WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: AdvDx Malaria Pf Rapid Malaria Ag Detection Test
WHO reference number: PQDx 0345-101-00

AdvDx Malaria Pf Rapid Malaria Ag Detection Test with product codes 00-DKM-RK-MAL-ADX-004-001, 00-DKM-RK-MAL-ADX-004-025, 00-DKM-RK-MAL-ADX-004-010, 00-DKM-RK-MAL-ADX-004-050, 00-DKM-RK-MALADX- 004-001-010 and 00-DKM-RK-MALADX- 004-001-25, manufactured by Advy Chemical Pvt Ltd., Rest-of-World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 16 May 2019.

Summary of WHO Prequalification Assessment for AdvDx Malaria Pf Rapid Malaria Ag Detection Test

	Date	Outcome
Prequalification listing	16 May 2019	listed
Dossier assessment	5 December 2018	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 the WHO has been notified and has undertaken a review. The amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment and change request reference, where applicable.	Date of report amendment
2.0	Modified artwork components (carton, pouch, buffer bottle labels) and IFU to reflect a new manufacturing license. The manufacturer introduced new configurations to the prequalified product with new product codes, 00-DKM-RK-MAL-ADX-004-001, 00-DKM-RK-MAL-ADX-004-010, and 00-DKM-RK-MAL-ADX-004-050.	3 October 2023.
3.0	Updated the IFU to remove the inverted cup and blood lancets included in the IFU ADFE025KI-1, issued on 2023-04.	4 July 2024.
4.0	Updated the public report to include the product codes for complete single test kits, with product codes 00-DKM-RK-MALADX- 004-001-010 and 00-DKM-RK-MALADX- 004-001-25.	11 October 2024.

5.0	1. Change of the lancet from a stainless-steel lancet to a plastic blood lancet (PQC-IVD-2024-0048). 2. Change of the sample applicator from a sample dropper to an inverted cup applicator (PQC-IVD-2025-0014). 3. Change of the CE Authorised Representative name and address on the product labelling (IFU and kit carton), with no change to the legal entity (PQC-IVD-2025-0040).	8 January 2026

Intended use

According to the manufacturer, "*AdvDx Malaria Pf Rapid Malaria Ag Detection Test is an in-vitro diagnostic Immunochromatographic assay for the qualitative detection of malaria infection caused by Plasmodium falciparum parasites in humans. It detects HRP-II (Histidine Rich Protein-II) antigen of Plasmodium falciparum in whole blood specimens. It does not assess parasite densities. The test must be performed by a trained professional user and not by lay users.*"

Test kit contents

Component	**1 Test/kit (T/kit)** (00-DKM-RK-MAL-ADX-004-001)	**10 T/kit** (00-DKM-RK-MAL-ADX-004-010)	**25 T/kit** (00-DKM-RK-MAL-ADX-004-025)	**50 T/kit** (00-DKM-RK-MAL-ADX-004-050)	Qty. in Complete Single Test kit 25 Tests/Carton (00-DKM-RK-MALADX-004-001-250	Qty. in Complete Single Test kit 10 Tests /Carton (00-DKM-RK-MALADX-004-001-010)
The AdvDx Malaria Pf Test Device is individually foil-pouched with a desiccant.	1	10	25	50	Complete Single Test Kit: 25 Tests	Complete Single Test Kit: 10 Tests
Sample applicator	1	10	25	50		
Alcohol Swab	1	10	25	50		
Lancet	1	10	25	50		
Buffer solution	1 x 0.2 ml/ ampoule	3.0 ml/ ampoule	1 x 3.0 ml/ampoule	3 x 3.0 ml/Bottle		
Product Insert (IFU)	1	1	1	1		

Items required but not provided

- Timer;
- New pair of disposable gloves;
- Pen/pencil;
- Biosafety sharps container;
- Biohazard waste container (for potentially infectious waste);
- If whole blood is collected by venipuncture, Venipuncture blood collection materials and precision pipette, plus tips, and;
- Sterile gauze or cotton.

Storage

The test must be stored between 2 and 40 °C.

Shelf-life upon manufacture[1]

24 months.

Dossier assessment

Advy Chemical Pvt Ltd. submitted a product dossier for the AdvDx Malaria Pf Rapid Malaria Ag Detection Test as per the "*Instructions for compilation of a product dossier*" (PQDx_018 v1). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

Based on the product dossier screening and assessment findings, the AdvDx Malaria Pf Rapid Malaria Ag Detection Test product dossier meets WHO prequalification requirements.

Manufacturing site inspection

The inspection of the manufacturing site(s) was conducted to assess whether the manufacturer's quality management system (QMS) and manufacturing practices are in alignment with:
(i) applicable international standards, such as ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes);
(ii) the manufacturer's own documented procedures and quality requirements; and
(iii) other relevant international standards and guidelines applicable to in vitro diagnostic (IVD) medical devices. The WHO's Public Inspection Reports are accessible at:

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

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

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, a P. falciparum wild-type parasite panel, a P. vivax wild-type parasite panel and a Plasmodium spp. negative panel. Thermal stability was assessed after two 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 (80.0% at 200 parasites/µl), false-positive rates (0.0% for clean negatives, 0.0% for P. vivax at 200 parasites/µl, 0.0% for P. vivax at 2000 parasites/µl) and invalid rate (0.0%), AdvDx Malaria Pf Rapid Malaria Ag Detection Test meets the current laboratory evaluation requirements for prequalification.

Summary performance characteristics	***Panel detection score (%)***	***False positive rate (%)***		***Invalid rate (%)***
	200 parasites/µl	***200 parasites/µl***	***Clean negatives***	
	Pf	***Pv***		
AdvDx Malaria Pf Rapid Malaria Ag Detection Test	*80.0*	*0.0*	*0.0*	*0.0*

Labelling review

The labelling submitted for Abbott RealTime HIV-1 Qualitative (m2000sp) assay was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

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

Controlled Labelling References

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	Complete single Test kit (English)	2	Nov-25	ADFE001IC-2
	25 T Inner carton (English)	2	Nov-25	ADFE025IC-2
	10 T Inner carton (English)	2	Nov-25	ADFE010IC-2
	50 T Inner carton (English)	2	Nov-25	ADFE050IC-2
Pouch / Device label	Aluminium Pouch	1	Apr-23	ADFE001AP-1
Reagent bottle labels	Buffer bottle 5 ml	1	Apr-21	ADXBL-1
Instructions for Use (IFU)	Kit Insert (English)	7	Jul-25	ADFE025KI-7
Alcohol Swab	Amkay	NA	NA	NA
	Mac	NA	NA	NA
Blood Lancet	Tianjin	NA	NA	NA
	Shandong	NA	NA	NA

Labels

Adv Dx™ MALARIA Pf

Complete Single Test Kit

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

Not for Self-testing

For *In Vitro* Diagnostic Use Only
Store at 2 - 40°C

Adv Dx™

MALARIA Pf

Rapid Malaria Ag Detection Test
Detection of Pf (HRP-II) Antigen

Adv Dx™ MALARIA Pf

CONTENTS:

- Product Insert : 1 NO.
- Test Device individual foil : 1 NO. pouched with a desiccant
- Sample Applicator (Inverted Cup) : 1 NO.
- Alcohol Swab : 1 NO.
- Blood Lancet : 1 NO.
- Buffer Solution (0.2 ml/ampoule) : 1 NO.

Materials required but not Provided :

- Timer
- Suitable eye protection
- New pair of disposable gloves
- Pen/pencil
- BioSafety sharps container
- Biohazard waste container (for potentially infectious waste)
- If whole blood is collected by venipuncture, Venipuncture blood collection materials and precision pipette, plus tips.
- Sterile Gauze or cotton.

REF : 00-DKM-RK-MAL-ADX-004-001

Mfg. Lic. No. : MFG/IVD/2021/000020

LOT :

MFG :

EXP :

M.R.P. ₹. :
(Incl. of all Taxes)

Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only

Disposal: Dispose all the samples and kit properly as per the instructions after test in accordance with GLP.

2°C 40°C IVD

EC REP QbD RepS BV, Groenenborgerlaan 16 2610 Wilrijk, Belgium

CE

Manufactured in India by:
ADVY CHEMICAL PVT. LTD.
Plot No. A - 334 / 336 / 338,
A - 337 & 339, Road No. 25 & 26,
Wagle Industrial Estate, Thane - 400 604, INDIA.
info@advychemical.com
www.advychemical.com

Customer Care :
Contact No. +91 8657428614
E-mail: customerfeedback@advychemical.com

ADFE001IC-2

Adv Dx™

MALARIA Pf

Rapid Malaria Ag Detection Test
Detection of Pf(HRP-II) Antigen

Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing

Σ 25

D
ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

REF : 00-DKM-RK-MAL-ADX-004-025

CONTENTS:

Product Insert	: 1 No.
Test Device individual foil pouched with a desiccant	: 25 Nos.
Sample Applicator (Inverted Cup)	: 25 Nos.
Alcohol Swab	: 25 Nos.
Blood Lancet	: 25 Nos.
Buffer Solution (3.0 ml/Bottle)	: 1 No.

Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only

Disposal: Dispose all the samples and kit properly as per the instructions after test in accordance with GLP.

2°C 40°C IVD

EC REP QbD RepS BV, Groenenborgerlaan 16 2610 Wilrijk, Belgium CE

Materials required but not Provided :

- Timer
- Suitable eye protection
- New pair of disposable gloves
- Pen/pencil
- BioSafety sharps container
- Biohazard waste container (for potentially infectious waste)
- If whole blood is collected by venipuncture, Venipuncture blood collection materials and precision pipette, plus tips.
- Sterile Gauze or cotton.

MALARIA Pf
Rapid Malaria Ag Detection Test

ADFED25IC-2

Adv Dx™

MALARIA Pf

Rapid Malaria Ag Detection Test
Detection of Pf(HRP-II) Antigen

Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing

Σ 25

D
ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

Mfg. Lic. No.: MFG/IVD/2021/000020

LOT :
MFG :
EXP :
M.R.P. ₹. :
(Incl. of all Taxes)

Manufactured in India by :
ADVY CHEMICAL PVT. LTD.
Plot No. A - 334 / 336 / 338,
A - 337 & 339, Road No. 25 & 26,
Wagle Industrial Estate, Thane - 400 604, INDIA.
info@advychemical.com • www.advychemical.com

Customer Care :
Contact No. **+91 8657428614**
E-mail: customerfeedback@advychemical.com

MALARIA Pf
Rapid Malaria Ag Detection Test

Adv Dx™

MALARIA Pf

Rapid Malaria Ag Detection Test
Detection of Pf (HRP-II) Antigen

Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only

Not for Self-testing

Σ 10

D
ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

REF : 00-DKM-RK-MAL-ADX-004-010

CONTENTS:

Product Insert	: 1 No.
Test Device individual foil pouched with a desiccant	: 10 Nos.
Sample Applicator (Inverted Cup)	: 10 Nos.
Alcohol Swab	: 10 Nos.
Blood Lancet	: 10 Nos.
Buffer Solution (3.0 ml/Bottle)	: 1 No.

Materials required but not Provided :
- Timer
- Suitable eye protection
- New pair of disposable gloves
- Pen/pencil
- BioSafety sharps container
- Biohazard waste container (for potentially infectious waste)
- If whole blood is collected by venipuncture, Venipuncture blood collection materials and precision pipette, plus tips
- Sterile Gauze or cotton.

Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only

Disposal: Dispose all the samples and kit properly as per the instructions after test in accordance with GLP.

2°C 40°C IVD

EC REP QbD RepS BV, Groenenborgerlaan 16
2610 Wilrijk, Belgium CE

ADFE010IC-2

Adv Dx™

MALARIA Pf

Rapid Malaria Ag Detection Test
Detection of Pf (HRP-II) Antigen

Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only

Not for Self-testing

Σ 10

D
ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

Mfg. Lic. No.: MFG/IVD/2021/000020

LOT :

MFG :

EXP :

M.R.P. ₹. :
(Incl. of all Taxes)

Manufactured in India by:
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Plot No. A - 334 / 336 / 338,
A - 337 & 339, Road No. 25 & 26,
Wagle Industrial Estate, Thane - 400 604, INDIA.
info@advychemical.com
www.advychemical.com

Customer Care :
Contact No. +91 8657428614
E-mail: customerfeedback@advychemical.com

MALARIA Pf
Rapid Malaria Ag Detection Test

Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing

Σ 10

D
ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

Adv Dx™

MALARIA Pf

Rapid Malaria Ag Detection Test
Detection of Pf (HRP-II) Antigen

Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing
50
ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified
MALARIA Pf
Rapid Malaria Ag Detection Test
Detection of Pf (HRP-II) Antigen
Adv Dx™

Adv Dx™

MALARIA Pf

Rapid Malaria Ag Detection Test
Detection of Pf (HRP-II) Antigen

Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing

Σ 50

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

REF : 00-DKM-RK-MAL-ADX-004-050

CONTENTS:

Product Insert	: 1 No.
Test Device individual foil pouched with a desiccant	: 50 Nos.
Sample Applicator (Inverted Cup)	: 50 Nos.
Alcohol Swab	: 50 Nos.
Blood Lancet	: 50 Nos.
Buffer Solution (3.0 ml/Bottle)	: 3 Nos.

Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only

Disposal: Dispose all the samples and kit properly as per the instructions after test in accordance with GLP.

2°C 40°C IVD

EC REP QbD RepS BV, Groenenborgerlaan 16 2610 Wilrijk, Belgium

CE

Materials required but not Provided :

- Timer
- Suitable eye protection
- New pair of disposable gloves
- Pen/pencil
- BioSafety sharps container
- Biohazard waste container (for potentially infectious waste)
- If whole blood is collected by venipuncture, Venipuncture blood collection materials and precision pipette, plus tips.
- Sterile Gauze or cotton.

MALARIA Pf
Rapid Malaria Ag Detection Test

ADFE050IC-2

Adv Dx™

MALARIA Pf

Rapid Malaria Ag Detection Test
Detection of Pf (HRP-II) Antigen

Store at 2 - 40°C
For In Vitro Diagnostic Use Only
Not for Self-testing

Σ 50

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

Mfg. Lic. No. : MFG/IVD/2021/000020
LOT :
MFG :
EXP :
M.R.P. ₹. :
(Incl. of all Taxes)

Manufactured in India by:
ADVY CHEMICAL PVT. LTD.
Plot No. A - 334 / 336 / 338,
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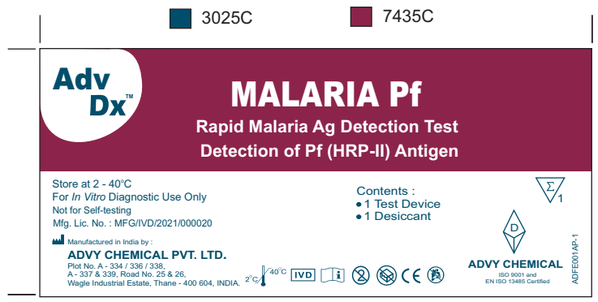
Wagle Industrial Estate, Thane - 400 604, INDIA.
info@advychemical.com • www.advychemical.com

Customer Care :
Contact No. **+91 8657428614**
E-mail: customerfeedback@advychemical.com

MALARIA Pf
Rapid Malaria Ag Detection Test

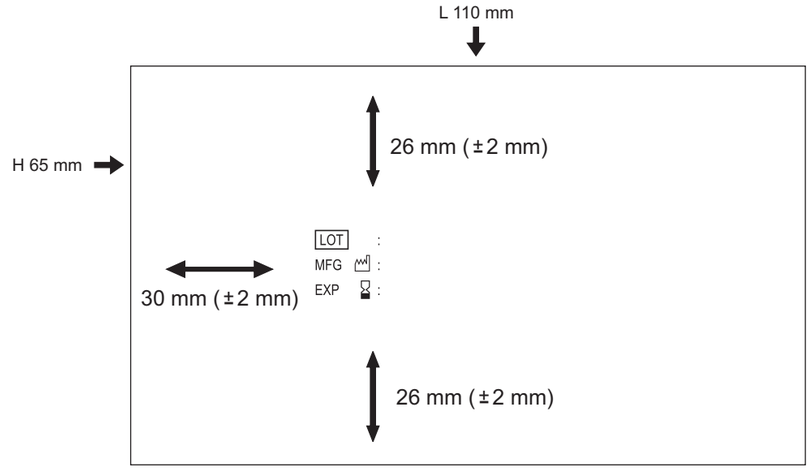
Advdx Malaria Pf_Pouch Label Front side

Lable Size L Text 90mm x H 40mm (Final Pouch Dimension 110 mm x 65 mm)



Advdx Malaria Pf_Pouch Label Back side

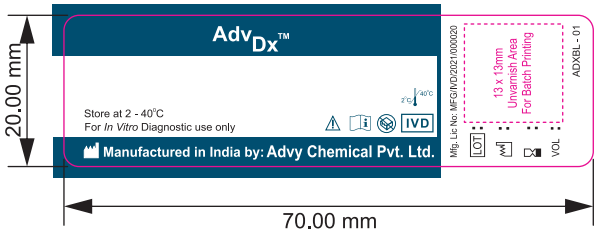
Pouch Size: L 110 mm x H 65 mm



Size: L 70mm x H 20mm

3025C Black

Ref.no: ADXBL- 01
Mfg. Lic. NO. MFG/IVD/2021/000020



CE

ISO 9001:2015

Amkay™ SWAB

70% IPA

Isopropyl Alcohol Swab

For Single Use

Tear Here

For External Use Only

Lot No. : AS / 0622

Mfg. : 06 / 2022

Exp. : 5 yrs. from mfg.

MFG/MD/2018/000084

Manufactured by

AMKAY PRODUCTS PVT. LTD.

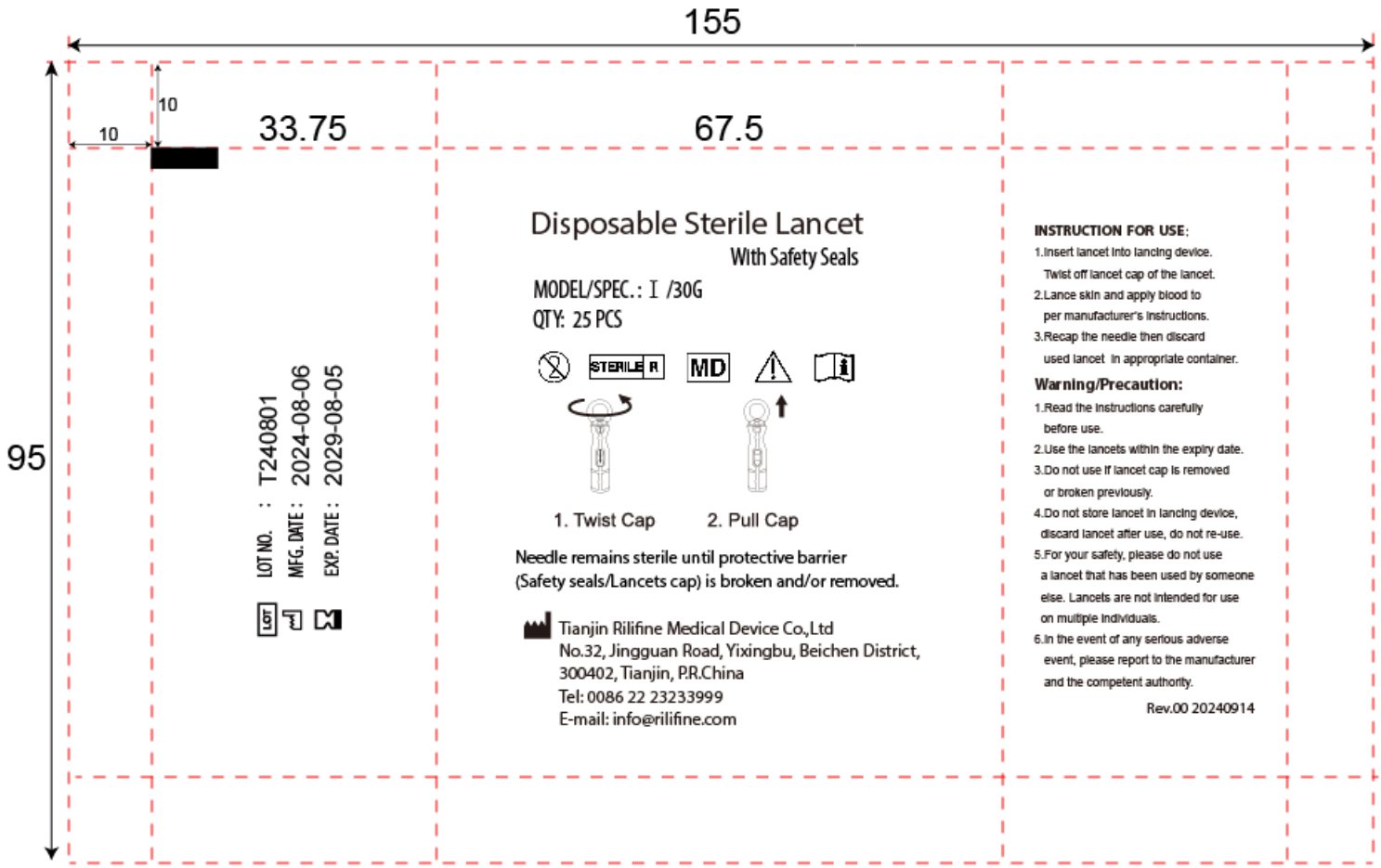
www.amkayproducts.com

Email : info@amkayproducts.com

Customer Care No : +91-77200 85358


MAK SWAB®
Alcohol Swab
FOR SINGLE USE


Alcohol Swab
70% Isopropyl Alcohol
FOR EXTERNAL USE ONLY
EACH SACHET CONTAINS
A non woven swab measuring
approx. 25x55mm, wetted with
a mixture of Isopropyl Alcohol and
Purified water (70:30v/v)
KEEP IN A COOL DRY & DARK PLACE
ISO 13485:2016
01/2028
02/2024
LOT 383
MAK MEDICALS PVT. LTD.
No.2, Shoghi Industrial Area Ph-II,
Shimla - 171219, Himachal Pradesh, India.
Mfg. Lic.No.: MFG/MD/2019/000028
Customer Care No.: +91- 9315102337
E-mail : makmedicalsltd@gmail.com


155
95
10
10
33.75
67.5
LOT NO. : T240801
MFG. DATE : 2024-08-06
EXP. DATE : 2029-08-05
Disposable Sterile Lancet
With Safety Seals
MODEL/SPEC.: I /30G
QTY: 25 PCS
STERILE R
MD
1. Twist Cap
2. Pull Cap
Needle remains sterile until protective barrier
(Safety seals/Lancets cap) is broken and/or removed.
Tianjin Rilifine Medical Device Co.,Ltd
No.32, Jingguan Road, Yixingbu, Beichen District,
300402, Tianjin, P.R.China
Tel: 0086 22 23233999
E-mail: info@rilifine.com
INSTRUCTION FOR USE:
1.Insert lancet into lancing device.
Twist off lancet cap of the lancet.
2.Lance skin and apply blood to
per manufacturer's instructions.
3.Recap the needle then discard
used lancet in appropriate container.
Warning/Precaution:
1.Read the instructions carefully
before use.
2.Use the lancets within the expiry date.
3.Do not use if lancet cap is removed
or broken previously.
4.Do not store lancet in lancing device,
discard lancet after use, do not re-use.
5.For your safety, please do not use
a lancet that has been used by someone
else. Lancets are not intended for use
on multiple individuals.
6.In the event of any serious adverse
event, please report to the manufacturer
and the competent authority.
Rev.00 20240914


Sterile Blood Lancets
Shandong Lianfa Medical Plastic Products Co., Ltd.
No.1 Shuangshan Sanjian Road, Zhangqiu, Jinan City,
250200, Shandong P. R. China
Model/Spec.: I/30G
08-07-2024
07-07-2029
Store the Product in a cool and dry place
25 Nos
LOT 24073090
STERILE R
Do not re-use
0197

Size: 50*40mm

Instructions for use[2]

[2] 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.

Adv Dx™

MALARIA Pf

Rapid Malaria Ag Detection Test

Detection of Pf (HRP-II) Antigen

ENGLISH

Identification number Product insert (IFU).: ADFE025KI-7

INTENDED USE

AdvDx™ Malaria Pf test kit is an in-vitro diagnostic Immunochromatographic assay for the qualitative detection of malaria infection caused by **Plasmodium *falciparum*** parasites in human. It detects HRP-II (Histidine Rich Protein-II) antigen of Plasmodium *falciparum* in whole blood specimens. It does not assess parasite densities. The test must be performed by trained professional user and not by lay users. The test is not intended for self-testing.

CLINICAL SIGNIFICANCE

Malaria is a serious, sometimes fatal, parasitic disease. It is characterized by fever with chills, anemia and is caused by Plasmodium parasite that is transmitted from one human being to another by the bite of infected Anopheles mosquitoes. Four species of the *Plasmodium parasite are* responsible for malaria infections in humans viz. *P. falciparum*, *P. vivax*, *P. ovale* and *P. malariae*. Of these, *P. falciparum* and *P. vivax* are the most prevalent. Early detection and differentiation of malaria is of paramount importance due to incidence of cerebral malaria and drug resistance associated with *falciparum* malaria causing most of the morbidity and mortality worldwide.

PRINCIPLE

AdvDx™ Malaria Pf test kit utilizes the principle of immunochromatography. It has the test strip coated with monoclonal Anti-HRP-II (test line Pf) which is specific to the histidine-rich protein-II of *P. falciparum*. As the test sample flows through the membrane assembly of the device after the addition of the buffer solution, the colored colloidal gold and the anti-HRP-II antibody conjugate complexes with the HRP-II antigen in the lysed blood sample. This antigen-antibody and colloidal gold complex binds with the antibody on the test line on the nitrocellulose membrane, which leads to the formation of the red / purple colored test band. The unreacted conjugate continues to migrate and is subsequently immobilized at the control "C" region, forming a red/purple band. The appearance of the control band proves that the sample or buffer has migrated through it, but it does not indicate that the specimen used was correct or that the assay procedure was followed correctly.

MATERIALS PROVIDED

A) **AdvDx™ Malaria Pf test** kit contains the following items to perform the assay:

Content	Qty. in 1T pack	Qty. in 10T pack	Qty. in 25T pack	Qty. in 50T pack	Qty. in Complete Single Test kit 25 Nos./Carton	Qty. in Complete Single Test kit 10 Nos./Carton
Product Insert	01 No.	01 No.	01 No.	01 No.	Complete Single Test Kit: 25 Nos.	Complete Single Test Kit: 10 Nos.
Test device Individually Foil pouched with a desiccant	01 No.	10 Nos.	25 Nos.	50 Nos.		
Sample Applicator (Inverted Cup)	01 No.	10 Nos.	25 Nos.	50 Nos.		
Alcohol swab	01 No.	10 Nos.	25 Nos.	50 Nos.		
Blood Lancet	01 No.	10 Nos.	25 Nos.	50 Nos.		
Buffer Solution	0.2 ml/ampoule	3.0 ml/Bottle	3.0 ml/Bottle	03 Nos. (3.0 ml/Bottle)		

B) Active ingredients of main components are:

- 1 test strip includes : Gold conjugate: Mouse monoclonal antibodies specific to Pf - HRP-II conjugated to colloidal gold, Control line : Goat anti-mouse IgG.
- Buffer Solution: Casein, Triton X-100 and Sodium azide as preservative.

Materials required but not provided

- Timer
- Suitable eye protection
- New pair of disposable gloves
- Pen/pencil
- BioSafety sharps container
- Biohazard waste container (for potentially infectious waste)
- If whole blood is collected by venipuncture, venipuncture blood collection materials and precision pipette, plus tips.
- Sterile gauze or cotton.

PRECAUTIONS

1. Read this insert carefully before carrying out the test and instructions must be followed exactly to get accurate results.
2. The device is sensitive to humidity as well as to heat. Therefore, take out the device from sealed pouch just before carrying out the test.
3. Ensure that **AdvDx™ Malaria Pf** test kits are stored between 2° C to 40° C for continued best performance. The deviation in the storage conditions can also cause weak test lines.
4. Do not use the kit after the expiration date.
5. Do not mix reagents from different lots.
6. For in-vitro diagnostic use only.
7. Wear protective gloves while handling samples and wash hands thoroughly after performing the test.
8. Do not pipette reagents or blood samples by mouth.
9. Do not re-use the test.
10. Buffer Solution contains Sodium azide as a preservative. In case of contact with skin, wash immediately. Wear gloves and eye protection as the buffer contains sodium azide.
11. Do not use any other buffer than the buffer supplied within this kit.
12. Dispose any left-over specimen, tested device, blood lancet, sample applicator (inverted cup), empty buffer vial, used alcohol swab and used hand gloves biohazard waste container in accordance with local regulation at the point of use. Silica pouch shall be opened and discarded in the local waste bin.Decontaminate and dispose all specimens, reaction kits and potentially contaminated materials (i.e. blood lancet, specimen applicator, test device) in a biohazard container as if they were infectious waste.

SPECIMEN COLLECTION, STORAGE & PRECAUTION

Specimen Required:

Capillary whole blood or whole blood with the following anticoagulants: EDTA, Citrate or Heparin

Collection by venipuncture

1. Collect the whole blood into the collection tube containing anticoagulant (EDTA, Citrate or Heparin) by venipuncture. Anticoagulant such as Heparin, EDTA and Citrate do not affect the test result.
2. If immediate testing is not possible then the samples may be stored at 2-8°C for upto 3 days. The samples should be brought to room temperature prior to use. Using samples kept for more than 3 days can cause non-specific reactions.

Collection with blood lancet:

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 that 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 need it again to stop the bleeding after you have collected the patient's blood).
6. Twist off the cap of the blood lancet to expose the needle. Prick the 3rd or 4th finger and wipe away the first drop of blood with sterile cotton gauze or cotton.
7. Hold the sample applicator (inverted cup) vertically, allow the blood drop from the pricked finger to touch the cup of the sample applicator (inverted cup)

Precaution:

1. Use separate sample applicator (inverted cup) (5µL) for each sample to avoid cross-contamination and erroneous results.
2. Do not use any other specimen than whole blood.
3. Do not re-cap the blood lancet and do not re-use.
4. Immediately dispose off the blood lancet in sharp container to avoid injury during disposal.

TEST PROCEDURE:

1. Allow **AdvDx™ Malaria Pf** test kit components and specimens to attain room temperature.
2. Open the pouch and take out the device from it.
   Note: The device contains a blue control line made up of water soluble dye that disappears as the test runs. (Refer Point 3 of test Procedure, Page No. 4)
3. Tighten the cap of the buffer bottle provided with the kit in a clockwise direction to pierce the bottle nozzle. Do not pierce with any sharp object or cut the nozzle with scissors.
4. In case of venipuncture whole blood specimen, evenly mix the anticoagulated blood sample by gently swirling and then dip the sample applicator (inverted cup) to draw 5 µL of the blood as shown in the figure. Failing to do so may lead to erroneous results.
   OR
   Into Sample Port 1 (S) of the test device, add the 5µL of venous blood drawn into the sample applicator (inverted cup), or capillary blood collected according to the instructions provided above (Collection with blood lancet).
5. Add 4 drops (110 µL ± 5µL) of buffer solution into the "Buffer Port 2 (B)" on the test device as low volumes of buffer may cause incomplete flow, delayed flow, incomplete background clearance making it difficult to interpret the result or increase in the likelihood of invalid results. Do not use excess buffer as it may alter the reaction time, resulting in reduced test sensitivity (false negatives).
6. Read the result at the end of 20 minutes.
7. Interpret the result. Refer figure mentioned in point No. 10 in page number 4.
   CAUTION: Do not read test after 30 minutes, since it may give incorrect results.
   INTERPRETATION OF THE RESULTS:

Whole blood samples may cause red background to appear in the result window.

NEGATIVE:

Only the Purple-coloured control band appears. Negative results indicate no malaria antigens present in the blood sample, indicating no malaria infection or the number of malaria antigens present in the blood sample is below the detectable range.

POSITIVE:

1)Pf Positive: Two bands ("Pf" Test line and Purple-coloured "C" Control line) appears within the result window indicates the infection of *P. falciparum*.

The shade of colour / intensity of band may vary, but it should be considered positive whenever there is a faint line. Faint lines may arise in case of samples with low parasite density as only a low concentration of detectable antigen will be present.

INVALID:

Absence of purple - colored band or blue colored band at control line (C) Blue colored or no band at control line (C) indicates that the test is invalid.

STORAGE AND EXPIRATION:

1. **AdvDx™ Malaria Pf** test Kit should be stored between 2°C to 40°C (36°F to 104°F). **Do Not freeze.**
2. The kit has a shelf-life of 24 months from the date of manufacture. The kit is stable until the expiration date marked on the product when stored as specified. The buffer is stable for 6 months after opening.

LIMITATIONS OF THE TEST:

1. **AdvDx™ Malaria Pf** test kit is designed for primary screening of malaria infection by *P. falciparum*. Although the test is accurate in detecting HRP-II specific to *P. falciparum* in blood samples, a low incidence of false results can occur. If you observe false positive in more than one cassette per kit immediately report to the contact provided. Other clinically available tests are required if questionable results are obtained as with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. Malaria RDTs can give positive results after successful anti-malarial treatment. Therefore, the **AdvDx™ Malaria Pf** test kit is not recommended for monitoring response to anti-malarial treatment.

QUALITY CONTROL

The control band acts as procedural control it must appear to prove active ingredients of test strip are functional and that sample or buffer have migrated properly. The control line is not meant for specimen addition monitoring.

PERFORMANCE CHARACTERISTICS:

The **AdvDx™ Malaria Pf** test kit has been tested with positive and negative clinical samples tested by microscopic examination of whole blood.

A.Sensitivity and Specificity

The sensitivity and specificity for **AdvDx™ Malaria Pf** test kit for P. *falciparum* malaria is 96.66% and 98.42% respectively. The performance of test was established by comparison with the results of microscopic examination of thick and thin films.

Result of AdvDx™ Malaria Pf	*Reference Method (Microscopic examination)*		*Total*
	Pf Positive	**Pf Negative**	
Positive	87	03	90
Negative	03	187	190
Total	90	190	280

% Sensitivity	5 % CI	% Specificity	5 % CI
96.6%	90.5% - 99.3%	98.4%	95.4% - 99.6%

B. Analytical Sensitivity (Limit of detection)

Analytical Sensitivity (LoD) of **AdvDx™ Malaria Pf** test kit is 200 P/µl of *P. falciparum* samples and comparable to microscopic observations.

C. Analytical Specificity (Cross reactivity)

Analytical Specificity of **AdvDx™ Malaria Pf** test kit studied with Infectious samples and different anticoagulants is 100%. Rheumatoid factor, dengue Ab, chikungunya and syphilis positive sample showed no cross reactivity and anti coagulants EDTA, heparin and sodium citrate did not show any interference with the performance of **AdvDx™ Malaria Pf** test kit

D. Precision:

Repeatability and Reproducibility of **AdvDx™ Malaria Pf** test kit is 100%.

REFERENCES:

1. World Health Organization – Geneva (2000). New perspectives Malaria diagnosis.
2. Perlmann, P and Troye-Blomberg, M. 2002. Malaria Parasites and disease. Malaria Immunology.
3. Malcolm, J.G., et al, 2002. Genome sequence of the human malaria parasite Plasmodium falciparum. Nature 419:498-511
4. Histidine Rich protein II: a novel approach to malaria drug sensitivity testing, Antimicrobial agents and Chemotherapy, June 2002, P. 1658-1664 Vol. 46, No.6.

DISCLAIMER:

Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. This product is used outside of the control of the manufacturer and the 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.

For any complaint / query and suggestions: **Customer Care No. +91 8657428614, feedback@advychemical.com, https://advychemical.com/**

ORDERING INFORMATION

PACK SIZE	REF
1 Test/Kit	00-DKM-RK-MAL-ADX-004-001
10 Test/Kit	00-DKM-RK-MAL-ADX-004-010
25 Test/Kit	00-DKM-RK-MAL-ADX-004-025
50 Test/Kit	00-DKM-RK-MAL-ADX-004-050
Single Test Kit 10 Nos./Carton	00-DKM-RK-MAL-ADX-004-001-010
Single Test Kit 25 Nos./Carton	00-DKM-RK-MAL-ADX-004-001-025

Mfg. Lic. No.: MFG/IVD/2021/000020

Manufactured in India By:

ADVY CHEMICAL PVT. LTD.

Plot No. A - 334 / 336 / 338,
A - 337 & 339, Road No. 25 & 26,
Wagle Industrial Estate, Thane - 400 604.
Email : info@advychemical.com
Website : www.advychemical.com

SYMBOL LEGENDS

Symbol Explanation of symbol		Symbol Explanation of symbol	
i	Consult instruction for use	☂	Keep Dry
	Do not use if package is damaged	LOT	Batch code No.
IVD	In vitro diagnostic device		Manufacturer
2°C – 40°C	Store at 2°c - 40°c		Date of Manufacture
	Keep away from sunlight		Use by (date or month of expiry)
2	Do not re-use	EC REP	Authorized representative in the European community
REF	Product code	Σ	Summation no. of test
	Not For Self-testing		

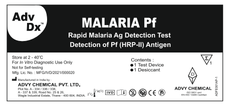
CE | EC REP | QbD RepS BV, Groenenborgerlaan 16, 2610 Wilrijk, Belgium

Date Issued: 2025-07

AdvDx™ Malaria Pf Test Procedure

1. First, carefully read the product insert on how to use the **AdvDx™ Malaria Pf** test kit.
2. Now open the kit and look for the following.

1) Test device individually foil pouched with a desiccant.



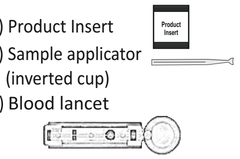
2) Buffer Solution

(For Multiple test Pack)

3) Product Insert

4) Sample applicator (inverted cup)

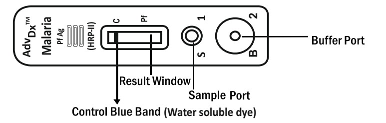
5) Blood lancet



6) Alcohol Swab

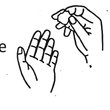
3. Next, look at the expiry date at the back of the pouch.
   Use another kit, if expiry date has passed.
   Open the pouch and look for the following.

7) Silica gel

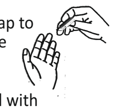


Note: Control blue band (water soluble dye) disappears as test runs and does not affect the test performance. Control blue band is visible in result window only before carrying out the test.

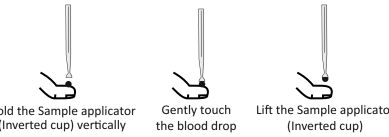
4. Clean the patient's finger.
   The alcohol MUST be dried before pricking, or test may not work.



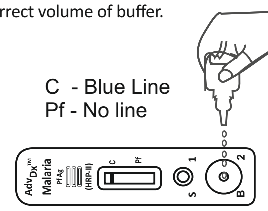
5. Twist off the blood lancet cap to expose the needle. Prick the patient' s finger with the lancet to get blood. (Wipe away the first drop of blood with sterile gauze or cotton. Do not apply excessive pressure or make multiple punctues)



6. Take 5µl Blood using the sample Applicator (inverted cup) provided.

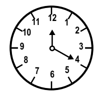


7. Add 5µLblood into sample Port 1(S).
8. Remove buffer bottle cap and add 4 drops of buffer solution into the buffer port (B) of the test device.
   Hold the buffer bottle vertically after dispensing the buffer. This ensures that the drop contains correct volume of buffer.

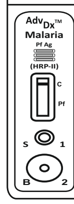
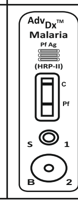


Add 4 drops(110 µL ± 5µL)
of buffer solution with even pressure

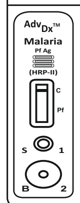
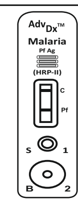
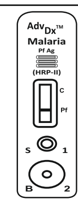
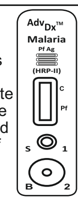
9. **INTERPRET TEST RESULTS AT THE END OF 20 MINUTES.**
   CAUTION : Do not read test after 30 minutes, as it may give incorrect results



10. Interpretation of Test Results.

Negative For Malaria		**Positive For Malaria**	
		Pf Positive	
	Only one purple colored Control band appears in the result window		In addition to purple colored Control band 'Pf' band appears in the result window

Invalid

	If the colour of the "C" control band is Blue, then result considered Invalid		If the colour of control line is blue and test band is purple, the result is considered invalid		If no purple color Control band appears in the result window in spite of appearance of Purple band at Test line Pf the test is considered Invalid		If no purple colour band appears at control as well as Test line, the test is considered invalid.