



STANDARD Q

Malaria P.f/Pan Ag Test

KEY FEATURES

- WHO Pre-Qualified & TGA Approved
- Cost-effective and fast malaria screening test
- Fast test result in 15 minutes
- Easy to collect specimen with provided sampler (Inverted cup)
- Minimized specimen volume of 5 µl whole blood
- Wider and more durable storage temperature ranging from 2 ~ 40°C
- Optimized for on-site diagnosis and practical for large scale testing

WHO
PQ

CE

TGA



GLOBAL BURDEN OF MALARIA

Malaria remains an important cause of illness and death in children and adults in countries in which it is endemic. According to the World Malaria Report 2022, there were 247 million cases of malaria globally in 2021 which is an estimated increase of 2 million cases from the 2020 estimated cases of 245 million. The protozoal parasites that cause malaria range from *Plasmodium falciparum*, *vivax*, *ovale*, *malariae* and *knowlesi* with the first two species causing the most infections worldwide. Classic symptoms of malaria include fever, headache, chills, vomiting, shivering and convulsions. In some rare forms of *P. falciparum*, the patient may present with delirium or coma. Severe anemia is often attributed to the cause of death from malaria.

[Reference] WHO World Malaria Report 2022

PRODUCT INFORMATION



STANDARD Q Malaria P.f/Pan Ag	
Target antigens	Histidine-Rich Protein II (HRP-II) of <i>Plasmodium falciparum</i> and <i>plasmodium</i> acetate dehydrogenase (pLDH) of <i>Plasmodium</i> (P.f, P.v, P.m, P.o) species
Specimen type	Whole blood
Specimen Volume	5 μ l
Regulatory	WHO PQ, CE, TGA
Testing time	15 ~ 30 minutes
Storage temperature	2 ~ 40°C (36 ~ 104°F)
Shelf life	24 months

PERFORMANCE CHARACTERISTICS

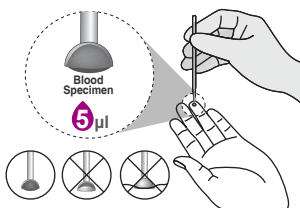
Clinical Evaluation

As part of WHO PQ clinical evaluation data, the evaluation took place in 4 sites (Cambodia, India, Malawia, Zambia) and the summary of the clinical performance is as below.

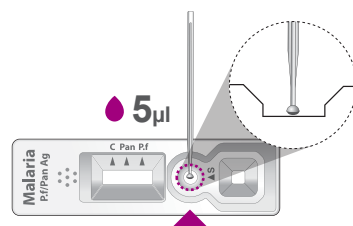
Product	Specimen Type	Malaria Type	Sensitivity	Specificity
STANDARD Q Malaria P.f/Pan Ag Test	Venous WB	P.f	99.58% (95% CI: 98.50-99.95%)	100% (95% CI: 99.63-100%)
		Pan	100% (95% CI: 97.18-100%)	100% (95% CI: 99.63-100%)
	Capillary WB	P.f	99.68% (95% CI: 98.23-99.99%)	100% (95% CI: 98.54-100%)
		Pan	100% (95% CI: 88.78-100%)	100% (95% CI: 98.54-100%)

TEST PROCEDURE

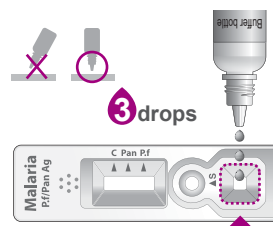
1 Collecting of Specimen



2 Adding of Specimen



3 Adding the Buffer



4 Reading the Test Result



ORDERING INFORMATION

Cat No	Product	Type	Tests / Kit
09MAL30D	STANDARD Q Malaria P.f/Pan Ag Test	Device	25T / Kit
10MALC10	STANDARD Malaria Ag Control (RUO)	Control	10T / Kit

The beginning of all things that protect lives

SD BIOSENSOR

LEF-QMALFA-EN / Rev.00 / 2023.11

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