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, and 00-DKM-RK-MAL-ADX-004-050, 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
Site inspection(s) of the quality management system	2 October 2017	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. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment	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

Intended use

According to the manufacturer, **"*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.**"**.**

Assay description

According to the manufacturer, ***"AdvDx Malaria Pf** test utilizes the principle of Immuno-chromatography. 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 lysed blood sample. The malarial antigens get immobilized on the respective test lines on the nitrocellulose membrane which leads to the formation of red/purple colored band/s. The unreacted conjugate continues to migrate and is subsequently immobilized at the control "C" region forming a red/purple band. The control band demonstrates that liquid has migrated, but does not demonstrate that the assay procedure has been followed correctly. The control band must appear to prove that sample or buffer have migrated though it does not indicate that the specimen is correct and the assay procedure is followed correctly".*

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	Qty. in Complete Single Test kit 10 Tests /Carton
AdvDx Malaria Pf Test Device 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 kit should be stored at 2 - 40 °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 the WHO product testing of malaria RDTs results for Round 7 and eligibility criteria, the AdvDx Malaria Pf Rapid Malaria Ag Detection Test was prioritized for WHO prequalification assessment.

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.

The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 5 December 2018.

Commitments for prequalification

The manufacturer provided studies regarding the validation of 24 months of in-use and shipping stability. In addition, the manufacturer has provided an explanation regarding the inability of the manufacturer to provide a study responding to the commitment to prequalification for the clinical evaluation at this stage. The manufacturer's response is currently under review.
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

A comprehensive inspection was performed at the site(s) of manufacture (Plot No.A-334,336,338 & A-337 & 339 Road No. 25 & 26, Wagle Industrial Estate, Thane, India 400604) of **AdvDx Malaria Pf Rapid Malaria Ag Detection Test** on 2-4 October 2017 as per the "*Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics*" (PQDx_014). The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality.

The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 22 August 2018.

Based on the site inspection and corrective action plan review, the quality management system for **AdvDx Malaria Pf Rapid Malaria Ag Detection Test** meets WHO prequalification requirements.

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

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

1. Packaging Artwork and Labels

Adv Dx™ MALARIA Pf

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

Complete Single Test Kit

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

Adv Dx™ **MALARIA Pf**

CONTENTS :
- Product Insert
- Test Device individually foil pouched with a desiccant
- Sample Applicator
- Alcohol Swab
- Sterile Lancet
- Buffer Solution (0.2 ml/Ampoule)

Materials required but not Provided :
- Timer

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 Qarad EC-REP BV
Pas 257, 2440 Geel, Belgium

CE

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)

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 :
Telephone No: +91 8657428614
E-mail : customerfeedback@advychemical.com

ADFE001IC-1

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 individually foil pouched with a desiccant	: 10 Nos.
Sample Applicator	: 10 Nos.
Alcohol Swab	: 10 Nos
Sterile Lancet	: 10 Nos.
Buffer Solution (3.0 ml/Bottle)	: 1 No.

Materials required but not Provided :
• Timer

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 Qarad EC-REP BV
Pas 257, 2440 Geel, Belgium

CE

ADFE010IC-1

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

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

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Σ 10

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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

Σ 25

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

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

CONTENTS :

Product Insert	: 1 No.
Test Device individually foil pouched with a desiccant	: 25 Nos.
Sample Applicator	: 25 Nos.
Alcohol Swab	: 25 Nos
Sterile 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 Qarad EC-REP BV
Pas 257, 2440 Geel, 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

ADFE025IC-1

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

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

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

LOT :
MFG :
EXP :
M.R.P. ₹. :
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Manufactured in India by :
ADVY CHEMICAL PVT. LTD.
Plot No. A - 334 / 336 / 338,
A - 337 & 339, Road No. 25 & 26,
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info@advychemical.com • www.advychemical.com

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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 25

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

REF : 00-DKM-RK-MAL-ADX-004-001-025

CONTENTS :
Complete Single Test Kit : 25 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.

IFU | 2-40°C | IVD | 1

EC REP | Qarad EC-REP BV, Kha 257, 2440 Geel, 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

ADFE02050C-1

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

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

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

LOT :
MFG :
EXP :
M.R.P. ₹ :
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info@advychemical.com • www.advychemical.com

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MALARIA Pf
Rapid Malaria Ag Detection Test

Store at 2 - 40°C
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Σ 25

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EN ISO 13485 Certified

Adv Dx™

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

Store at 2 - 40°C
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Not for Self-testing

Σ 25

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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

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 individully foil pouched with a desiccant	: 50 Nos.
Sample Applicator	: 50 Nos.
Alcohol Swab	: 50 Nos
SterileLancet	: 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 Qarad EC-REP BV
Pas 257, B-2440 Geel, 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-1

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. ₹. :
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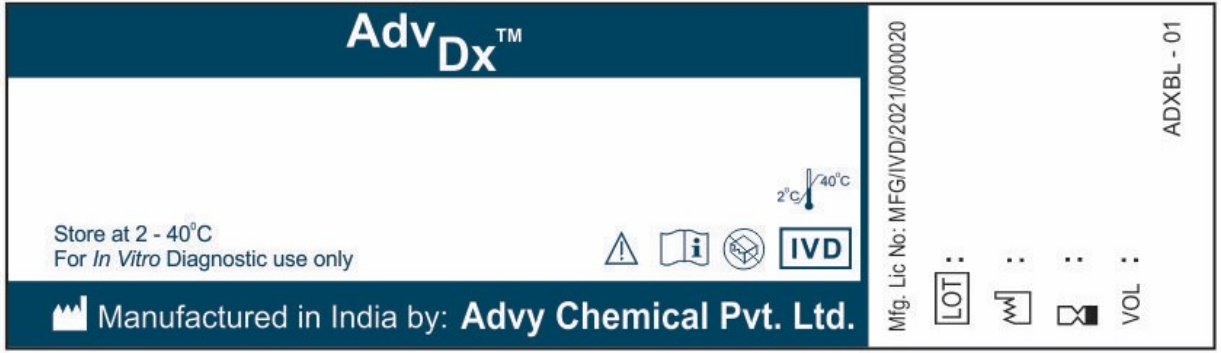
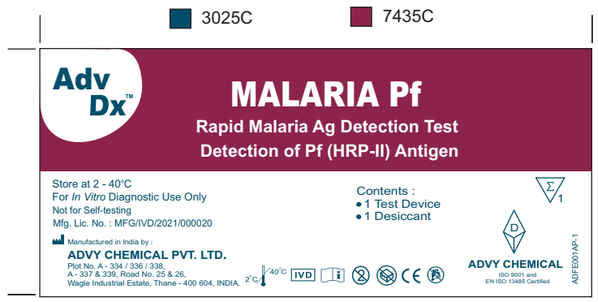
MALARIA Pf

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


Adv Dx™
2°C
40°C
Store at 2 - 40°C
For In Vitro Diagnostic use only
IVD
Manufactured in India by: Advy Chemical Pvt. Ltd.
Mfg. Lic No: MFG/IVD/2021/000020
LOT
VOL
ADXBL - 01

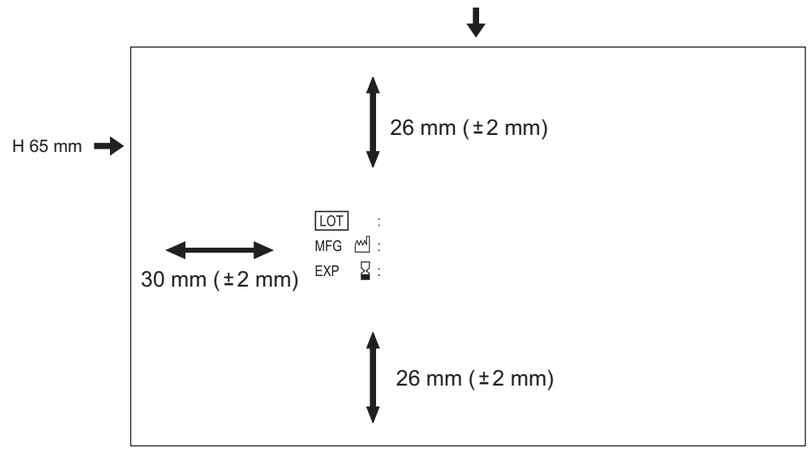
Advdx Malaria Pf_Pouch Label Front side

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



2. Instructions for use[1]

[1] 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 Test Procedure

1. FIRST, read carefully the Product Insert on how to use the Adv$_{Dx}$™ **Malaria Pf** kit.
2. Now open the kit and look for the following.

1) Test device individually foil pouched with a desiccant.

2) Buffer Solution

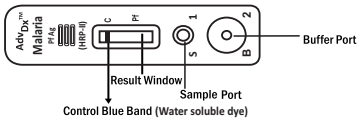
3) Product Insert

4) Inverted cup (Sample Applicator)

6) Alcohol Swab

5) Lancet

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.

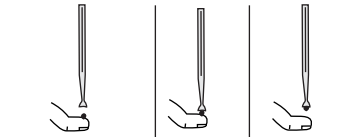


Note: Control blue band (water soluble dye) disappears as test runs and does not affect the test performance. Control blue band is visible in result window only before carrying out the test.

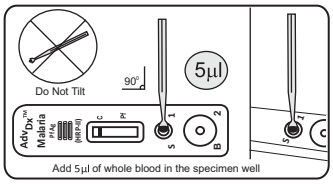
4. Clean the patient's finger.
The alcohol MUST be dried before pricking, or test may not work.

5. Prick the patient's finger with the lancet to get blood
(Wipe away the first drop of blood with sterile gauze or cotton)

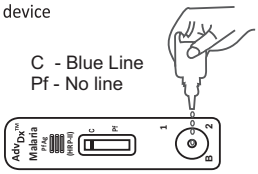
6. Take 5µl blood using the Inverted cup(Sample Applicator) Provided.



7. Add 5µl blood into sample Port 1(S).



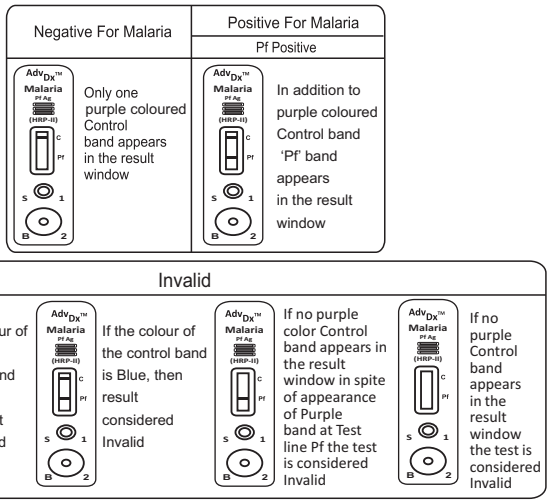
8. Add Buffer Solution into the Buffer Port 2(B) of the test device



Add 4 drops (110µl ± 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, since it may give incorrect results.

10. Interpretation of Test Results.



MALARIA Pf

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

Identification number IFU.: ADFE025KI-1

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 utilizes the principle of Immuno-chromatography. 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 addition of the buffer solution, the colored colloidal gold, and the anti- HRP-II antibody conjugate complexes with the lysed blood sample. The malarial antigens get immobilized on the respective test lines on the nitrocellulose membrane which leads to the formation of red/purple colored band/s. The unreacted conjugate continues to migrate and is subsequently immobilized at the control "C" region forming a red/purple band. The control band demonstrates that liquid has migrated, but does not demonstrate that the assay procedure has been followed correctly. The control band must appear to prove that sample or buffer have migrated though it does not indicate that the specimen is correct and the assay procedure is followed correctly.

INCLUDED REAGENTS AND MATERIALS

A) **AdvDx™ Malaria Pf** 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	01 No.	10 Nos.	25 Nos.	50 Nos.		
Alcohol swab	01 No.	10 Nos.	25 Nos.	50 Nos.		
Sterile Lancet	01 No.	10 Nos.	25 Nos.	50 Nos.		
Buffer Solution	0.2 ml/ ampoule	3.0 ml/ ampoule	3.0 ml/ ampoule	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 instruction 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. Store the **AdvDx™ Malaria Pf** kit at the temperature mentioned on the kit in a dry atmosphere.
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. Dispose all the samples and kits properly as per the instructions after test in accordance with GLP.
9. Do not pipette reagents or blood samples by mouth.
10. Do not re-use the test.
11. Buffer Solution: It contains Sodium azide as a preservative, in case of contact with skin, wash immediately. Wear gloves and eye protective.
12. Do not use any other buffer than the buffer supplied within this kit.

13. Dispose any left-over specimen, tested device, lancet, sample dropper, empty buffer vial, used alcohol swab and used hand gloves as 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.

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 results.
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 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 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. Gently squeeze the finger area until you get enough blood specimen. Hold the Inverted cup (sample applicator) vertically, gently touch the blood drop lift the inverted cup (Sample applicator).(Refer point 6 of test procedure, Page no.4).

Precaution:

1. Use separate inverted cup (sample applicator) fresh pipette tip for each sample to avoid cross-contamination and erroneous results.
2. Do not use any other specimen than whole blood.

TEST PROCEDURE:

1. Allow **AdvDx™ Malaria Pf** 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 Text Procedure, Page No. 4)
3. Tighten the bottle cap of the buffer solution provided with the kit in the clockwise direction to pierce the dropper bottle nozzle. Hold the buffer bottle vertically this ensures that drops contain the correct volume of the buffer.
4. Evenly mix the anti coagulated blood sample by gently swirling and then hold the inverted cup (sample applicator) vertically, gently touch the blood specimen lift the inverted cup (sample applicator) to draw 5µL of blood as shown in the figure. (Refer point 6 of test procedure, Page no.4)

   OR

   Incase of finger prick, clean the fingertip with an alcohol swab dry completely; prick the fingertip with a "Single Use Lancet". Wipe away the first drop of blood with sterile gauze cotton; with the help of the inverted cup (sample applicator) (5µL), provided, draw 5µL of blood as shown in the figure. (Refer point 6 of test procedure, Page no.4)
5. Load 5µL of blood into the "Sample Port 1 (S)"
6. Add 4 drops (110 µL ± 5µL) of buffer solution into the "Buffer Port 2 (B)" on the test device.
7. Read the result at the end of 20 minutes.
8. Interpret the result. Refer to figure for interpretation of the result.

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 result indicates no malaria antigens present in the blood sample, indicating no malaria infection or the number of malaria antigens 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.

INVALID:

1)Absence of color band or blue color band at Control line (C) . with or without color band at the test line 'Pf' indicates the test is invalid. In this case, please repeat the test using a fresh device and follow the test procedure exactly.

STORAGE AND EXPIRATION:

1. **AdvDx™ Malaria Pf** 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** 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. 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** Rapid test 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** 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	% CI	% Specificity	% CI
96.66%	96.3 - 96.9	98.42%	98.3 - 98.5

A. Analytical Sensitivity (Limit of detection)

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

B. Analytical Specificity (Cross reactivity)

Analytical Specificity of **AdvDx™ Malaria Pf** Rapid Malaria Ag Detection Test 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** Rapid Malaria Ag Detection Test

C. Precision:

Repeatability and Reproducibility of **AdvDx™ Malaria Pf** Rapid Malaria Ag Detection Test is 100%.

D. Residual Risk: None

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**

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

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Email : info@advychemical.com
Website : www.advychemical.com

Date Issued: 2023-04

SYMBOL LEGENDS

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

CE EC REP Qarad EC-REP BV Pas 257, 2440 Geel, Belgium