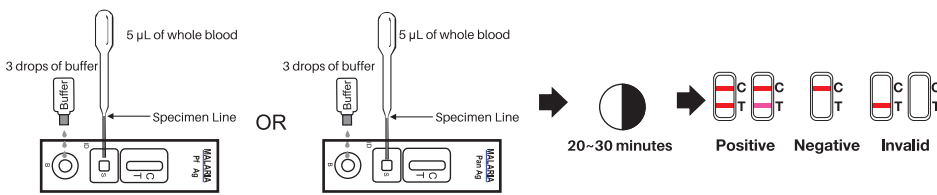


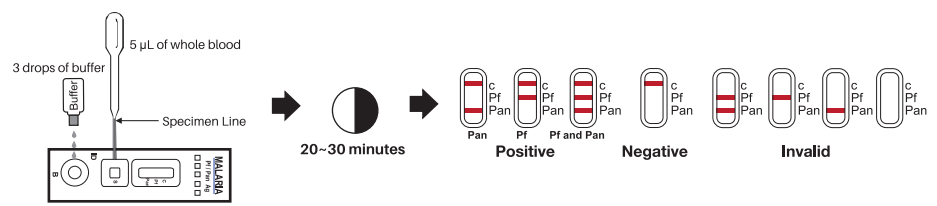


TEST PROCEDURE & INTERPRETATION OF RESULTS

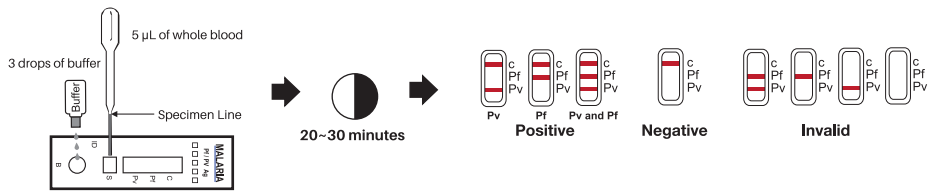
Pf or Pan Ag



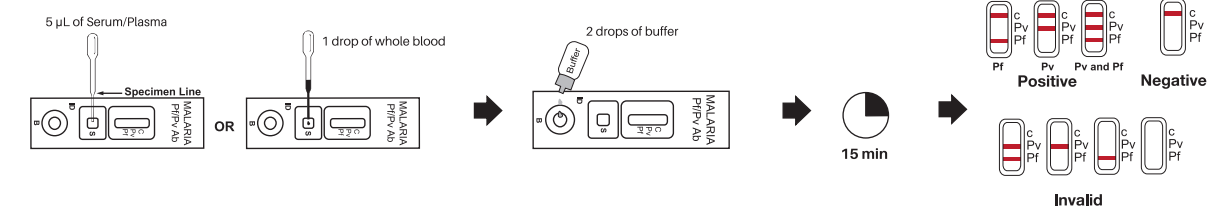
Pf/Pan Ag



Pf/Pv Ag



Pf/Pv Ab



ORDERING INFORMATION

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Malaria Pf Ag Rapid Test	Whole Blood	GCMAL(pan) 402a√	Cassette	200parasites	25 Tests/Kit
Malaria Pan Ag Rapid Test	Whole Blood	GCMAL(pf) 402a√	Cassette	200 parasites	25 Tests/Kit
Malaria Pf/Pv Ag Rapid Test	Whole Blood	GCMAL(pf/pan) 402a√	Cassette	200 parasites	25 Tests/Kit
Malaria Pf/Pan Ag Rapid Test	WholeBlood	GCMAL(pf/pv) 402a√	Cassette	200 parasites	25 Tests/Kit
Malaria Pf/Pv Ab Rapid Test	Serum/Plasma	GCMAL(pf/pv Ab) -302a√	Cassette	/	25 Tests/Kit
Malaria Pf/Pv Ab Rapid Test	Whole Blood/ Serum/Plasma	GCMAL(pf/pv Ab) -402a√	Cassette	/	25Tests/Kit

√ CE Marked

Revision date:2022-09

1. WHO Malaria Report 2021. <https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2021>

Malaria Rapid Diagnostic Solution

Accurate differential diagnosis plays a key role in the fight against malaria

- Rapid results in 15 to 30 minutes
- Only requires a small blood collected by fingerpick
- Easy to read, objective, qualitative results

Key Facts

Malaria is a mosquito-borne disease caused by a parasite. People with malaria often experience fever, chills, and flu-like illness. Left untreated, they may develop severe complications and die. In 2020 an estimated 241 million cases of malaria occurred worldwide and 627,000 people died, mostly children in sub-Saharan Africa. About 2,000 cases of malaria are diagnosed in the United States each year. The vast majority of cases in the United States are in travelers and immigrants returning from countries where malaria transmission occurs, many from sub-Saharan Africa and South Asia. ¹



Impact 3.3 billion people

Malaria occurs in more than 90 countries worldwide, nearly 3.3 billion people are in risk.



241 million cases

241 million cases occurred worldwide between 2019 and 2020.



602,000 deaths

602,000 deaths were confirmed by WHO in African region between 2019 and 2020, 80% of them are children aged under 5 years. ¹



Diagnostic testing prior to providing treatment.

As per WHO recommendation, all cases of suspected malaria need to be confirmed by diagnostic testing.

Malaria Rapid Diagnostic Solution

Specimen: Whole Blood, Serum or Plasma

Clinical Sensitivity & Specificity:

	P.f. or P.v. Single		P.f./P.v. Combo		P.f./Pan Combo	
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
Antigen	>99%	98.7%	>99%	98.7%	>99%	98.7%
Antibody	/	/	93.5%/91.4%	99.1%/98.2%	/	/

For fast, qualitative detection of antigen and antibody to three species of malaria: P. falciparum, P. vivax, P. malariae and P. ovale.



In association with Bill & Melinda Gates Foundation



Evaluated as excellent in WHO Round 7 assessment



CE Certificates obtained

RAPID

- Results seen in 15 to 30 minutes, enabling immediate treatment

EASY TO USE

- Simple-to-use test using only one reagent
- Requires just a small blood sample easily collected by fingerpick
- No need for skilled microscopist

EASY TO INTERPRET

- Differentiated results that aid in the diagnosis of P. f. & P.v. & Pan
- Objective, qualitative results
- No subjective assessment required

ACCURATE AND RELIABLE

- High specificity and sensitivity
- Built-in procedural control ensures test viability
- Reduces unnecessary use of antimalarial drugs, thereby helping to minimise the development of drug-resistant malaria strains



INTENDED USE

The Malaria Rapid Test is a rapid lateral flow chromatographic immunoassay for the detection and differentiation of Malaria P. falciparum specific histidine rich protein-2 (Pf HRP-II), pLDH (Plasmodium lactate dehydrogenase) specific to Plasmodium species (Pan), Malaria P. vivax specific lactate dehydrogenase (Pv-LDH) and antibodies including IgG, IgM and IgA to P. falciparum (P.f.) and P. vivax (P.v.) in human blood specimen as an aid in the diagnosis of Malaria infection.

KIT CONTENTS

- Test cassettes
- Buffer
- Droppers
- Package insert

