

**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 the
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	<ol style="list-style-type: none"> 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
6.0	<ol style="list-style-type: none"> 1. Inclusion of a dedicated label for the inverted cup sample applicator. The label will clearly identify the component and its intended use. No change to the design, material, dimensions, or function of the inverted cup. No change to the sample application procedure described in the IFU. Malaria Pf product carton and IFU are provided in English-only. Labeling content complies with current approved claims and instructions. 2. Inclusion of bilingual labeling for Malaria Pf: English-French versions, and English-Portuguese versions, for carton and IFU. English content remains unchanged; No change to intended use, performance claims, test principle, or interpretation criteria (PQC-IVD-2026-0011). 	21 May 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 manufacture¹

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:

<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

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.

P. vivax at 2000 parasites/ μ L) 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 the AdvDx Malaria Pf Rapid Malaria Ag Detection Test was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

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

Controlled Labelling References

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	Complete single Test kit (English)	2	May -26	ADFE001IC-2
	Complete single Test kit (English - French)	2	May -26	ADFEF001IC-2
	Complete single Test kit (English-Portuguese)	2	May -26	ADFEP001IC-2
	25 T carton (English)	2	Nov-25	ADFE025IC-2
	10 T carton (English)	2	Nov-25	ADFE010IC-2

	50 T carton (English)	2	Nov-25	ADFE050IC-2
	25 T carton (English - French)	2	Nov-25	ADFEF025IC-2
	10 T carton (English - French)	2	Nov-25	ADFEF010IC-2
	50 T carton (English - French)	2	Nov-25	ADFEF050IC-2
	25 T carton (English-Portuguese)	2	Nov-25	ADFEF025IC-2
	10 T carton (English-Portuguese)	2	Nov-25	ADFEF010IC-2
	50 T carton (English-Portuguese)	2	Nov-25	ADFEF050IC-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)	IFU English	7	Jul-25	ADFE025KI-7
	IFU (English-French)	2	July-25	ADFEF025KI-2
	IFU (English-Portuguese)	2	July-25	ADFEF025KI-2
Blood Lancet	Tianjin	NA	NA	NA
	Shandong	NA	NA	NA
Inverted Cup (5µL)	Pk size 25 Nos.	1	Jan 26	ACC/INC/25-1

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
IFU	Kit Insert (English)	7	Jul-25	ADFE025KI-7
Blood Lancet	Tianjin	NA	NA	NA
	Shandong	NA	NA	NA

Labels

Adv
Dx™ PALUDISME Pf

Kit complet de test à usage unique
Complete Single Test Kit

Not for Self-testing
For In Vitro Diagnostic Use Only

À conserver entre 2 et 40°C
Pour usage diagnostique *in vitro* uniquement
Ne pas utiliser pour l'autodiagnostic

ADV CHEMICAL
ISO 9001 and
EN ISO 13485 Certified



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

MALARIA Pf

Test de détection rapide de l'antigène du paludisme
Détection de l'antigène Pf (HRP-II)

PALUDISME Pf



Adv
Dx™ PALUDISME Pf

CONTENU :

- Fiche produit : 1 unité.
- Appareil d'essai individuellement : 1 unité.
emballé avec un dessiccant
- Applicateur d'échantillons (coupe inversée) : 1 unité.
- Tampon imbibé d'alcool : 1 unité.
- Lancettes pour prélèvement sanguin : 1 unité.
- Solution tampon (3,0 ml par ampoule) : 1 unité.

À conserver entre 2 et 40°C
Pour usage diagnostique *in vitro* uniquement

Élimination: Jeter les échantillons et le kit
correctement selon les instructions ci-jointes
le test en conformité avec GLP.



Matériaux nécessaires

mais non fourni :

- Minuteur
- Lunettes de protection appropriées
- Nouvelle paire de gants jetables
- Stylo / crayon
- Conteneur pour objets tranchants de biosécurité
- Conteneur de déchets Bio Hazard (pour les déchets potentiellement infectieux)
- Si le sang total est collecté par ponction veineuse, sang de ponction veineuse matériaux de collection et précision pipette, plus des pointes
- Gaze ou coton stérile.

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

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

LOT :

MFG :

EXP :

M.R.P. ₹ :

(Toutes taxes comprises)



Fabriqué en Inde par :

ADV 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

Service client :
N° de téléphone: +91 8657428614
Courriel: customerfeedback@advychemical.com

ADFEF001IC-2

Adv Dx™ MALARIA Pf

Complete Single Test Kit

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

ADV CHEMICAL
ISO 9001 and
EN ISO 13485 Certified



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.

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.



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



**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)

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www.advychemical.com

Customer Care :
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E-mail: customerfeedback@advychemical.com

ADFE001IC-2

Adv Dx™ MALÁRIA Pf

Kit de teste único completo
Complete Single Test Kit

Armazenar entre 2 e 40°C
Apenas para utilização em diagnóstico *in vitro*
Não utilizar para autodiagnóstico
Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified



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

MALÁRIA Pf

Teste Rápido de Detecção de Ag da Malária
Detecção do Antígeno Pf (HRP-II)

Adv Dx™

Adv Dx™ MALÁRIA Pf

CONTEÚDO :

- Folheto de produto : 1 un.
- Dispositivo de teste embalado : 1 un.
em folha de alumínio com um
dessecante
- Aplicador de amostra (copo invertido) : 1 un.
- Esfregação com álcool : 1 un.
- Lanceta para punção digital : 1 un.
- Solução tampão (3,0 ml/garrafa) : 1 un.

Materiais necessários mas não fornecidos :

- Temporizador
- Proteção ocular adequada
- Par de luvas descartáveis novas
- Caneta/lápis
- Contedor de Resíduos Cortantes e Perfurantes
- Contedor de resíduos de risco biológico (para resíduos potencialmente infecciosos)
- Se toda a colheita de sangue for realizada por punção venosa, os materiais de colheita de sangue venipuncture, Venipuncture blood por punção venosa e a pipeta de precisão, bem como as respetivas pontas.
- Gaze esterilizada ou algodão

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

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

LOT :

MFG  :

EXP  :

M.R.P. ₹. :
(Incl. todos os impostos)

Armazenar entre 2 e 40°C

Apenas para utilização em diagnóstico *in vitro*

Eliminação: Após o teste, eliminar todas as amostras e o kit corretamente, de acordo com as instruções, em conformidade com as BPL.



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2610 Wilrijk, Belgium 



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ADFEP001C-2

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified



Armazenar entre 2 e 40°C
Apenas para utilização em diagnóstico *in vitro*
Não utilizar para autodiagnóstico
Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing

MALÁRIA Pf
Teste Rápido de Detecção de Ag da Malária
Detecção do Antígeno Pf (HRP-II)
MALÁRIA Pf
Rapid Malaria Ag Detection Test
Detection of Pf(HRP-II) Antigen



**Adv
Dx™**

MALÁRIA 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



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

CONTEÚDO :
Folheto de produto : 1 un.
Dispositivo de teste embalado individualmente em folha de alumínio com um dessecante : 25 un.
Aplicador de amostra (copo invertido) : 25 un.
Esfregão com álcool : 25 un.
Lanceta para punção digital : 25 un.
Solução tampão (3,0 ml/garrafa) : 1 un.

Armazenar entre 2 e 40°C
Apenas para utilização em diagnóstico *in vitro*
Eliminação: Após o teste, eliminar todas as amostras e o kit corretamente, de acordo com as instruções, em conformidade com as BPL.



Materiais necessários mas não fornecidos :

- Temporizador
- Proteção ocular adequada
- Par de luvas descartáveis novas
- Caneta/lápis
- Contentor de Resíduos Cortantes e Perfurantes
- Contentor de resíduos de risco biológico (para resíduos potencialmente infecciosos)
- Se toda a colheita de sangue for realizada por punção venosa, os materiais de colheita de sangue por punção venosa e a pipeta de precisão, bem como as respetivas pontas.
- Gaze esterilizada ou algodão.

MALÁRIA Pf

Teste Rápido de Detecção de Ag da Malária

ADFEF025C-2

**Adv
Dx™**

MALÁRIA Pf
Teste Rápido de Detecção de Ag da Malária
Detecção do Antígeno Pf (HRP-II)

Armazenar entre 2 e 40°C
Apenas para utilização em diagnóstico *in vitro*
Não utilizar para autodiagnóstico



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

LOT :
MFG :
EXP :
M.R.P. ₹ :
(Incl. todos os impostos)



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MALÁRIA Pf

Teste Rápido de Detecção de Ag da Malária

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified



À conserver entre 2 et 40°C
Pour usage diagnostique *in vitro* uniquement
Ne pas utiliser pour l'autodiagnostic
Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing



PALUDISME Pf
Test de détection rapide de l'antigène du paludisme
ADV Dx™

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

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



ADV CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

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

CONTENU :
Fiche produit : 1 unité.
Appareil d'essai individuellement : 25 unités.
Emballé avec un dessiccant
Applicateur d'échantillons (coupe inversée) : 25 unités.
Tampon imbibé d'alcool : 25 unités.
Lancettes pour prélèvement sanguin : 25 unités.
Solution tampon (3,0 ml par flacon) : 1 unité.

À conserver entre 2 et 40°C
Pour usage diagnostique *in vitro* uniquement
Élimination: Jeter les échantillons et le kit correctement
selon les instructions ci-jointes le test en conformité
avec GLP.



EC REP QMS Reg'd By: Groenendorgaan 16
2070 Willep, Belgium

Matériaux nécessaires
mais non fourni :

- Minuteur
- Lunettes de protection appropriées
- Nouvelle paire de gants jetables
- Stylo / crayon
- Conteneur pour objets tranchants de biosécurité
- Conteneur de déchets Bio Hazard (pour les déchets potentiellement infectieux)
- Si le sang total est collecté par ponction veineuse, sang de ponction veineuse matériaux de collection et précision pipette, plus des pointes.
- Gaze ou coton stérile.

PALUDISME Pf

Test de détection rapide de l'antigène du paludisme

ADFEF025IC-2

Adv
Dx™

PALUDISME Pf
Test de détection rapide de l'antigène du paludisme
Détection de l'antigène Pf (HRP-II)

À conserver entre 2 et 40°C
Pour usage diagnostique *in vitro* uniquement
Ne pas utiliser pour l'autodiagnostic



ADV CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

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

LOT :
MFG :
EXP :
M.R.P. ₹ :
(Toutes taxes comprises)

Fabriqué en Inde par
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PALUDISME Pf

Test de détection rapide de l'antigène du paludisme



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

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



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



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

CONTENTS:

Product Insert	: 1 No.	Materials required but not Provided :
Test Device individual foil	: 10 Nos.	• Timer
pouched with a desiccant		• Suitable eye protection
Sample Applicator (Inverted Cup)	: 10 Nos.	• New pair of disposable gloves
Alcohol Swab	: 10 Nos.	• Pen/pencil
Blood Lancet	: 10 Nos.	• BioSafety sharps container
Buffer Solution (3.0 ml/Bottle)	: 1 No.	• 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.



EC REP Q&D RepS B.V. Groenenborgerlaan 16
2610 Wierik, Belgium



ADFE010IC-2



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



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

MALARIA Pf
Rapid Malaria Ag Detection Test

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified



Armazenar entre 2 e 40°C
Apenas para utilização em diagnóstico *in vitro*
Não utilizar para autodiagnóstico
Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing



MALÁRIA Pf
Teste Rápido de Detecção de Ag da Malária
Detecção do Antígeno Pf (HRP-II)
MALÁRIA Pf
Rapid Malaria Ag Detection Test
Detection of Pf (HRP-II) Antigen



MALÁRIA 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



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

CONTEÚDO:

Bula do produto : 1 un.
Dispositivo de teste em folha individual embalado com dessecante : 10 un.
Aplicador de amostra (copo invertido) : 10 un.
Cotonete com álcool : 10 un.
Lanceta de Sangue : 10 un.
Solução tampão (3,0 ml/frasco) : 1 un.

Materiais necessários mas não fornecidos

- Temporizador
- Proteção ocular adequada
- Par de luvas descartáveis novas
- Caneta/Ápis
- Contêntor de Resíduos Cortantes e Perfurantes
- Contêntor de resíduos de risco biológico (para resíduos potencialmente infecciosos)
- Se toda a colheita de sangue for realizada por punção venosa, os materiais de colheita de sangue venipuncture, Venipuncture blood por punção venosa e a pipeta de precisão, bem como as respetivas pontas.
- Gaze ou algodão estéril

Armazenar entre 2 e 40°C
Apenas para utilização em diagnóstico *in vitro*

Eliminação: Após o teste, eliminar todas as amostras e o kit corretamente, de acordo com as instruções, as instruções, em conformidade com as BPL.



EC REP Q&D RepS BV, Groenenborgerlaan 16
2610 Wilrijk, Belgium



MALÁRIA Pf
Teste Rápido de Detecção de Ag da Malária
Detecção do Antígeno Pf (HRP-II)

Armazenar entre 2 e 40°C
Apenas para utilização em diagnóstico *in vitro*
Não utilizar para autodiagnóstico



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

LOT :
MFG :
EXP :
M.R.P. ₹. :
(Incl. todos os impostos)

Fabricado na Índia por :
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

Apoio ao cliente :
N.º de telefone : +91 8657428614
E-mail : customerfeedback@advychemical.com

ADFE0101C-2

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified



À conserver entre 2 et 40°C
Pour usage diagnostique *in vitro* uniquement
Ne pas utiliser pour l'autodiagnostic
Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing



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

PALUDISME Pf
Test de détection rapide de l'antigène du paludisme
Détection de l'antigène Pf (HRP-II)



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



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

CONTENU :

Fiche produit : 1 unité.
Appareil d'essai individuellement emballé avec un dessiccant : 10 unités.
Applicateur d'échantillons (coupe inversée) : 10 unités.
Tampou imbibé d'alcool : 10 unités.
Lancettes pour prélèvement sanguin : 10 unités.

Matériaux nécessaires mais non fournis:

- Minuteur
- Lunettes de protection adaptées
- Nouvelle paire de gants jetables
- Stylo/crayon
- Conteneur pour objets tranchants de biosécurité
- Conteneur pour déchets Bio Hazard (pour les déchets potentiellement infectieux)
- Si le sang total est collecté par ponction veineuse, sang de ponction veineuse matériaux de collection et précision pipette, plus des pointes.
- Gaze ou coton stérile

À conserver entre 2 et 40°C
Pour usage diagnostique *in vitro* uniquement
Élimination: Jeter les échantillons et le kit correctement selon les instructions ci-jointes le test en conformité avec GLP.



EC REP Q&D RepS B.V. Groenenborgerlaan 16 2610 Wilrijk, Belgium



PALUDISME Pf

Test de détection rapide de l'antigène du paludisme
Détection de l'antigène Pf (HRP-II)

À conserver entre 2 et 40°C
Pour usage diagnostique *in vitro* uniquement
Ne pas utiliser pour l'autodiagnostic



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

LOT :

MFGSM :

EXP :

M.R.P. ₹. :

(Toutes taxes comprises)

Fabriqué en Inde par :
ADV 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

Service client :
N° de téléphone: +91 8657428614
Courriel : customerfeedback@advychemical.com

ADFEF010IC-2



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

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



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



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

CONTENTS:
Product Insert : 1 No.
Test Device individual foil : 25 Nos.
pouched with a desiccant
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.



**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-2



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



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

ADY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified



À conserver entre 2 et 40°C
Réservez au diagnostic *in vitro*
Ne pas utiliser pour l'autodiagnostic
Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing



Test de détection rapide de l'antigène du paludisme
Détection de l'antigène Pf (HRP-II)

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



ADY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

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

CONTENU :
Fiche produit : 1 unité.
Appareil d'essai individuellement emballé avec un dessiccant : 50 unités.
Applicateur d'échantillons (coupe inversée) : 50 unités.
Tampon imbibé d'alcool : 50 unités.
Lancettes pour prélèvement sanguin : 50 unités.
Solution tampon (3,0 ml par flacon) : 3 unités.

À conserver entre 2 et 40°C
Pour usage diagnostique *in vitro* uniquement
Élimination: Jeter les échantillons et le kit correctement selon les instructions ci-jointes le test en conformité avec GLP.



Matériaux nécessaires
mais non fourni :

- Mineur
- Lunettes de protection appropriées
- Nouvelle paire de gants jetables
- Stylo / crayon
- Conteneur pour objets tranchants de biosécurité
- Conteneur de déchets Bio Hazard (pour les déchets potentiellement infectieux)
- Si le sang total est collecté par ponction veineuse, sang de ponction veineuse matériaux de collection et précision pipette, plus des pointes.
- Gazze ou coton stérile.

PALUDISME Pf

Test de détection rapide de l'antigène du paludisme

ADFEEDBIC-2

Adv
Dx™

PALUDISME Pf
Test de détection rapide de l'antigène du paludisme
Détection de l'antigène Pf (HRP-II)

À conserver entre 2 et 40°C
Pour usage diagnostique *in vitro* uniquement
Ne pas utiliser pour l'autodiagnostic



ADY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

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

LOT :
MFG :
EXP :
M.R.P. ₹ :

(Toutes taxes comprises)



Fabriqué en Inde par
ADY CHEMICAL PVT. LTD.
Plot No. A - 334 / 336 / 338,
A - 337 & 339, Road No. 25 & 26,
Wagle Industrial Estate, Thane - 400 604, INDIA.
info@gadychemical.com • www.advychemical.com

Service client :
N° de contact : +91 8657428614
Courriel : customerfeedback@advychemical.com Test de détection rapide de l'antigène du paludisme

PALUDISME Pf

ADYV CHEMICAL
ISO 9001 and
EN ISO 13485 Certified



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

MALARIA Pf

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



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



ADYV 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 : 50 Nos.
pouched with a desiccant
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.



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

ADFE850C-2



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



MALARIA Pf

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



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

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

MALARIA Pf
Rapid Malaria Ag Detection Test

ADVY CHEMICAL
ISO 9001 and
EN ISO 13485 Certified



Armazenar entre 2 e 40°C
Apenas para utilização em diagnóstico *in vitro*
Não utilizar para autodiagnóstico
Store at 2 - 40°C
For *In Vitro* Diagnostic Use Only
Not for Self-testing



MALÁRIA Pf
Teste Rápido de Detecção de Ag da Malária
(HRP-II)

MALÁRIA Pf
Rapid Malaria Ag Detection Test
(HRP-II)

Dx

**Adv
Dx™**

MALÁRIA 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



ADV CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

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

CONTEÚDO:

Bula do produto : 1 un.
Dispositivo de teste em folha individual
embalado com dessecante : 50 un.
Aplicador de amostra (copo invertido) : 50 un.
Cotonete com álcool : 50 un.
Lanceta de Sangue : 50 un.
Solução tampão (3,0 ml/frasco) : 3 un.

Armazenar entre 2 e 40°C
Apenas para utilização em diagnóstico *in vitro*
Eliminação: Após o teste, eliminar todas as amostras
e o kit corretamente, de acordo com as instruções, as
instruções, em conformidade com as BPL.



Materiais necessários mas não fornecidos

- Temporizador
- Proteção ocular adequada
- Par de luvas descartáveis novas
- Caneta/lápis
- Contedor de Resíduos Cortantes e Perfurantes
- Contedor de resíduos de risco biológico (para resíduos potencialmente infecciosos)
- Se toda a colheita de sangue for realizada por punção venosa, os materiais de colheita de sangue venipuncture, Venipuncture blood por punção venosa e a pipeta de precisão, bem como as respetivas pontas.
- Gaze ou algodão estéril

MALÁRIA Pf
Teste Rápido de Detecção de Ag da Malária

ADPFP060C-2

**Adv
Dx™**

MALÁRIA Pf
Teste Rápido de Detecção de Ag da Malária
Detecção do Antígeno Pf (HRP-II)

Armazenar entre 2 e 40°C
Apenas para utilização em diagnóstico *in vitro*
Não utilizar para autodiagnóstico



ADV CHEMICAL
ISO 9001 and
EN ISO 13485 Certified

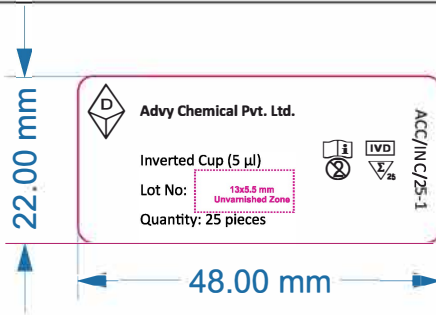
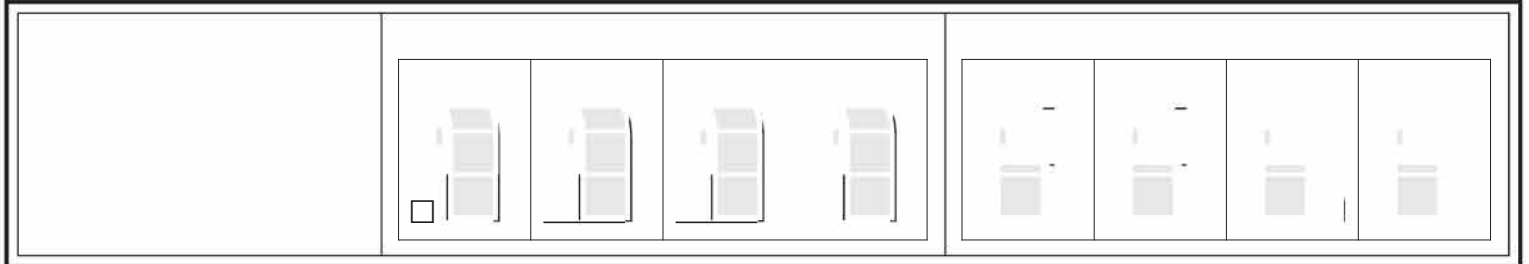
Mfg. Lic. No.: MFG/IVD/2021/000020

LOT :
MFG :
EXP :
M.R.P. ₹ :
(Incl. todos os impostos)

Fabricado na Índia por:
ADV CHEMICAL PVT. LTD.
Plot No. A - 334 / 335 / 338,
A - 337 & 339, Road No. 25 & 26,
Wagle Industrial Estate, Thane - 400 604, INDIA.
info@advychemical.com • www.advychemical.com

Apoio ao cliente :
N.º de contacto : +91 8657428614
E-mail : customerfeedback@advychemical.com

MALÁRIA Pf
Teste Rápido de Detecção de Ag da Malária



Advy Chemical Pvt. Ltd.
 Inverted Cup (5 μ l)
 Lot No: 13x5.5 mm
Unvarnished Zone
 Quantity: 25 pieces

 ACC/INC/25-1

Advy Chemical Pvt. Ltd.

Inverted Cup (5 μ l)

Lot No: 13x5.5 mm
Unvarnished Zone

Quantity: 25 pieces

ACC/INC/25-1

Enlarged

CE

ISO 9001:2015
CERTIFIED COMPANY

*Amkay*TM **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



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

CE ISO 13485:2016

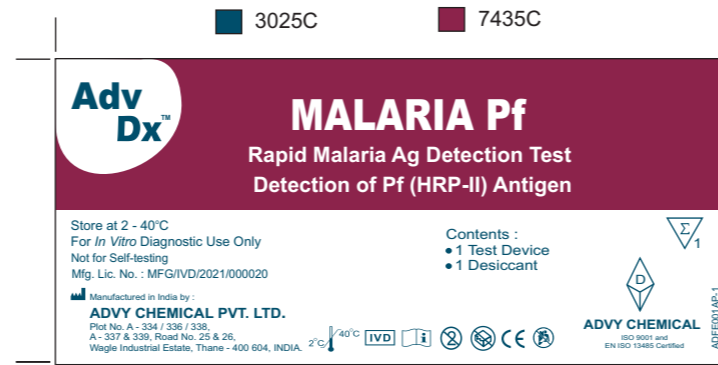
01/2026

02/2024

LOT 383

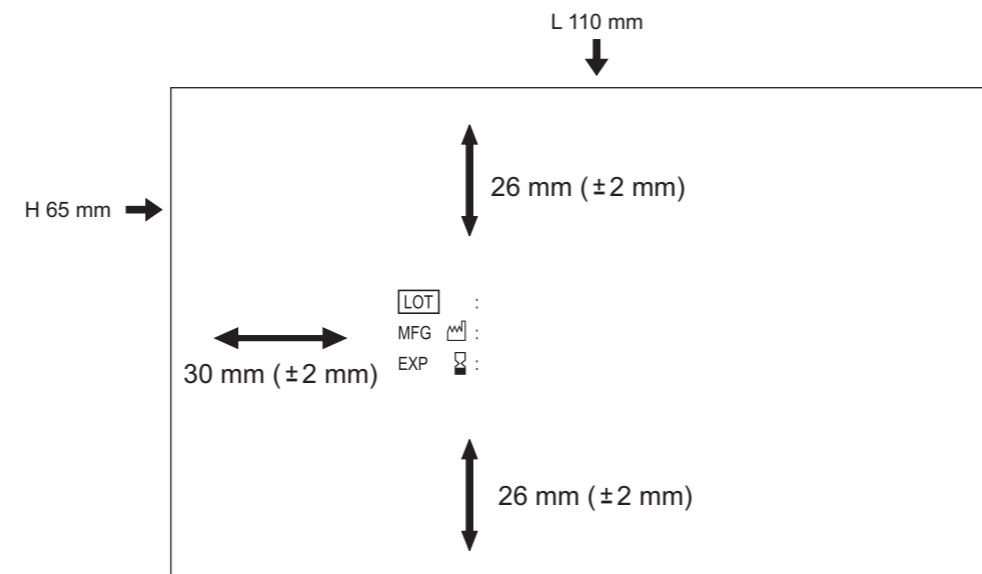
Advdx Malaria Pf_Pouch Label Front side

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

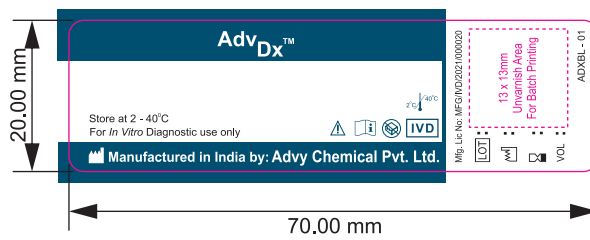


Size: L 70mm x H 20mm

■ 3025C ■ Black

Ref.no: ADXBL- 01

Mfg. Lic. NO. MFG/IVD/2021/000020



155

95

10

10

33.75

67.5

Disposable Sterile Lancet With Safety Seals

MODEL/SPEC.: I /30G
QTY: 25 PCS



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

LOT NO. : T240801
MFG. DATE : 2024-08-06
EXP. DATE : 2029-08-05



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



24073090

STERILE R



0197

Size: 50*40mm

Instructions for use²

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

Identification number Product insert (IFU): ADFEF025KI-2

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.

(1)

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 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 96.6% 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

SYMBOL LEGENDS

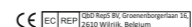
Symbol Explanation of symbol	Symbol Explanation of symbol
Consult instruction for use	Keep Dry
Do not use if package is damaged	Batch code No.
In vitro diagnostic device	Manufacturer
Store at 2°C - 40°C	Date of Manufacture
Keep away from sunlight	Use by (date or month of expiry)
Do not re-use	Authorized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

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

Manufactured in India By:

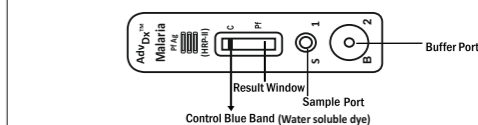
ADV CHEMICAL PVT. LTD.
Plot No. A - 334 / 336 / 338,
A - 337 & 339, Road No. 25 & 26,
Wagle Industrial Estate, Thane - 400 604.
Email : info@advychemical.com
Website : www.advvychemical.com

Date Issued: 2025-07



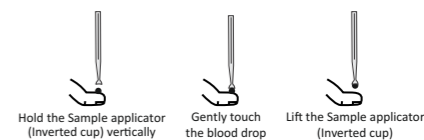
AdvDx™ Malaria Pf Test Procedure

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
 - 3) Product Insert
 - 4) Sample applicator (inverted cup)
 - 5) Blood lancet
 - 6) Alcohol Swab
 - 7) Silica gel

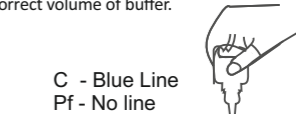


Note: Control blue band (water soluble dye) disappears as test runs and does not affect the test performance. Control blue band is visible in result window only before carrying out the test.

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

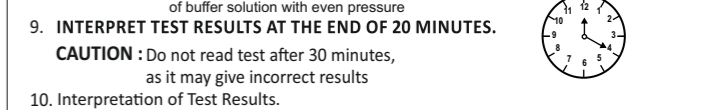


7. Add 5µL blood into sample Port 1(S).
8. Remove buffer bottle cap and add 4 drops of buffer solution into the buffer port (B) of the test device. Hold the buffer bottle vertically after dispensing the buffer. This ensures that the drop contains correct volume of buffer.



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
<p>Only one purple colored Control band appears in the result window</p>	<p>In addition to purple colored Control band 'Pf' band appears in the result window</p>

Invalid			
<p>If the colour of the "C" control band is Blue, then result considered Invalid</p>	<p>If the colour of control line is blue and test band is purple, the result is considered invalid</p>	<p>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</p>	<p>If no purple colour band appears at control as well as Test line, the test is considered invalid.</p>

(4)

(2)

(3)

Adv Dx™ PALUDISME Pf

Test de détection rapide de l'Ag du paludisme Détection de l'antigène Pf (HRP-II)

Numéro d'identification de la notice de produit (IFU). : ADFEF025KI-2
FRENCH
UTILISATION PRÉVUE

Le kit de test **AdvDx™ Paludisme Pf** est une analyse immunochromatographique de diagnostic in vitro pour la détection qualitative de l'infection au **paludisme causée** par les parasites *Plasmodium falciparum* chez l'homme. Il détecte l'antigène HRP-II (Protéine riche en histidine-II) qui est l'antigène du *Plasmodium falciparum* dans des échantillons de sang total. Il n'évalue pas les densités parasitaires. Le test doit être effectué par un professionnel formé en laboratoire et non par des profanes. Le test n'est pas destiné à être utilisé pour un autodiagnostic.

SIGNIFICATION CLINIQUE

Le paludisme est une maladie parasitaire grave, parfois mortelle. Il se caractérise par une fièvre avec frissons, une anémie et est causé par le parasite *Plasmodium* qui se transmet d'un être humain à un autre par la piqûre de moustiques anophèles infectés. Quatre espèces du *parasite Plasmodium* sont responsables d'infections au paludisme chez l'homme, à savoir : *P. falciparum*, *P. vivax*, *P. ovale* et *P. malariae*. Parmi ceux-ci, *P. falciparum* et *P. vivax* sont les plus courantes. La détection précoce et la différenciation du paludisme sont d'une importance capitale en raison de l'incidence du paludisme cérébral et de la résistance aux médicaments associée au paludisme à *P. falciparum* qui est à l'origine de la plupart des cas de morbidité et de mortalité dans le monde.

PRINCIPE

Le kit de test **AdvDx™ Paludisme Pf** utilise le principe de l'immunochromatographie. La bandelette de test est recouverte d'un anticorps monoclonal Anti-HRP-II (ligne de test Pf) qui est spécifique à la protéine II riche en histidine de *P. falciparum*. Lorsque l'échantillon de test passe à travers la membrane du dispositif après l'ajout de la solution tampon, l'or colloïdal coloré et l'anticorps anti-HRP-II se conjuguent en complexes avec l'antigène HRP-II dans l'échantillon de sang lysé. Ce complexe antigène-anticorps et or colloïdal se lie à l'anticorps sur la ligne de test sur la membrane de nitrocellulose, ce qui conduit à la formation de la bande de couleur rouge/violet. Le conjugué n'ayant pas réagi continue sa migration et est ensuite immobilisé au niveau de la région témoin « C », formant une bande rouge/violette. L'apparence de la bande de contrôle prouve que l'échantillon ou le tampon a migré à travers celle-ci, mais elle n'indique pas que l'échantillon utilisé était correct ou que la procédure d'essai a été suivie correctement.

MATÉRIAUX FOURNIS

A) Le kit de test AdvDx™ Paludisme Pf contient les éléments suivants pour effectuer le test :

Contenu	Qté dans l'emballage 1T	Qté dans l'emballage 10T	Qté dans l'emballage 25T	Qté dans l'emballage 50T	Qté dans le kit complet à usage unique 25 Unités/ Carton	Qté dans le kit complet à usage unique 10 Unités/ Carton
Notice du produit	01 Unité	01 Unité	01 Unité	01 Unité		
Dispositif de test individuellement emballé dans un sachet en aluminium avec un désiccant	01 Unité	10 Unités	25 Unités	50 Unités	Kit complet de test à usage unique 25 Unités	Kit complet de test à usage unique 10 Unités
Applicateur d'échantillons (coupe inversée)	01 Unité	10 Unités	25 Unités	50 Unités		
Écouvillon d'alcool	01 Unité	10 Unités	25 Unités	50 Unités		
Lancette stérile	01 Unité	10 Unités	25 Unités	50 Unités		
Solution tampon	0,2 ml/ampoule	3,0 ml/bouteille	3,0 ml/bouteille	03 N° (3,0 ml/bouteille)		

B) Les ingrédients actifs des principaux composants sont :

- 1 bandelette de test comprend : Conjugué d'or : Anticorps monoclonaux de souris spécifiques à Pf - HRP-II conjugués à l'or colloïdal, Ligne de contrôle : IgG anti-souris Caprin.
- Solution tampon : Caséine, Triton X-100 et azide de sodium comme conservateur.

Matériel requis mais non fourni

- Minuteur
- Protection oculaire appropriée
- Paire de gants neufs jetables
- Stylo/crayon
- Conteneur pour objets pointus à usage biomédical
- Conteneur de déchets biologiques dangereux (pour les déchets potentiellement infectieux)
- SE n cas de prélèvement de sang total par ponction veineuse, matériel de prélèvement sanguin par ponction veineuse et pipette de précision, ainsi que pointes.
- Gaze stérile ou coton.

PRÉCAUTIONS

1. Lisez attentivement cette notice avant d'effectuer le test et les instructions doivent être suivies à la lettre pour obtenir des résultats exacts.
2. Le dispositif est sensible à l'humidité ainsi qu'à la chaleur. Par conséquent, retirez le dispositif du sachet scellé juste avant d'effectuer le test.
3. Assurez-vous que les kits de test **AdvDx™ Paludisme Pf** sont stockés entre 2°C et 40°C pour un rendement optimal continu. L'écart dans les conditions de stockage peut également entraîner des lignes de test faibles.
4. N'utilisez pas le kit après la date d'expiration.
5. Ne mélangez pas les réactifs de différents lots.
6. Pour diagnostic in vitro uniquement.
7. Portez des gants de protection lors de la manipulation des échantillons et lavez-vous soigneusement les mains après avoir effectué le test.
8. Ne pipetez pas de réactifs ou d'échantillons de sang avec la bouche.
9. Ne réutilisez pas le test.
10. La solution tampon contient de l'azote de sodium comme conservateur. En cas de contact avec la peau, immédiatement. Portez des gants et des lunettes de protection car le tampon contient de l'azote de sodium.
11. N'utilisez pas d'autre tampon que celui tampon fourni dans ce kit.
12. Éliminez tout échantillon restant, dispositif testé, lancette de sang, applicateur d'échantillon (coupe inversée), flacon de tampon vide, compresse imbibée d'alcool usagée et gants usagés dans un conteneur de déchets biologiques dangereux conformément à la réglementation locale au point d'utilisation. Le sachet de silice doit être ouvert et jeté dans la poubelle locale. Décontaminez et éliminez tous les échantillons, les trousseaux de réaction et les matériaux potentiellement contaminés (c.-à-d. lancette de sang, applicateur d'échantillons, dispositif d'analyse) dans un conteneur pour déchets biologiques dangereux comme s'il s'agissait de déchets infectieux.

(1)

PRÉLÈVEMENT, CONSERVATION ET PRÉCAUTION DES ÉCHANTILLONS

Échantillons require :

sang total capillaire ou sang total avec les anticoagulants suivants : EDTA, citrate ou héparine

Prélèvement par ponction veineuse

1. Prélevez le sang total dans le tube de prélèvement contenant l'anticoagulant (EDTA, citrate ou héparine) par ponction veineuse. Les anticoagulants tels que l'héparine, l'EDTA et le citrate n'affectent pas les résultats des tests.
2. Si un test immédiat n'est pas possible, les échantillons peuvent être stockés à 2-8 °C jusqu'à 3 jours. Les échantillons doivent être portés à température ambiante avant d'être utilisés. L'utilisation d'échantillons conservés pendant plus de 3 jours peut provoquer des réactions non spécifiques.

Prélèvement avec une lancette de sang :

1. Portez des gants.
2. Choisissez un doigt pour la piqûre au doigt :
 - Ne choisissez pas un doigt enflé, contusionné ou cicatrisé.
 - Choisissez de préférence le 3e ou 4e doigt de la main que le patient n'utilise pas pour écrire.
3. Ouvrez l'emballage du tampon imbibé d'alcool. Retirez le tampon imbibé d'alcool. Ne jetez pas l'emballage vide (emballage extérieur) mais gardez-le de côté.
4. Essayez tout le bout du doigt avec le tampon imbibé d'alcool. Attendez que le doigt soit complètement sec (minimum 30 secondes).
5. Placez le tampon d'alcool dans l'emballage et mettez-le de côté (vous en aurez à nouveau besoin pour arrêter le saignement après avoir prélevé le sang du patient).
6. Dévissez le capuchon de la lancette de sang pour exposer l'aiguille. Piquez le 3e ou 4e doigt et essuyez la première goutte de sang avec de la gaze de coton stérile ou du coton.
7. Tenez l'applicateur d'échantillon (coupe inversée) verticalement, laissez la goutte de sang du doigt piqué toucher le gobelet de l'applicateur d'échantillon (coupe inversée)

Précaution:

1. Utilisez un applicateur d'échantillon séparé (coupe inversée) (5 µL) pour chaque échantillon afin d'éviter la contamination croisée et les résultats erronés.
2. N'utilisez pas d'autre échantillon que le sang total.
3. Ne rebouchez pas la lancette de sang et ne la réutilisez pas.
4. Jetez immédiatement la lancette de dans un conteneur pour objets pointus à usage biomédical pour éviter de vous blesser lors de l'élimination.

PROCÉDURE DU TEST:

1. Laissez les composants et les échantillons du kit de test **AdvDx™ Paludisme Pf** atteindre la température ambiante.
 2. Ouvrez la pochette et retirez le dispositif.
- Remarque :** le dispositif contient une ligne de contrôle bleue composée d'un colorant soluble dans l'eau qui disparaît au fur et à mesure de l'exécution du test. (Voir le point 3 de la procédure de test page n° 4)
3. Serrez le bouchon de la bouteille de la bouteille tampon fournie avec le kit dans le sens des aiguilles d'une montre pour percer l'embout du flacon. Ne percez pas avec un objet pointu et ne coupez pas l'embout avec des ciseaux.
 4. Dans le cas d'un échantillon de sang total par ponction veineuse, mélangez uniformément l'échantillon de sang anticoagulé en tournant doucement, puis trempez l'applicateur d'échantillon (coupe inversée) pour prélever 5 µL de sang comme indiqué sur la figure. Le non-respect de cette consigne peut entraîner des résultats erronés.

OU

Dans l'orifice d'échantillonnage 1 (S) du dispositif de test, ajoutez les 5 µL de sang veineux prélevés dans l'applicateur d'échantillon (coupe inversée), ou le sang capillaire recueilli selon les instructions fournies ci-dessus (prélèvement avec une lancette de sang).

5. Ajoutez 4 gouttes (110 µL ± 5 µL) de solution tampon dans le « port tampon 2 (B) » du dispositif de test, car de faibles volumes de tampon peuvent entraîner un écoulement incomplet, un écoulement retardé, une élimination incomplète du bruit de fond, ce qui rend difficile l'interprétation du résultat ou augmente la probabilité de résultats invalides. N'utilisez pas trop de tampon car cela pourrait altérer le temps de réaction, ce qui entraînerait une réduction de la sensibilité du test (faux négatifs).
6. Lisez le résultat au bout de 20 minutes.
7. Interprétez le résultat. Reportez-vous à la figure mentionnée au point n° 10 de la page numéro 4. **ATTENTION :** ne lisez pas le test après 30 minutes, car il pourrait donner des résultats incorrects.

INTERPRÉTATION DES RÉSULTATS :

Les échantillons de sang total peuvent faire apparaître un fond rouge dans la fenêtre de résultats.

NÉGATIF :

Seule la bande de contrôle de couleur violette apparaît. Les résultats négatifs indiquent qu'il n'y a pas d'antigènes du paludisme dans l'échantillon de sang, qu'il n'y a pas d'infection palustre ou que le nombre d'antigènes du paludisme présents dans l'échantillon de sang est inférieur à la plage détectable.

POSITIF :

1) Pf positif : deux bandes (la ligne de test « Pf » et la ligne de contrôle « C » de couleur violette) apparaissent dans la fenêtre de résultat et indiquent l'infection à *P. falciparum*. La nuance de couleur / l'intensité de la bande peut varier, mais elle doit être considérée comme positive chaque fois qu'il y a une ligne faible. De faibles lignes peuvent apparaître dans le cas d'échantillons à faible densité parasitaire, car seule une faible concentration d'antigène détectable sera présente.

NON VALIDE :

L'absence de bande de couleur violette ou de bande bleue à la ligne de contrôle (C) La couleur bleue ou l'absence de bande à la ligne de commande (C) indique que le test n'est pas valide.

STOCKAGE ET EXPIRATION :

1. Le kit de test **AdvDx™ Paludisme Pf** doit être conservé entre 2°C et 40°C (36°F à 104°F). **Ne pas congeler**
2. Le kit a une durée de conservation de 24 mois à compter de la date de fabrication. Le kit est stable jusqu'à la date d'expiration indiquée sur le produit lorsqu'il est stocké comme spécifié. Le tampon est stable pendant 6 mois après ouverture.

LIMITES DU TEST :

1. Le kit de test **AdvDx™ Paludisme Pf** est conçu pour le dépistage primaire de l'infection palustre par *P. falciparum*. Bien que le test soit précis pour détecter la HRP-II spécifique à *P. falciparum* dans les échantillons de sang, une faible incidence de résultats erronés peut survenir. Si vous observez un faux positif dans plus d'une cassette par kit, signalez-le immédiatement à la personne de contact fournie. D'autres tests cliniquement disponibles sont nécessaires si des résultats douteux sont obtenus, comme pour tous les tests diagnostiques. Un diagnostic clinique définitif ne doit pas être basé sur les résultats d'un seul test, mais doit être établi par le médecin après évaluation de tous les résultats cliniques et de laboratoire.
2. Les TDR contre le paludisme peuvent donner des résultats positifs après un traitement antipaludique réussi. Par conséquent, le kit de test **AdvDx™ Paludisme Pf** n'est pas recommandé pour le suivi de la réponse au traitement antipaludique.

CONTRÔLE QUALITÉ

La bande de contrôle sert de contrôle de procédure et doit apparaître pour prouver que les ingrédients actifs de la bandelette de test sont fonctionnels et que l'échantillon ou le tampon ont migré correctement. La ligne de contrôle est destinée à la surveillance de l'ajout d'échantillons.

CARACTÉRISTIQUES DE PERFORMANCE:

Le kit de test **AdvDx™ Paludisme Pf** a été testé avec des échantillons cliniques positifs et négatifs testés par examen microscopique du sang total.

A.Sensibilité et spécificité

La sensibilité et la spécificité du kit de test **AdvDx™ Paludisme Pf** pour le paludisme à *P. falciparum* sont respectivement de 96,66 % et 98,42 %. La performance du test a été établie par comparaison avec les résultats de l'examen microscopique de films épais et minces.

Résultat de l'étude AdvDx™ Paludisme Pf	Méthode de référence (examen microscopique)		Total
	Pf Positif	Pf Négatif	
Positif	87	03	90
Négatif	03	187	190
Total	90	190	280
% de sensibilité	IC à 5 %	% de spécificité	IC à 5 %
96.6%	90.5% - 99.3%	98.4%	95.4% - 99.6%

B. Sensibilité analytique (limite de détection)

La sensibilité analytique (LoD) du kit de test **AdvDx™ Paludisme Pf** est de 200 P/µl d'échantillons de *P. falciparum* et comparable aux observations microscopiques.

C. Spécificité analytique (réactivité croisée)

La spécificité analytique du kit de test **AdvDx™ Paludisme Pf** étudié avec des échantillons infectieux et différents anticoagulants est de 100%. Le facteur rhumatoïde, l'échantillon positif pour la dengue, le chikungunya et la syphilis n'ont montré aucune réactivité croisée et les anticoagulants EDTA, l'héparine et le citrate de sodium n'ont montré aucune interférence avec les performances du kit de test **AdvDx™ Paludisme Pf**

D. Précision :

La répétabilité et la reproductibilité du kit de test **AdvDx™ Paludisme Pf** sont de 100%.

RÉFÉRENCES:

1. Organisation Mondiale de la santé – Genève (2000). Nouvelles perspectives : Diagnostic du paludisme.
2. Perlmann, P et Troye-Blomberg, M. 2002. Paludisme Parasites et maladies. Immunologie du paludisme.
3. Malcolm, J.G., et al, 2002. Séquence du génome du parasite du paludisme humain *Plasmodium falciparum*. Nature 419:498-511
4. Protéin II riche en histidine : a novel approach to malaria drug sensitivity testing, Antimicrobial agents and Chemotherapy, juin 2002, p. 1658-1664 Vol. 46, No.6.

CLAUDE DE NON-RESPONSABILITÉ:

Toutes les mesures ont été prises pour garantir la fiabilité et la précision de ce produit. L'utilisation de ce produit n'est plus sous la responsabilité du fabricant et du distributeur et le résultat peut, par conséquent, être affecté par les facteurs environnementaux / ou l'erreur de l'utilisateur. Une personne qui est soumise à ce diagnostic doit consulter un médecin afin d'obtenir plus d'informations sur le résultat.

AVERTISSEMENT:

Le fabricant et le distributeur de ce produit ne sont pas responsables de toute perte, obligation, toutes déclarations, tous coûts ou dommages qu'ils soient directs ou indirects découlant ou relatifs au diagnostic erroné, positif ou négatif dans l'utilisation de ce produit.

Pour toute réclamation / question et suggestions : **Service clientèle No. +91 8657428614, feedback@advychemical.com https://advychemical.com/**

INFORMATIONS DE COMMANDE

TAILLE DE L'EMBALLAGE	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
Kit de test unique 10 Unités/carton	00-DKM-RK-MAL-ADX-004-001-010
Kit de test unique 25 Unités/carton	00-DKM-RK-MAL-ADX-004-001-025

Mfg. Lic. Réf. : MFG/VD/2021/000020

Manufactured in India By:

ADV 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

Date de publication : 2025-07



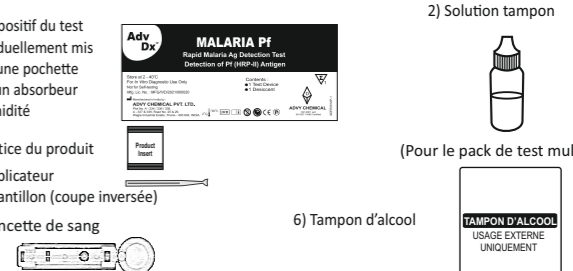
LÉGENDES DE SYMBOLES

Légendes des symboles	Légendes des symboles
Consulter le mode d'emploi	Garder au sec
Ne pas utiliser si l'emballage est endommagé	LOT N° de code de lot
Dispositif de diagnostic in vitro	Fabricant
Conserver à - 2°c - 40°c	Date de fabrication
Tenir à l'abri de la lumière du soleil	A conserver jusqu'au date ou mois de l'expiration
Ne pas réutiliser	Représentant autorisé dans le
Code de produit	Résumé n° de test
Ne pas utiliser pour l'auto-diagnostic	


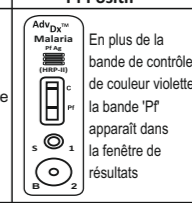
CE EEC REP 2021/0021/000020/2021/000020/2021/000020

Procédure de test avec AdvDx™ Paludisme Pf

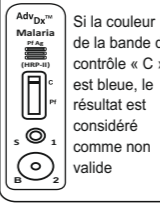
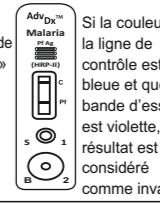
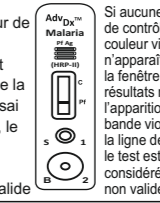
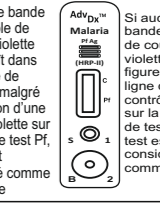
1. Premièrement, lisez attentivement la notice du produit pour savoir comment utiliser le kit **AdvDx™ Paludisme Pf**.
2. Ouvrez maintenant le kit et retrouvez les éléments suivants.
 - 1) Dispositif de test individuellement mis dans une pochette avec un absorbeur d'humidité
 - 2) Solution tampon
 - 3) Notice du produit
 - 4) Applicateur d'échantillon (coupe inversée)
 - 5) Lancette de sang
 - 6) Tampon d'alcool
 - 7) Gel de silice



3. Ensuite, vérifiez la date de péremption à l'arrière du sachet. Utilisez un autre kit, si la date de péremption est dépassée. Ouvrez le sachet et retrouvez les éléments suivants.
 4. Nettoyez le doigt du patient. L'alcool DOIT être séché avant la piqûre ou le test peut ne pas fonctionner.
 5. Dévissez le capuchon de la lancette de sang pour exposer l'aiguille. Piquez le doigt du patient avec la lancette pour prélever du sang. (Essuyez la première goutte de sang avec de la gaze stérile ou du coton. n'appliquez pas de pression excessive et ne faites pas plusieurs piqûres.)
6. Prélever 5 µl de sang à l'aide de l'applicateur d'échantillon (coupe inversée) fourni.
 - Tenez l'applicateur d'échantillon (coupe inversée) verticalement
 - Touchez doucement la goutte de sang
 - Soulevez l'applicateur d'échantillon (coupe inversée)
7. Ajoutez 5 µl de sang dans le port d'échantillon 1 (S).
8. Retirez le bouchon de la bouteille tampon et ajoutez 4 gouttes de solution tampon dans le port tampon (B) du dispositif de test. Tenez le flacon tampon verticalement après avoir distribué le tampon. Cela permet de s'assurer que la goutte contient le bon volume de mémoire tampon.
 - C- Ligne bleue Pf - Pas de ligne
9. **INTERPRÉTEZ LES RÉSULTATS DU TEST À LA FIN DES 20 MINUTES.** **ATTENTION:** ne pas lire le test après 30 minutes, car cela peut donner des résultats incorrects
 - Interprétation des résultats des tests.
10. Interprétation des résultats des tests.

Négatif pour le paludisme	Positif pour le paludisme Pf Positif
	

Non valide

			
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(2)

(3)

(4)

Adv Dx™ MALARIA Pf

Rapid Malaria Ag Detection Test

Detection of Pf (HRP-II) Antigen

Identification number Product insert (IFU): ADFEP025KI-2
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.

(1)

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 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 96.6% 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

SYMBOL LEGENDS

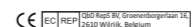
Symbol Explanation of symbol	Symbol Explanation of symbol
Consult instruction for use	Keep Dry
Do not use if package is damaged	Batch code No.
In vitro diagnostic device	Manufacturer
Store at 2°C - 40°C	Date of Manufacture
Keep away from sunlight	Use by (date or month of expiry)
Do not re-use	Authorized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

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

Manufactured in India By:

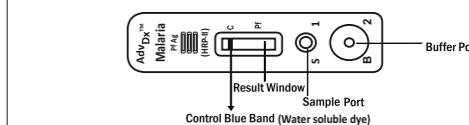
ADV CHEMICAL PVT. LTD.
 Plot No. A - 334 / 336 / 338,
 A - 337 & 339, Road No. 25 & 26,
 Wagle Industrial Estate, Thane - 400 604.
 Email : info@advychemical.com
 Website : www.advvychemical.com

Date Issued: 2025-07



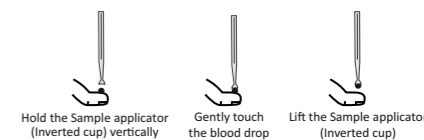
AdvDx™ Malaria Pf Test Procedure

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
 - 3) Product Insert
 - 4) Sample applicator (inverted cup)
 - 5) Blood lancet
 - 6) Alcohol Swab
 - 7) Silica gel

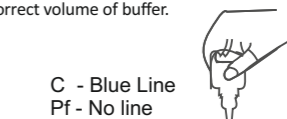


Note: Control blue band (water soluble dye) disappears as test runs and does not affect the test performance. Control blue band is visible in result window only before carrying out the test.

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



7. Add 5µL blood 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.



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
<p>Only one purple colored Control band appears in the result window</p>	<p>In addition to purple colored Control band 'Pf' band appears in the result window</p>

Invalid			
<p>If the colour of the "C" control band is Blue, then result considered Invalid</p>	<p>If the colour of control line is blue and test band is purple, the result is considered invalid</p>	<p>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</p>	<p>If no purple colour band appears at control as well as Test line, the test is considered invalid.</p>

(4)

(2)

(3)

Adv Dx™ MALARIA Pf

Teste rápido de detecção de antígeno para malária
Detecção do antígeno Pf (HRP-II)

PORTUGUESE

Número de identificação do folheto informativo do produto (IFU): ADFEP025KI-2
USO PRETENDIDO

O kit de testes AdvDx™ Malaria pf é um ensaio imunocromatográfico in vitro para a detecção qualitativa de infeção por malária causada por parasitas *Plasmodium falciparum* em humanos. Ele detecta o antígeno HRP-II (proteína rica em histidina-II) de *Plasmodium falciparum* em amostras de sangue total. O teste não avalia a densidade parasitária. Deve ser realizado por profissional treinado e não por usuários leigos. O teste não se destina a autoteste.

SIGNIFICADO CLÍNICO

A malária é uma doença parasitária grave e, por vezes, fatal. Caracteriza-se por febre com calafrios e anemia, sendo causada pelo parasita *Plasmodium*, transmitido de uma pessoa a outra por meio da picada de mosquitos *Anopheles* infectados. Quatro espécies do *parasita Plasmodium* causam infecções em humanos: *P. falciparum*, *P. vivax*, *P. ovale* e *P. malariae*. Dentre essas, *P. falciparum* e *P. vivax* são as mais prevalentes. A detecção precoce e a diferenciação da malária são de extrema importância devido à ocorrência de malária cerebral e à resistência medicamentosa associada ao *P. falciparum*, que é a principal causa de incidência de morbidades e mortalidade mundialmente.

PRINCÍPIO

O kit de teste AdvDx™ Malaria Pf baseia-se no princípio da imunocromatografia. A fita de teste é revestida com anticorpos monoclonais Anti-HRP-II (linha de teste Pf), específicos para a proteína rica em histidina II (HRP-II) de *P. falciparum*. À medida que a amostra de teste flui através do conjunto de membranas do dispositivo após a adição da solução tampão, o ouro coloidal colorido e o conjugado do anticorpo anti-HRP-II formam complexos com o antígeno HRP-II presente na amostra de sangue lisada. Esse complexo antígeno-anticorpo com ouro coloidal se liga ao anticorpo presente na linha de teste da membrana de nitrocelulose, o que leva à formação de uma faixa de teste de coloração vermelha ou roxa. O conjugado não reagido continua a migrar e é subsequentemente imobilizado na região de controle "C", formando uma faixa de coloração vermelha / roxa. O aparecimento da faixa de controle comprova que a amostra ou o tampão migraram através do dispositivo, mas não indica que a amostra utilizada era adequada ou que o procedimento do ensaio foi seguido corretamente.

MATERIAIS FORNECIDOS

A) O kit de teste AdvDx™ Malaria Pf contém os seguintes itens para a realização do ensaio:

Conteúdo	Qtd. na embalagem com 1 teste	Qtd. na embalagem com 10 tests	Qtd. na embalagem com 25 tests	Qtd. na embalagem com 50 tests	Qtd. no kit individual completo com 25 unidades	Qtd. no kit individual completo com 10 unidades
Folheto informativo	01 Unid.	01 Unid.	01 Unid.	01 Unid.	Kit individual completo: 25 unid.	Kit individual completo: 10 unid.
Dispositivo de teste embalado individualmente em sachê aluminizado com dessicante	01 Unid.	10 Unid.	25 Unid.	50 Unid.		
Aplicador de amostras (copo invertido)	01 Unid.	10 Unid.	25 Unid.	50 Unid.		
Swab com álcool	01 Unid.	10 Unid.	25 Unid.	50 Unid.		
Lanceta para punção digital	01 Unid.	10 Unid.	25 Unid.	50 Unid.		
Solução tampão	0,2 mL/ampola	3,0 mL/frasco	3,0 mL/frasco	03 unid. (3,0 mL/frasco)		

B) Os ingredientes ativos dos componentes principais são:

- 1 tira de teste inclui: Conjugado de ouro: anticorpos monoclonais murinos específicos para Pf - HRP-II conjugados com ouro coloidal; linha de controle: IgG anti-murina de cabra.
- Solução tampão: caseína, Triton X-100 e azida de sódio como conservante.

Materiais necessários mas não fornecidos:

- Cronômetro
- Óculos de proteção adequados
- Novo par de luvas descartáveis
- Caneta/lápis
- Recipiente para descarte de perfurocortantes com segurança biológica
- Recipiente para descarte de resíduos biológicos (para materiais potencialmente infecciosos)
- Caso o sangue total seja coletado por punção venosa: materiais para coleta venosa e micropipeta de precisão, além de ponteiros.
- Gaze ou algodão estéril.

PRECAUÇÕES

1. Leia atentamente este folheto informativo antes de realizar o teste; as instruções devem ser seguidas exatamente para garantir resultados precisos.
2. O dispositivo é sensível à umidade e ao calor. Portanto, retire o dispositivo do sachê aluminizado somente imediatamente antes da realização do teste.
3. Certifique-se de que os kits AdvDx™ Malaria Pf estejam armazenados entre 2 °C e 40 °C para garantir o melhor desempenho. A variação nas condições de armazenamento pode causar formação de linhas de teste fracas.
4. Não utilize o kit após a data de validade.
5. Não misture reagentes de diferentes lotes.
6. Uso exclusivo para diagnóstico in vitro.
7. Utilize luvas de proteção ao manusear as amostras e lave bem as mãos após a realização do teste.
8. Não pipetar reagentes ou amostras de sangue com a boca.
9. Não reutilize o teste.
10. A solução tampão contém azida de sódio como conservante. Em caso de contato com a pele, lave imediatamente. Utilize luvas e proteção ocular, pois a solução tampão contém azida de sódio.
11. Não utilize outra solução tampão que não seja a fornecida neste kit.
12. Descarte qualquer amostra remanescente, dispositivo testado, lanceta, aplicador de amostras (copo invertido), frasco de tampão vazio, swab com álcool usado e luvas usadas em recipiente para resíduos biológicos conforme regulamentação local no local de uso. O sachê de sílica deve ser aberto e descartado no lixo comum. Descontamine e descarte todas as amostras, kits de reação e materiais potencialmente contaminados (ou seja, lanceta, aplicador de amostra, dispositivo de teste) em recipiente para resíduos biológicos como se fossem resíduos infecciosos.

(1)

COLETA, ARMAZENAMENTO E PRECAUÇÕES COM A AMOSTRA

Amostra necessária:

Sangue total capilar ou sangue total com os seguintes anticoagulantes: EDTA, citrato ou heparina

Coleta por punção venosa

1. Coletar o sangue total em tubo de coleta contendo anticoagulante (EDTA, citrato ou heparina) por punção venosa. Anticoagulantes como heparina, EDTA e citrato não interferem nos resultados do teste.
2. Caso o teste não possa ser realizado imediatamente, as amostras podem ser armazenadas de 2 a 8 °C por até 3 dias. As amostras devem ser trazidas à temperatura ambiente antes do uso. A utilização de amostras armazenadas por mais de 3 dias pode gerar reações inespecíficas.

Coleta com lanceta para punção digital:

1. Utilize luvas.
2. Escolha um dedo para a punção digital:
 - Não escolha um dedo inchado, com hematomas ou cicatrizes.
 - Preferencialmente utilize o 3º ou 4º dedo da mão que o(a) paciente não usa para escrever.
3. Abra a embalagem do swab com álcool. Retire o swab com álcool. Não descarte a embalagem vazia (invólucro); reserve-a.
4. Limpe completamente a ponta do dedo com o swab com álcool. Aguarde até que o dedo esteja completamente seco (mínimo de 30 segundos).
5. Coloque o swab com álcool no invólucro e reserve-o (será necessário para estancar o sangramento após a coleta do sangue do(a) paciente).
6. Gire a tampa da lanceta para punção digital para expor a agulha. Faça a punção no 3º ou 4º dedo e descarte a primeira gota de sangue com gaze ou algodão estéril.
7. Segure o aplicador de amostra (copo invertido) na posição vertical e permita que a gota de sangue proveniente do dedo perfurado entre em contato com a borda do copo do aplicador de amostra (copo invertido).

Precaução:

1. Utilize um aplicador de amostra separado (copo invertido) (5 µL) para cada amostra, a fim de evitar contaminação cruzada e resultados errôneos.
2. Não utilize qualquer outro tipo de amostra além de sangue total.
3. Não recolha a tampa da lanceta para punção digital e não reutilize-a.
4. Descarte imediatamente a lanceta em recipiente apropriado para perfurocortantes, a fim de evitar acidentes durante o descarte.

PROCEDIMENTO DO TESTE:

1. Deixe os componentes do kit AdvDx™ Malaria Pf e as amostras atingirem a temperatura ambiente.
2. Abra o sachê e retire o dispositivo.

Nota: o dispositivo contém uma linha de controle azul composta por corante hidrossolúvel, que desaparece durante a execução do teste. (Ver item 3 do Procedimento do Teste, página 4)

3. Gire a tampa do frasco da solução tampão no sentido horário para perfurar o bico do frasco. Não perfure com objetos pontiagudos nem corte o bico com tesoura.
4. No caso de amostra de sangue total venoso, misture homogeneamente o sangue anticoagulado agitando suavemente e, em seguida, utilize o aplicador de amostra (copo invertido) para coletar 5 µL do sangue, conforme ilustrado. A não observância deste procedimento pode levar a resultados errôneos.

OU

No Porta-amostra 1 (S) do dispositivo de teste, adicione os 5 µL de sangue venoso coletado com o aplicador de amostra (copo invertido), ou o sangue capilar coletado conforme as instruções anteriores (Coleta com lanceta para punção digital).

5. Adicione 4 gotas (110 µL ± 5 µL) da solução tampão no Porta-tampão 2 (B) do dispositivo de teste. Volumes insuficientes podem causar fluxo incompleto, fluxo retardado, limpeza de fundo incompleta, dificultando a interpretação do resultado ou aumentando a probabilidade de resultados inválidos. Não utilize tampão em excesso, pois isso pode alterar o tempo de reação, reduzindo a sensibilidade do teste (falsos negativos).
6. Leia o resultado ao final de 20 minutos.
7. Interprete o resultado. Consulte a figura indicada no item 10 da página 4.

ATENÇÃO: não leia o teste após 30 minutos, pois poderá apresentar resultados incorretos.

INTERPRETAÇÃO DOS RESULTADOS:

Amostras de sangue total podem causar o aparecimento de fundo avermelhado na janela de resultados.

NEGATIVO:

Apenas a faixa de controle de coloração roxa aparece. Resultados negativos indicam ausência de antígenos da malária na amostra de sangue, o que significa ausência de infecção por malária ou que a quantidade de antígenos presentes na amostra está abaixo do limite de detecção.

POSITIVO:

1) Pf Positivo: o aparecimento de duas faixas (linha de teste "Pf" e linha de controle "C" de coloração roxa) na janela de resultados indica infecção por *P. falciparum*.

A tonalidade ou intensidade da faixa pode variar, mas o resultado deve ser considerado positivo sempre que houver uma linha visível, mesmo que fraca. Linhas fracas podem ocorrer em amostras com baixa densidade parasitária, devido à presença de baixa concentração de antígeno detectável.

INVÁLIDO:

Ausência de faixa roxa ou presença de faixa azul na linha de controle (C). A presença de faixa azul ou a ausência de qualquer faixa na linha de controle (C) indica que o teste é inválido.

ARMAZENAMENTO E VALIDADE:

1. O kit de teste AdvDx™ Malaria Pf deve ser armazenado entre 2 °C e 40 °C (36 °F a 104 °F). Não congelar.
2. O kit possui prazo de validade de 24 meses a partir da data de fabricação. O kit permanece estável até a data de validade indicada no produto, desde que armazenado conforme especificado. A solução tampão permanece estável por 6 meses após a abertura.

LIMITAÇÕES DO TESTE:

1. O kit de teste AdvDx™ Malaria Pf é destinado à triagem primária de infecção por *P. falciparum*. Embora o teste seja preciso na detecção da proteína HRP-II específica de *P. falciparum* em amostras de sangue, pode ocorrer uma baixa incidência de resultados falso-positivos ou falso-negativos. Caso sejam observados falsos positivos em mais de uma cassette por kit, notifique imediatamente o contato informado. Outros testes clínicos disponíveis são necessários em casos de resultados duvidosos. Assim como com todos os testes diagnósticos, um diagnóstico clínico definitivo não deve ser baseado no resultado de um único teste, devendo ser estabelecido pelo médico com base na avaliação de todos os achados clínicos e laboratoriais.
2. Testes rápidos de diagnóstico para malária (RDTs) podem apresentar resultados positivos mesmo após tratamento antimalárico bem-sucedido. Portanto, o kit de teste AdvDx™ Malaria Pf não é recomendado para monitoramento da resposta ao tratamento.

CONTROLE DE QUALIDADE

A faixa de controle atua como controle procedimental e deve estar presente para comprovar que os ingredientes ativos da tira de teste estão funcionais e que a amostra ou o tampão migraram corretamente. A linha de controle também permite o monitoramento da adição da amostra.

CARACTERÍSTICAS DE DESEMPENHO:

O kit de teste AdvDx™ Malaria Pf foi avaliado com amostras clínicas positivas e negativas, testadas por exame microscópico de sangue total.

A. Sensibilidade e especificidade

A sensibilidade e a especificidade do kit de teste AdvDx™ Malaria Pf para detecção de malária por *P. falciparum* são, respectivamente, de 96,66% e 98,42%. O desempenho do teste foi estabelecido por comparação com os resultados do exame microscópico de esfregaços espessos e finos.

Resultado do AdvDx™ Malaria Pf	Método de referência (exame microscópico)		Total
	Pf Positivo	Pf Negativo	
Positivo	87	03	90
Negativo	03	187	190
Total	90	190	280
% sensibilidade	5 % CI	% especificidade	5 % CI
96.6%	90.5% - 99.3%	98.4%	95.4% - 99.6%

B. Sensibilidade analítica (limite de detecção)

A sensibilidade analítica (LoD) do kit de teste AdvDx™ Malaria Pf é de 200 parasitas/µL em amostras de *P. falciparum*, sendo comparável às observações por exame microscópico.

C. Especificidade analítica (reatividade cruzada)

A especificidade analítica do kit de teste AdvDx™ Malaria Pf, avaliada com amostras infecciosas e diferentes anticoagulantes, é de 100%. Fator reumatoide, anticorpos contra dengue, chikungunya e amostras positivas para sífilis não apresentaram reatividade cruzada, e os anticoagulantes EDTA, heparina e citrato de sódio não interferiram no desempenho do kit de teste AdvDx™ Malaria Pf.

D. Precisão:

A repetibilidade e reprodutibilidade do kit de teste AdvDx™ Malaria Pf é de 100%.

REFERÊNCIAS:

1. Organização Mundial da Saúde — Genebra (2000). Novas perspectivas no diagnóstico da malária.
2. Perlmann, P. e Troye-Blomberg, M. (2002). Parasitas da malária e doença. *Imunologia da malária*.
3. Malcolm, J.G., et al. (2002). Sequenciamento do genoma do parasita humano da malária *Plasmodium falciparum*. *Nature* 419:498–511.
4. Histidine Rich Protein II: uma nova abordagem para testes de sensibilidade a fármacos antimaláricos. *Antimicrobial Agents and Chemotherapy*, junho de 2002, p. 1658–1664, Vol. 46, n.º 6.

AVISO LEGAL:

Todas as precauções foram tomadas para assegurar a capacidade diagnóstica e a precisão deste produto. Este produto é utilizado fora do controle do fabricante e do distribuidor, de modo que o resultado pode ser afetado por fatores ambientais e/ou erro do usuário. A pessoa que for objeto do diagnóstico deve consultar um médico para confirmação adicional do resultado.

ADVERTÊNCIA:

Os fabricantes e distribuidores deste produto não se responsabilizam por quaisquer perdas, responsabilidades, reivindicações, custos ou danos, sejam diretos, indiretos ou consequentes, decorrentes de ou relacionados a um diagnóstico incorreto — positivo ou negativo — resultante do uso deste produto.

Para reclamações, dúvidas ou sugestões: **Atendimento ao Cliente: +91 8657428614, feedback@advychemical.com, https://advychemical.com/**

INFORMAÇÕES PARA PEDIDO

APRESENTAÇÃO	REF
1 teste/kit	00-DKM-RK-MAL-ADX-004-001
10 teste/kit	00-DKM-RK-MAL-ADX-004-010
25 teste/kit	00-DKM-RK-MAL-ADX-004-025
50 teste/kit	00-DKM-RK-MAL-ADX-004-050
Kit individual com 10 unid./caixa	00-DKM-RK-MAL-ADX-004-001-010
Kit individual com 25 unid./caixa	00-DKM-RK-MAL-ADX-004-001-025

LEGENDAS DOS SÍMBOLOS

Símbolo	Explicação do símbolo	Símbolo	Explicação do símbolo
	Consultar as instruções de uso		Manter em local seco
	Não utilizar se a embalagem estiver danificada		N.º código do lote
	Dispositivo para diagnóstico in vitro		Fabricante
	Armazenar entre -2 °C e 40 °C		Data de fabricação
	Manter afastado da luz solar		Validade (data ou mês de expiração)
	Não reutilizar		Representante autorizado na Europa
	Código do produto		Quantidade total de testes
	Não destinado a autoteste		

Data de emissão: 2025-07

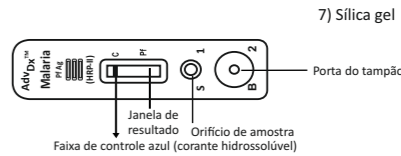
(2)

Procedimento do Teste AdvDx™ Malaria Pf

1. Primeiro, leia atentamente o folheto informativo sobre como utilizar o kit de teste AdvDx™ Malaria Pf.
2. Agora abra o kit e verifique se os seguintes itens estão presentes:

- 1) Dispositivo de teste embalado individualmente em sachê aluminizado com dessicante
- 2) Solução tampão
- 3) Folheto informativo
- 4) Aplicador de amostra (copo invertido)
- 5) Lanceta para punção digital
- 6) Swab com álcool

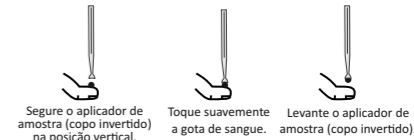
3. Em seguida, verifique a data de validade no verso do sachê. Utilize outro kit caso a data de validade tenha expirado. Abra o sachê e verifique a presença dos seguintes itens.



Nota: a faixa de controle azul (corante hidrossolúvel) desaparece durante a execução do teste e não afeta o desempenho do ensaio. A faixa azul de controle é visível na janela de resultado apenas antes da realização do teste.

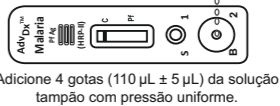
4. Limpe o dedo do(a) paciente. O álcool DEVE estar completamente seco antes da punção; caso contrário, o teste pode não funcionar.
5. Gire a tampa da lanceta para expor a agulha. Realize a punção no dedo do(a) paciente com a lanceta para obter o sangue. (Descarte a primeira gota de sangue com gaze ou algodão estéril. Não aplique pressão excessiva nem realize múltiplas punções)

6. Utilize o aplicador de amostra fornecido (copo invertido) para coletar 5 µL de sangue.



7. Adicione 5 µL de sangue no orifício de amostra 1 (S).
8. Remova a tampa do frasco da solução tampão e adicione 4 gotas da solução no Porta-tampão (B) do dispositivo de teste. Segure o frasco do tampão na posição vertical ao dispensar as gotas. Isso garante que cada gota tenha o volume correto.

C – Linha azul
Pf – Sem linha



Adicione 4 gotas (110 µL ± 5 µL) da solução tampão com pressão uniforme.

9. INTERPRETE OS RESULTADOS AO FINAL DE 20 MINUTOS.

ATENÇÃO: não leia o teste após 30 minutos, pois ele pode apresentar resultados incorretos.

10. Interpretação dos Resultados.

Negativo para Malária	Positivo para Malária Pf Positivo
<p>Apenas uma faixa de controle de coloração roxa aparece na janela de resultado.</p>	<p>Além da faixa de controle de coloração roxa, uma faixa "Pf" aparece na janela de resultado.</p>
Inválido	
<p>Se a cor da faixa de controle "C" for azul, o resultado é considerado inválido.</p>	<p>Se a linha de controle for azul e a linha de teste for roxa, o resultado é considerado inválido.</p>
<p>Se nenhuma faixa roxa aparecer na região de controle da janela de resultado, mesmo havendo faixa roxa na linha de teste "Pf", o teste é considerado inválido.</p>	<p>Se nenhuma faixa roxa aparecer na linha de teste, o teste é considerado inválido.</p>

(4)

Adv Dx™ MALARIA Pf

Rapid Malaria Ag Detection Test

Detection of Pf (HRP-II) Antigen

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.

(1)

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 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 96.6% 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

SYMBOL LEGENDS

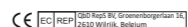
Symbol	Explanation of symbol	Symbol	Explanation of symbol
	Consult instruction for use		Keep Dry
	Do not use if package is damaged		Batch code No.
	In vitro diagnostic device		Manufacturer
	Store at 2°c - 40°c		Date of Manufacture
	Keep away from sunlight		Use by (date or month of expiry)
	Do not re-use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

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

Manufactured in India By:

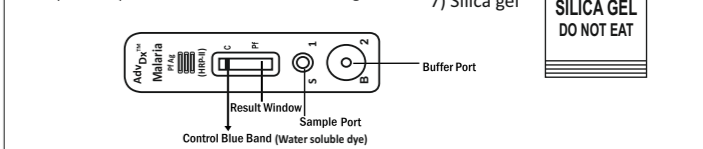
ADV CHEMICAL PVT. LTD.
Plot No. A - 334 / 336 / 338,
A - 337 & 339, Road No. 25 & 26,
Wagle Industrial Estate, Thane - 400 604.
Email : info@advychemical.com
Website : www.advvychemical.com

Date Issued: 2025-07



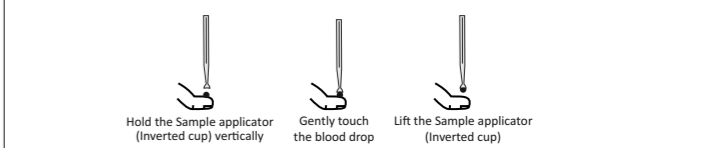
AdvDx™ Malaria Pf Test Procedure

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
 - 3) Product Insert
 - 4) Sample applicator (inverted cup)
 - 5) Blood lancet
 - 6) Alcohol Swab
 - 7) Silica gel

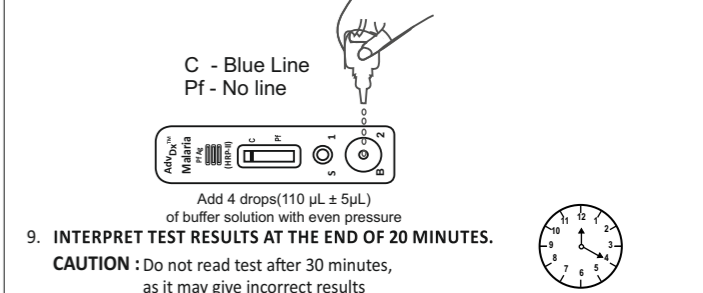


Note: Control blue band (water soluble dye) disappears as test runs and does not affect the test performance. Control blue band is visible in result window only before carrying out the test.

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



7. Add 5µL blood 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.



9. **INTERPRET TEST RESULTS AT THE END OF 20 MINUTES.**

CAUTION : Do not read test after 30 minutes, as it may give incorrect 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.

(4)