be capable of delivering 5µl of the specimen.

Storage

The test kit must be stored at 4°C to 45 °C.

Shelf-life upon manufacture

24 months.

Warnings/limitations

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

Prioritization for prequalification

Based on established criteria for acceptance in the WHO product testing of malaria RDTs for Round 8[2], Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3) was given priority for WHO prequalification assessment.

Dossier assessment

Orchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd submitted a product dossier for Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3) as per the "*Instructions for compilation of a product dossier*" (PQDx_018 version 3). 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 19 August 2020.

Commitment for prequalification:

To submit a complete study report investigating potential interference/cross-reactivity by 30 September 2020.

The manufacturer submitted additional studies. The additional information is currently under review.

Based on the product dossier screening and assessment findings, the product dossier for Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3) meets WHO prequalification requirements.

[2] https://www.who.int/malaria/publications/atoz/9789241514965/en/

Manufacturing site inspection

An inspection of Orchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd located at Plot nos 88/89, Phase II C, Verna Industrial Estate, *Verna, Goa, 403722, India,* was conducted from 21-25 January 2019. 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 a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. 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.

The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 13 May 2019.

Product performance evaluation

Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3) was evaluated in the eighth[3] round of WHO product testing of RDTs for malaria antigen detection, which was completed in 2018.

Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3) was evaluated against a *Plasmodium falciparum* cultured line panel, *P. falciparum wild type* parasite panel and a *P. falciparum* and *P.vivax* negative panel.

Performance characteristics	
	P. falciparum
Panel detection score at 200 parasites/µL (N=100)	94.0%
False positive results among clean negative specimens % (N= 207)	3.4
Invalid rate % (N= 1210)	0.1
Inter-reader variability* %	Not Applicable

[3] https://www.who.int/malaria/publications/atoz/9789241514965/en/

Lowest concentration of HRP2/pLDH detected using the 1st WHO International standard for Pf antigens (NIBSC code: 16/376)*	Not Applicable

** Not applicable for assays evaluated in WHO product testing of RDTs for malaria antigen detection*

Operational characteristics and ease of use

This assay does not require laboratory equipment and can be performed in laboratories with limited facilities or non-laboratory settings.

Key operational characteristics	
Number of steps*	2 steps in total
Time to result	20 minutes
Endpoint stability (interval)	10 minutes (the test can be read between 20 and 30 minutes after the addition of diluent)
Internal QC	The test has a control line. The control line indicates the correct migration of the diluent. The control line does not indicate the following: • That the correct specimen type was used. • That the correct order of procedure was followed. • That the correct amount of specimen was added. • That the correct amount of diluent was added. • That the correct reading time was respected.

** Definition: each action required to obtain a result (excluding specimen collection, device preparation – opening the pouch), e.g. for RDTs: add specimen, add buffer (2 steps).*

Labelling

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

1. Labels

1.1. Device carton and labels

Size : 150 x 120 mm

Contents:

- 25 x Test devices.
- 25 x Clearing buffer bottles.
- 25 x Disposable specimen applicators.
- 25 x Instructions for use.
- 25 x Pictorial Instructions for use.
- 25 x Alcohol swabs.
- 25 x Sterile lancets.

4°C – 45°C Store at 4°C to 45°C
Do Not Freeze

Mfg. Lic. No.: MFG/IVD/2020/000118

EC REP
CMC Medical Devices & Drugs S.L.,
C/ Horacio Lengo No. 18,
CP 29006, Malaga, Spain.

(DO NOT ACCEPT IF THE SEAL IS BROKEN)

REF Cat No.: 302030025(1T)

8 906010 950521

CE

25 X 1 TESTS

Σ 25x1

paracheck® Pf

DEVICE

RAPID TEST FOR *P. FALCIPARUM* MALARIA (Ver.3)

0522/VER-01

Size : 55 x 65 mm

Contents:

- 1 x Test device.
- 1 x Clearing buffer bottle.
- 1 x Disposable specimen applicator.
- 1 x Instructions for use.
- 1 x Pictorial Instructions for use.
- 1 x Alcohol swab.
- 1 x Sterile lancet.

4°C – 45°C Store at 4°C to 45°C
Do Not Freeze

REF Cat No.: 302030025(1T)

Mfg. Lic. No.:
MFG/IVD/2020/000118

EC REP
CMC Medical Devices & Drugs S.L.,
C/ Horacio Lengo No. 18,
CP 29006, Malaga, Spain.

CE

1 TEST

Σ 1

paracheck® Pf

DEVICE

RAPID TEST FOR *P. FALCIPARUM* MALARIA (Ver.3)

0522/VER-01

Size : 55 x 18 mm

CE 4°C – 45°C paracheck® Pf

Mfg. Lic. No.:
MFG/IVD/2020/000118

CLEARING BUFFER

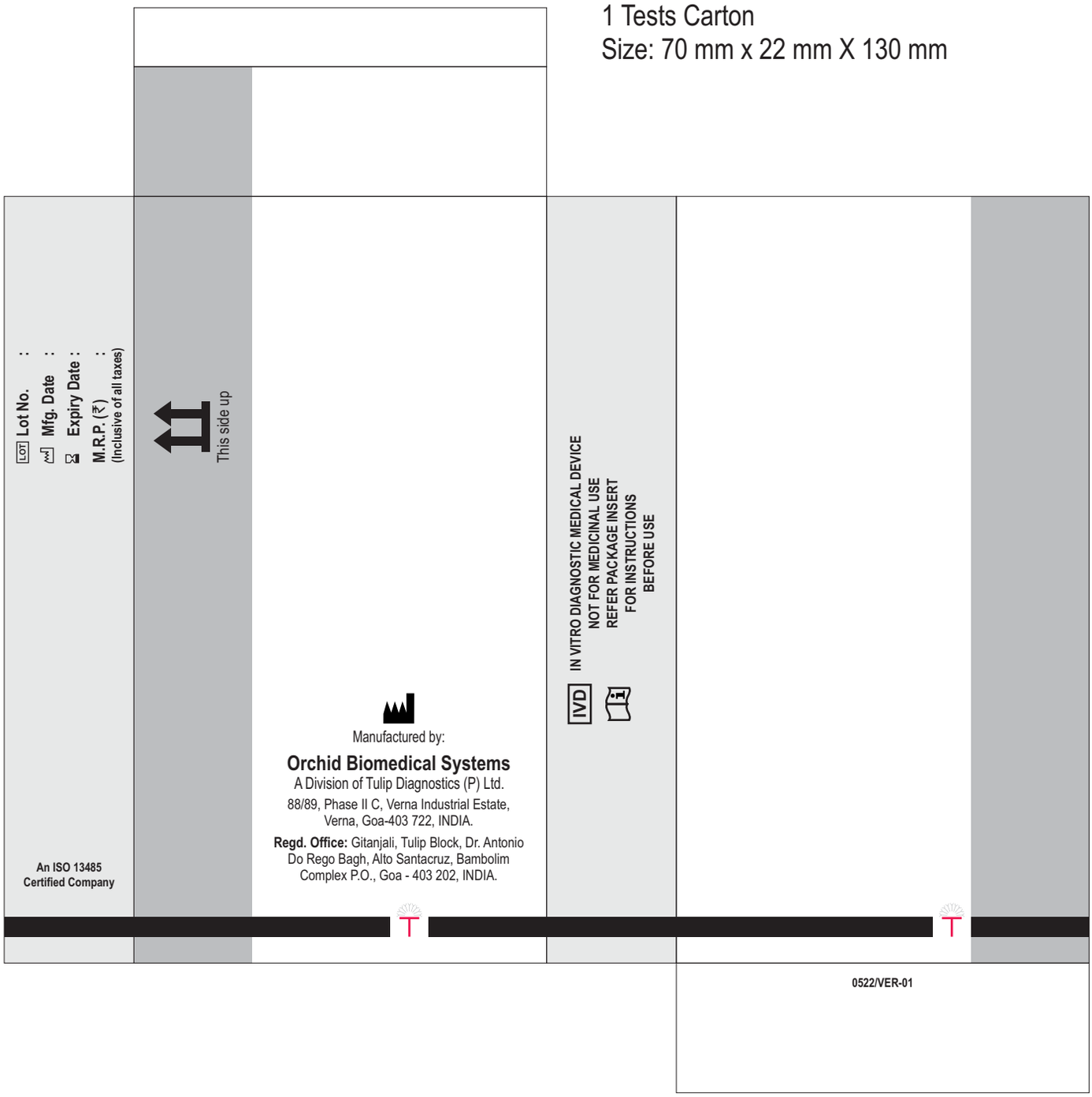
Manufactured by:
Orchid Biomedical Systems
A Division of Tulip Diagnostics (P) Ltd.
88/89, Phase II C, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa-403 202, INDIA.

BUF
1 ml

LOT

VER-01

1 Tests Carton
Size: 70 mm x 22 mm X 130 mm



25 x 1 Test Carton
Size: 300 mm x 135 mm X 145 mm

Manufactured by:

Orchid Biomedical Systems

A Division of Tulip Diagnostics (P) Ltd.

88/89, Phase II C, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.
Email address: sales@tulipgroup.com
Tel. : (0832) 2458546, (0832) 2458547

9522/VER-01

LOT **Lot No.** :

Mfg. Date :

Expiry Date :

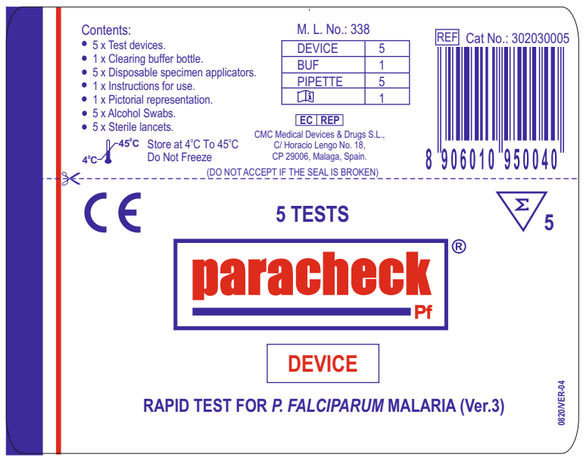
M.R.P. (₹) :
(Inclusive of all taxes)

This side up

An ISO 13485 Certified Company

IVD **IN VITRO DIAGNOSTIC MEDICAL DEVICE NOT FOR MEDICINAL USE**

REFER PACKAGE INSERT FOR INSTRUCTIONS BEFORE USE



orchid

Manufactured by:

Orchid Biomedical Systems

A Division of Tulip Diagnostics (P) Ltd.

88/89, Phase II C, Verna Industrial Estate, Verna, Goa-403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz,
Bambolim Complex P.O., Goa - 403 202, INDIA.
Email address: sales@tulipgroup.com
Tel. : (0832) 2458546, (0832) 2458547

0820/VER-02

Lot No. :

Mfg. Dt. :

Exp. Dt. :

M.R.P. (₹) :
(Inclusive of all taxes)

This side up

An ISO 13485
Certified Company

IVD IN VITRO DIAGNOSTIC MEDICAL DEVICE
NOT FOR MEDICINAL USE

REFER INSTRUCTIONS FOR USE

Contents:

- 10 x Test devices.
- 1 x Clearing buffer bottle.
- 10 x Disposable specimen applicators.
- 1 x Instructions for use.
- 1 x Pictorial representation.
- 10 x Alcohol Swabs.
- 10 x Sterile lancets.

4°C 45°C Store at 4°C To 45°C
Do Not Freeze

M. L. No.: 338

DEVICE	10
BUF	1
PIPETTE	10
	1

EC REP
CMC Medical Devices & Drugs S.L.,
C/ Horacio Lengo No. 18,
CP 29006, Malaga, Spain.

REF Cat No.: 302030010

8 906010 950071

(DO NOT ACCEPT IF THE SEAL IS BROKEN)

CE

10 TESTS

Σ 10

paracheck® Pf

DEVICE

RAPID TEST FOR *P. FALCIPARUM* MALARIA (Ver.3)

0820/VER-04

Manufactured by:

Orchid Biomedical Systems

A Division of Tulip Diagnostics (P) Ltd.

88/89, Phase II C, Verna Industrial Estate, Verna, Goa-403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz,
Bambolim Complex P.O., Goa - 403 202, INDIA.
Email address: sales@tulipgroup.com
Tel. : (0832) 2458546, (0832) 2458547

0820/VER-02

LOT **Lot No. :**

Mfg. Dt. :

Exp. Dt. :

M.R.P. (₹) :
(Inclusive of all taxes)

This side up

An ISO 13485
Certified Company

IVD **IN VITRO DIAGNOSTIC MEDICAL DEVICE**
NOT FOR MEDICINAL USE

REFER INSTRUCTIONS FOR USE

Manufactured by:

Orchid Biomedical Systems

A Division of Tulip Diagnostics (P) Ltd.

88/89, Phase II C, Verna Industrial Estate, Verna, Goa-403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.
Email address: sales@tulipgroup.com
Tel. : (0832) 2458546, (0832) 2458547

0820/VER-02

Contents:
- 25 x Test devices.
- 1 x Clearing buffer bottle.
- 25 x Disposable specimen applicators.
- 1 x Instructions for use.
- 1 x Pictorial representation.
- 25 x Alcohol Swabs.
- 25 x Sterile lancets.

M. L. No.: 338

DEVICE	25
BUF	1
PIPETTE	25
CAP	1

EC REP
CMC Medical Devices & Drugs S.L.,
C/ Horacio Lengo No. 18,
CP 29006, Malaga, Spain.

REF Cat No.: 302030025

8 906010 950088

4°C 45°C Store at 4°C To 45°C
Do Not Freeze

(DO NOT ACCEPT IF THE SEAL IS BROKEN)

CE

25 TESTS

Σ 25

paracheck® Pf

DEVICE

RAPID TEST FOR *P. FALCIPARUM* MALARIA (Ver.3)

0820/VER-04

LOT **Lot No. :**

Mfg. Dt. :

Exp. Dt. :

M.R.P. (₹) :
(Inclusive of all taxes)

This side up

An ISO 13485
Certified Company

IVD **IN VITRO DIAGNOSTIC MEDICAL DEVICE**

NOT FOR MEDICINAL USE

REFER INSTRUCTIONS FOR USE

Contents:
- 100 x Test devices
- 4 x Clearing buffer bottles
- 100 x Disposable specimen applicators.
- 1 x Instructions for use.
- 1 x Pictorial representation.
- 100 x Alcohol Swabs.
- 100 x Sterile lancets.

-45°C Store at 4°C To 45°C
4°C Do Not Freeze

M. L. No.: 338

DEVICE	100
BUF	4
PIPETTE	100
	1

EC REP
CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo No. 18,
CP 29006, Malaga, Spain

REF Cat No.: 302030100

8 906010 950118

(DO NOT ACCEPT IF THE SEAL IS BROKEN)

CE

100 TESTS

paracheck® Pf

Σ 100

DEVICE

RAPID TEST FOR *P. FALCIPARUM* MALARIA (Ver.3)

0020/VER-04

Manufactured by:

Orchid Biomedical Systems

A Division of Tulip Diagnostics (P) Ltd.

88/89, Phase II C, Verna Industrial Estate, Verna, Goa-403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz,
Bambolim Complex P.O., Goa - 403 202, INDIA.
Email address: sales@tulipgroup.com
Tel. : (0832) 2458546, (0832) 2458547

0020/VER-02

This side up

LOT **Lot No. :**

Mfg. Dt. :

Exp. Dt. :

M.R.P. (₹) :
(Inclusive of all taxes)

An ISO 13485
Certified Company

IVD **IN VITRO DIAGNOSTIC MEDICAL DEVICE**

NOT FOR MEDICINAL USE

REFER INSTRUCTIONS FOR USE

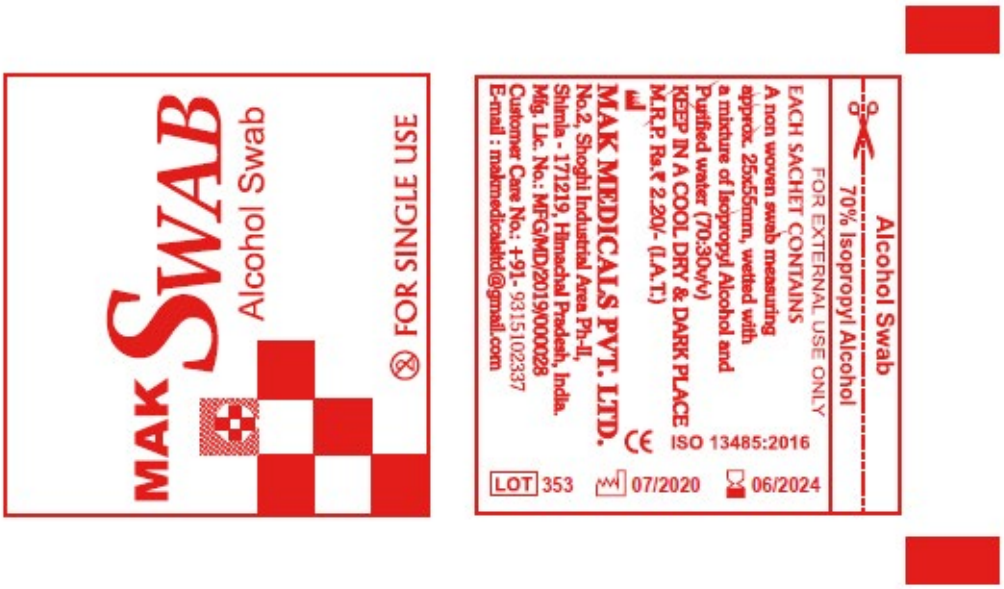
1.2 Pouch label


paracheck®
Pf
DEVICE
RAPID TEST FOR P. FALCIPARUM MALARIA (Ver.3)
CONTAINS ONE MEMBRANE TEST ASSEMBLY
WITH DESICCANT AND SAMPLE APPLICATOR
IVD
IN VITRO DIAGNOSTIC MEDICAL DEVICE
NOT FOR MEDICINAL USE
FOR SINGLE USE ONLY. DO NOT REUSE
45°C
4°C
STORE BETWEEN 4°C TO 45°C
REFER PACKAGE INSERT FOR INSTRUCTIONS
BEFORE USE
Σ 1
Manufactured by:
Orchid Biomedical Systems
A Division of Tulip Diagnostics (P) Ltd.
88/89, Phase II C, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz,
Bambolim Complex P.O., Goa - 403 202, INDIA.
EC REP
CMC Medical Devices & Drugs S.L., Spain
M.L. No. . .
Lot No. . .
Mfg. Dt. . .
Exp. Dt. . .
LOT
0817/VER-02

< ---------- 125 mm ---------- >

< -------- 65 mm --------- >

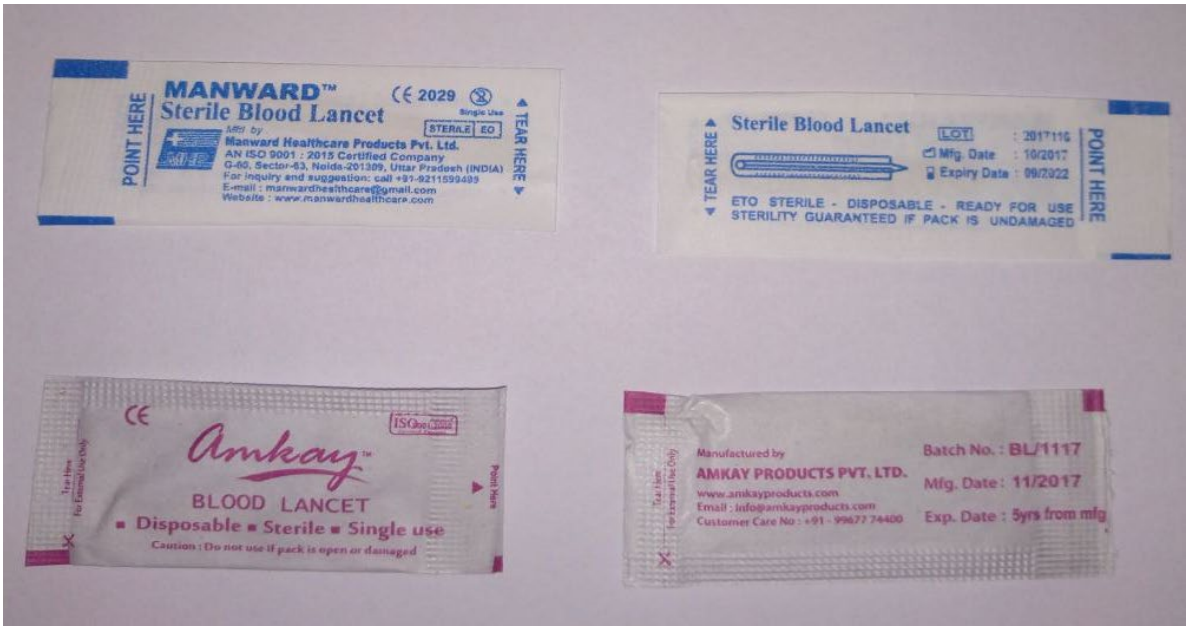
1.3 Alcohol swab label



1.4 Buffer vial label

1.5 Blood collection device (loop)

1.6 Blood lancet labels (stainless steel blood lancet)



2. Instructions for use[4]

[4] 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.

274 mm x 218 mm

CE

paracheck® Pf

RAPID TEST FOR *P. FALCIPARUM* MALARIA (Ver.3)

DEVICE

INTENDED USE

paracheck Pf® is an *invitro*, rapid, qualitative, two site sandwich immunoassay for the determination of *P. falciparum* specific histidine rich protein - 2 (Pf. HRP-2) in whole blood (capillary or venous) for the diagnosis of falciparum malaria in individuals with signs and symptoms consistent with malaria infection. The test is intended for healthcare professionals at the clinical setup and point of care sites.

SUMMARY

Four species of the Plasmodium parasites are responsible for malaria infections in humans viz. *P. falciparum, P. vivax, P. ovale* and *P. malariae*. Of these *P. falciparum* is the most prevalent and severe species that is responsible for most of the morbidity and mortality worldwide. Early detection of *P. falciparum* malaria is of paramount importance due to incidence of cerebral malaria and drug resistance associated with it. Pf. HRP-2 is a water soluble protein that is released from parasitised erythrocytes of infected individuals and is specific to the *P. falciparum* species.
paracheck Pf® detects the presence of Pf. HRP-2 in venous or capillary whole blood specimen and is a sensitive and specific test for the detection of *P. falciparum* malaria.

PRINCIPLE

paracheck Pf ® utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. As the test specimen flows through the membrane assembly of the device after addition of the clearing buffer, the colored Agglutinating Sera for HRP-2-colloidal gold conjugate complexes the HRP-2 in the lysed specimen. This complex moves further on the membrane to the test region where it is immobilised by the Agglutinating Sera for HRP-2 coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any, move further on the membrane and are subsequently immobilised by the Agglutinating Sera for Rabbit globulin coated on the membrane at the control region, forming a colored band. The control band formation is based on the 'Rabbit globulin / Agglutinating Sera for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED

paracheck Pf® kit contains :

A. Individual pouches, each containing :
   1. DEVICE Membrane assembly predispensed with Agglutinating Sera for HRP-2 - colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, Agglutinating Sera for HRP-2 and Agglutinating Sera for rabbit globulin at the respective regions.
   2. Desiccant pouch.
   3. PIPETTE Disposable 5µl specimen applicator.

B. BUF Clearing buffer containing surfactant and preservative in a dropper bottle.
C. Instructions for Use.
D. Pictorial representation.
E. Alcohol swabs.
F. Sterile lancets.

REF	302030001	302030005	302030010	302030025	302030025(1T)	302030100
Σ	1	5	10	25	25 x 1	100

MATERIALS REQUIRED BUT NOT PROVIDED

Calibrated micropipette capable of delivering 5µl specimen accurately, disposable micropipette tips. Permanent marker Pen/pencil, disposable gloves, timer. Biosafety sharps container and Biohazard waste container (for potentially infectious waste). Venipuncture blood collection kit (if whole blood is collected by venepuncture).Additional alcohol swabs (if any included in the kit are found dry) and additional sterile lancets (if any included in the kit misfire/ do not produce sufficient blood volume).

STORAGE AND STABILITY

The test kit may be stored between 4°C To 45°C till the duration of the shelf life as indicated on the pouch / carton.
After first opening of the clearing buffer, the buffer is stable until the expiry date mentioned on the vial label, if kept at 4°C To 45°C. DO NOT FREEZE the kit or components.

WARNINGS AND PRECAUTIONS

Read the instructions carefully before performing the test.
For *in vitro* diagnostic use only. NOT FOR MEDICINAL USE. For professional use.
The test is not intended for use in screening of asymptomatic individuals or for monitoring of success of therapy.
Do not use beyond expiry date.
Do not intermix components of one kit with another.
Handle all specimens as potentially infectious.
Follow standard biosafety guidelines for handling and disposal of potentially infective material.
Clearing buffer contains Sodium Azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.
The test device is intended for SINGLE USE ONLY.
Reduced light conditions increase risk of errors during testing and interpretation of test results. Make sure that the test performance and test interpretation is carried out in sufficient light conditions.
Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

Fresh anti coagulated whole blood should be used as test specimen and EDTA or Heparin or Oxalate can be used as suitable anticoagulant. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then specimen may be stored at 2°C To 8°C for upto 72 hours before testing. For long-term storage, freeze the specimen below -20ºC. Repeated freezing and thawing of the specimen should be avoided (Maximum of 2 freeze/thaw cycles are allowed). Thawed specimens must be mixed gently prior to testing. Hemolysed, clotted or contaminated blood specimens should not be used for performing the test. Fresh blood from finger prick / puncture may also be used as a test specimen.

TEST PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the **paracheck Pf**® kit components to room temperature before testing.
2. Check the expiration date of the kit (including buffer). If expired, do not use but take another unexpired kit.
3. Check that the cassette packaging is not damaged. If damaged, discard the test and use another test.
4. In case the pouch has been stored at 2°C To 8° C allow atleast 30 minutes for the device to come to room temperature.
5. Open the pouch and retrieve the device, specimen applicator and desiccant. Check the colour of the desiccant. It should be blue. If it has turned colourless or pink discard the device and use another device. ***Once opened, the device must be used immediately.***
6. Label the device with patient name or identifier.
7. Put on gloves. Use new gloves for each patient.
8. For 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. Preferably choose the 3rd or 4th finger of the hand the patient does not use to write.
    3. Open the packaging of the alcohol swab. Take out the alcohol swab. Do not throw away the empty packaging (wrapper) but keep it aside.
    4. Wipe the complete fingertip with the alcohol swab. Wait until the finger has completely dried (minimum 30 seconds).
    5. 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).
    6. Take the sterile lancet.
    7. Detach the sterile lancet from the pouch, taking care not to touch the tip/ point. 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.
    8. Make sure a well-formed drop of blood is present.
    9. If there is no well-formed drop of blood, repeat the finger prick using a new lancet and choose a different puncture site.
    10. Take the specimen applicator and collect 5 µl of blood by dipping the circular end of the specimen applicator into the whole blood drop.
    11. Place the circular end of the specimen applicator in the rectangular well (marked "A") so that it touches the strip (pad at the bottom of the well).Press down lightly to transfer all the blood to the strip. Put the used specimen applicator into the non-sharps disposal container for potentially infectious waste.
    12. 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 for potentially infectious waste.
    13. Take the buffer bottle. Hold the open buffer bottle vertically above the circular well (marked "B"). In a vertical position, squeeze the buffer bottle gently and apply exactly 2 drops into the circular well (marked "B") without contacting the device to avoid contamination.
    14. Remove your gloves and discard them into the non-sharps disposal container for potentially infectious waste.
    15. Write the time on the cassette or set a countdown timer to the required reading time.

16. Read test results after a minimum of 20 minutes but no later than 30 minutes. Use a good light source when reading the test results.

For Venous whole blood from venipuncture

1. Wear gloves.
2. Collect blood by standard venipuncture procedure into a tube containing the correct anticoagulant (EDTA,heparin or oxalate).
3. Mix the tube gently.
4. Transfer 5 µl of whole blood in the rectangular well (marked "A") of the cassette using a precision pipette.
5. Perform steps 12–16 of the previous section ("Capillary whole blood from finger prick").

INTERPRETATION OF RESULTS

NEGATIVE for *P. falciparum* malaria: A colored band appears in the control window 'C'.

POSITIVE for *P. falciparum* malaria : In addition to the control band, a distinct colored band also appears in the test window 'T'.

INVALID : The test should be considered invalid if no colored band appears on the device. The test should also be considered invalid if a colored band appears only at the test window 'T' and not at the control window 'C'. In such cases, repeat the test with a new device, ensuring that the test procedure has been followed accurately.

QUALITY CONTROL RECOMMENDATIONS

To control proper test performance, it is recommended to include internal positive and negative control specimens.

PERFORMANCE CHARACTERISTICS

Diagnostic Sensitivity And Specificity:

1. In an internal study, a panel of 498 specimens whose results were earlier confirmed with microscopy were tested with **paracheck Pf®**. The results obtained are as follows:

Specimen type	Total no. of specimens tested	paracheck Pf®		Sensitivity * %	Specificity* %
		Positive	Negative		
Malaria negative	210	2	208	-	99.05%
P. vivax positive	114	0	114	-	100%
P. falciparum positive	154	153	1	99.35%	-
RF positive (Malaria Negative)	20	0	20	-	100%

2. In an independent study, 192 whole blood specimens of febrile patients whose results were confirmed by microscopy were tested with **paracheck Pf®**. The results obtained are as follows:

Specimen type	Total no. of specimens tested	paracheck Pf®	
		Positive	Negative
Malaria negative	96	0	96
P. vivax positive	40	1	39
P. falciparum positive	50	49	1
P. vivax & *P. falciparum* positive (mixed infection)	6	6	0

paracheck Pf® was found to be 98.2% sensitive and 99.3% specific to *P. falciparum* malaria against microscopy.
* Relative Sensitivity and Specificity at 95% confidence intervals.

Possible Interferences:

paracheck Pf® was tested using a variety of potentially interfering substances as given:

a) Endogenous components: Substances such as bilirubin (direct, total), creatinine, triglycerides, uric acid, lipase proteins

and others at high physiological levels.

b) Exogenous components: substances such as anti-malarial drugs, antibiotics, anti-inflammatory drugs at high therapeutic concentrations.

c) Pathogens: e.g. HIV (1 and 2), HBV, HCV, *M. tuberculosis*, *S. typhi* and others. All specimens tested generated negative results in **paracheck Pf®**.

Precision:

Reproducibility and Repeatability studies (inter-assay and inter lot) were carried out using a number of malaria negative and Pv. positive specimens; and of strong, low positive and limit of detection Pf. positive specimens. **paracheck Pf®** generated results indicating 100% reproducibility and 100% repeatability.

From the above results and the results of in house data, **paracheck Pf®** is a highly sensitive and specific test for the diagnosis of malaria caused by *P. falciparum*.

LIMITATIONS OF THE TEST

1. As with all diagnostic tests, the test result must always be correlated with clinical findings. Negative results must be confirmed by microscopic examination of thick smear and thin blood films. As is often done in serial microscopy testing, another specimen may be collected and tested.
2. A positive result must be verified with a confirmation test.
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.
4. Interference due to presence of heterophile antibodies in patient's specimen can lead to erroneous analyte detection in immunoassay, has been reported in various studies. **paracheck Pf®** uses HETEROPHILIC BLOCKING REAGENT (HBR) to inhibit majority of this interference.
5. In *P. falciparum* malaria infection, HRP-2 is not secreted in gametogony stage. Hence, in "Carriers", the HRP-2 band may be absent.
6. Since the Pf. HRP-2 persists for upto a fortnight even after successful therapy, a positive test result does not indicate a failed therapeutic response.
7. Do not interpret the test results beyond 30 minutes.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Howard, R. J., et al., 1986 : Secretion of Malarial Histidine-Rich Protein (Pf. HRP II) from *Plasmodium falciparum*-infected Erythrocytes. J. Cell Biol., 103, 1269-1277.
2. Rock, E.P., et al., 1987 : Comparative Analysis of the *Plasmodium falciparum* Histidine-Rich Proteins HRP-I, HRP-II and HRP-III in Malaria Parasites of Diverse Origin. Parasitol., 95, 209-227.
3. Parra, M.E., et al., 1991 : Identification of *Plasmodium falciparum* Histidine-Rich Protein 2 in the Plasma of Humans with Malaria, J. Clin. Microbiol., 29, 1629-1634.
4. Rodriguez-Del Valle, M., et al., 1991 : Detection of Antigens and Antibodies in the Urine of Humans with *Plasmodium falciparum* Malaria. J. Clin. Microbiol., 29, 1236-1242.
5. Data on file : Orchid Biomedical Systems.

SYMBOL KEYS

Temperature Limitation	Manufacturer	DEVICE — Device	Contains sufficient for <n> tests
Use by	Consult Instructions for use	PIPETTE — Disposable Plastic Specimen Applicator	Do not reuse
Date of Manufacture	REF — Catalogue Number	BUF — Clearing Buffer	This side up
LOT — Batch Number / Lot Number	IVD — In vitro Diagnostic Medical Device	EC REP — Authorised Representative in the European Community	

0522/VER-05
Date of issue:2023-01

Manufactured by:
Orchid Biomedical Systems
A Division of Tulip Diagnostics (P) Ltd.
88/89, Phase II C, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.
Email address: sales@tulipgroup.com
Tel. : (0832) 2458546, (0832) 2458547

EC REP
CMC Medical Devices & Drugs S.L., Spain

137mm x 218mm

CE

paracheck® Pf

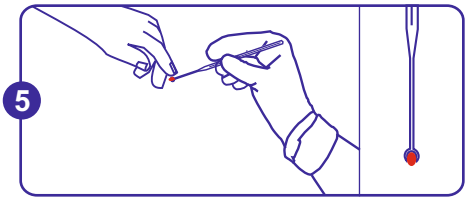
RAPID TEST FOR *P. FALCIPARUM* MALARIA (Ver.3)

Test Procedure

1

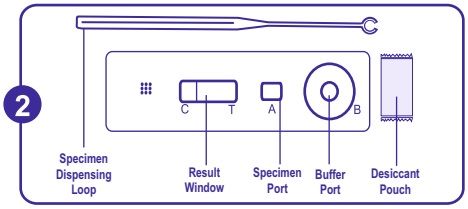
Open pouch at cut mark and remove all the contents; the device, disposable specimen applicator & desiccant pouch. Once opened, the device must be used immediately.

5



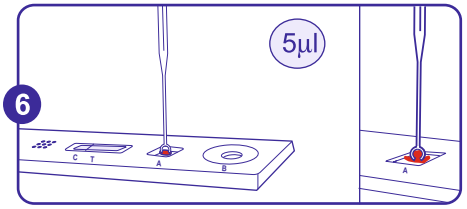
Touch the circular end of the specimen applicator to the blood specimen on the finger prick. Ensure that applicator full of blood is retrieved.

2



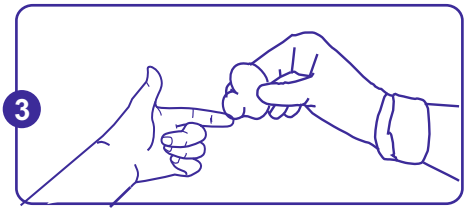
Component details are shown above. Check the colour of the desiccant. It should be blue, if it has turned colourless or pink, discard the device & use a new device.

6



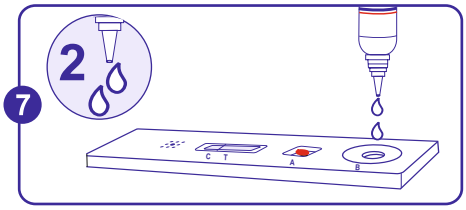
Blot the collected blood (5µl) in the specimen port 'A' by touching applicator vertically straight. Ensure that the blood from the applicator has been completely taken up at the specimen pad.

3



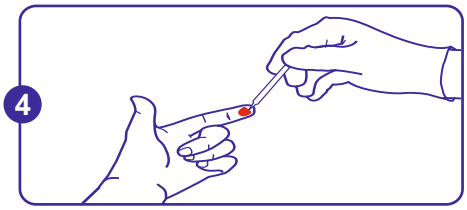
Clean finger to be pricked with an alcohol swab. Allow to dry

7



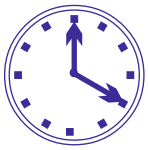
Hold the clearing buffer vial vertically straight over the buffer port 'B' & add exactly 2 drops of buffer onto the buffer port. Start the stopwatch.

4



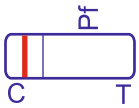
Take a lancet & prick the finger with the pointed end of the lancet.

8 **20 Minutes**

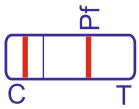


Read the test results at the end of 20 minutes.

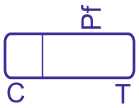
Interpretation of Results



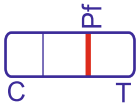
Band on 'C' Area
NEGATIVE
for *P.f.* Malaria



Band on 'C'&'T' Area
POSITIVE
for *P.f.* Malaria



No band on 'C'&'T' Area
INVALID
Repeat the test



No band on 'C',Band on 'T' Area
INVALID
Repeat the test

137mm x 218 mm

Precautions in Malaria RDT Procedure

Do's

- Once opened use the device immediately.
- Always check the colour of desiccant immediately after opening the pouch. It should be blue in colour, if it has turned colourless or pink, discard the device and use a new device.
- In case of anti-coagulated venous blood, ratio of blood & anticoagulant (1:9) should be accurate as recommended.
- In case test device pouches have been stored at 2°C To 8°C, they must be allowed to come to ambient temperature before pouches are opened.
- Always evenly mix anti-coagulated blood specimen gently before testing.
- Always make sure that the blood from specimen applicator/applicator has been completely transferred to the specimen pad.
- Stored cold whole blood specimen must be allowed to come to ambient temperature before testing.
- Read the result only at the end of recommended reading time of 20 minutes.
- Always lay the device horizontally on a flat surface before testing.
- Users, who interpret the test result must be trained to read the test band signals with low analyte concentration specimens.

Don'ts

- Do not use blood specimens, stored more than 72 hours.
- In case device pouches has been stored at 2°C To 8°C, do not open the pouches immediately after retrieval from 2°C To 8°C storage. Cold devices will attract moisture rush thereby altering migration properties of the membrane.
- Do not use the cold whole blood specimen (<25°C) as test specimen. Use of cold blood may affect the clearance of test window and also affect the sensitivity and specificity of the RDTs.
- Do not use clotted, partially clotted, lysed, or contaminated whole blood specimens.
- Do not reuse the specimen applicator/ applicator.
- Do not intermix the buffer and device of different lots.
- Do not dispense excess/less drops of buffer in the buffer port than those recommended in test procedure. This could affect the reaction kinetics between target antigen and capture elements of test system.
- Do not move the device during the assay. It could affect the buffer flow.
- Do not compare test band intensity with control band intensity.
- Do not repeatedly freeze/thaw test specimens. Freeze/thaw accelerates target antigen denaturation and hampers test's performance.

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