

SD

BIO LINE

One Step Malaria Rapid test

One Step
Simple
Rapid
Accurate



Malaria Antigen

- Malaria Ag
- Malaria Ag P.f
- Malaria Ag P.f/Pan
- Malaria Ag P.f/P.v

Malaria Antibody

- Malaria P.f/P.v Ab

Rapid, Accurate way to Diagnosis of Malaria



ONE STEP

- No blood lysis
- No need preprocessing

SIMPLE

- No equipment required
- All materials are included

RAPID

- Fast Test Result : 15 minutes
- One step test

ACCURATE

- Differential detection of P.falciparum and Non-P.f



Total Solution for Malaria Test



Comparison of Microscopy and Rapid Test

The current gold standard of diagnosis of malaria is a peripheral blood smear. However, trained staff and quality equipment and supervision are scarce within populations requiring such diagnosis. Alternative methods of diagnosis are available, the simplest of which are Rapid Tests. These are antigen detection tests which are simple to use and to interpret, and also use peripheral blood.

		MICROSCOPY (Blood Smear)	Rapid Test
Requirements	Equipment	Microscope	None
	Electricity	Preferred, not necessary	None
	Supplies	Blood collection, staining reagents, supplies, water	All supplies included in kit
	Training	Trained microscopist	Only minimal training required
Performance	Test Duration	Minimum 1 hr.	15 mins.
	Labour-Intensiveness	High	Low
Technical Specifications	Detection of all species	Yes	Yes
	Quantification	Possible	Not Possible
	Detection of sequestered parasites	No	Yes

What is different between pLDH and HRP-II?

pLDH [parasite Lactate Dehydrogenase]

pLDH is produced by asexual and sexual stages (*gametocytes*) of malaria parasites. Test kits currently available detect pLDH from all four *Plasmodium* species that infect human. They can distinguish *P. falciparum* from the non-*falciparum* species, but cannot distinguish between *P. vivax*, *P. ovale* or *P. malariae*.

HRP-II [Histidine Rich Protein-II]

HRP-II is a water-soluble protein produced by trophozoites and young (but not mature) *gametocytes* of *P. falciparum*.³ Commercial kits currently available detect HRP-II from *P. falciparum* only.

REFERENCE

1. DAVID R. BELL (2005), "False-positive results of a plasmodium falciparum histidine-rich protein 2-detecting malaria rapid diagnostic test due to high sensitivity in a community with fluctuating low parasite density". *Am. J. Trop. Med. Hyg.*, 73(1), 2005, pp. 199–203
2. Thomas Hain (1999), "False positivity of rapid antigen detection tests for diagnosis of plasmodium falciparum malaria: Issue appears to be more complicated than presented". *JOURNAL OF CLINICAL MICROBIOLOGY*, Nov. 1999, p. 3781 - 3782
3. James L. Regens (2009), "Patterns of Plasmodium vivax and Plasmodium falciparum malaria underscore importance of data collection from private health care facilities in India". *Malaria Journal* 2009, 8:227

Description	pLDH	HRP II
Sensitivity	· Approx. >95% (100 parasite/μl) · 95% (50 parasite/μl)	· Approx. >99.9% (100 parasite/μl) · >95% (50 parasite/μl)
Specificity	· Approx. >99.5%	Approx. >99.5%
False Result	· False negative result in small quantity of parasites (5~20) · Positive result for <i>gametocytes</i> (Unnecessary treatment)	· False positive result for 7–14 days following chemotherapy ^{1,2} · False positive result in specimen with rheumatoid factor
Differential Detection	Yes (3–lines) <i>P. Falciparum</i> / other species (Pan)	No (2–lines) <i>P. falciparum</i> only
Detection period	All stage of human life cycle Including <i>gametocyte</i>	Human life cycle except matured <i>gametocytes</i> ³
Purpose	· For monitoring with therapy · Suitable test for prevalence of <i>P. vivax</i>	· Suitable test for diagnosis of <i>P. falciparum</i>



Rapid, Accurate way to Diagnosis of Malaria

Malaria Antigen



Malaria Ag

Sensi.	P.f 96.8% / Pan 95.5%	Speci.	99.5%
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- Cat. No. : 05FK40
- Detection : pLDH from all four *Plasmodium* species
- Differential detection of *P.falciparum* and other species (*P.vivax*, *P.malariae* or *P.ovale*.)
- No blood lysis and preprocessing
- Interpretation : 3-Result line (Control / P.f / Pan)
- **For monitoring with therapy**



Malaria Ag P.f

Sensi.	99.7%	Speci.	99.5%
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- Cat. No. : 05FK50
- Detection : HRP-II Ag of *P. falciparum*
- No blood lysis and preprocessing
- Interpretation : 2-Result line (Control / P.f)
- **Specific and Accurate diagnosis for *P.falciparum***



Malaria Ag P.f/Pan

Sensi.	P.f 99.7% / Pan 95.5%	Speci.	99.5%
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- Cat. No. : 05FK60
- Detection : HRP-II Ag of *P.falciparum* and pLDH from other species (*P.vivax*, *P.malariae* or *P.ovale*.)
- No blood lysis and preprocessing
- Interpretation : 3-Result line (Control / P.f / Pan)
- **Advanced item for Malaria diagnosis**
- **Maximized sensitivity and specificity**



Malaria Ag P.f/P.v

Sensi.	P.f 99.7% / P.v 95.5%	Speci.	99.5%
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- Cat. No. : 05FK80
- Detection : HRP-II Ag of *P.falciparum* and pLDH of *P.vivax*
- No blood lysis and preprocessing
- Interpretation : 3-Result line (Control / P.f / P.v)
- **Accurate diagnosis for common species**
- **Differential diagnosis between P.f and P.v**

Malaria Antibody



Malaria P.f/P.v Ab

Sensi.	P.f 88.2% / P.v 91.3%	Speci.	98.5%
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- Cat. No. : 05FK30
- Detection : Antibodies of all isotypes (IgG, IgM, IgA) specific to *P.falciparum* and *P.vivax* simultaneously
- No blood lysis and preprocessing
- Specimen : 10µl of serum, plasma or 20µl of whole blood
- Test result : in 5~20 minutes
- Interpretation : 3-Result line (Control / P.f / Pan)
- **Screening donated blood to prevent transfusion-induced Malaria**

Total Solution for Malaria Test

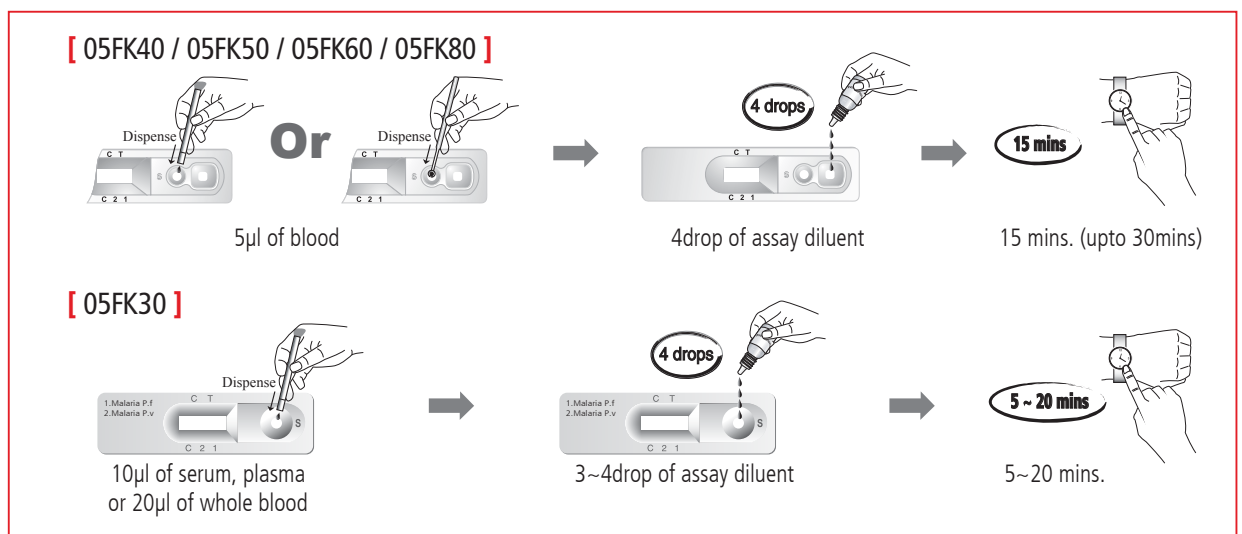
Total Solution for Malaria Test



- SD BIOLINE Malaria Ag
- SD BIOLINE Malaria Ag P.f
- SD BIOLINE Malaria Ag P.f/Pan
- SD BIOLINE Malaria Ag P.f/P.v
- SD BIOLINE Malaria P.f/P.v Ab



Test Procedure



Ordering Information

Cat. No.	Product	Detection	Specimen	Type	Sensitivity	Specificity	Storage
05FK40	Malaria Ag	P.f (pLDH) P.pan (pLDH)	Whole Blood	Device	P.f : 96.8% P.pan : 95.5%	99.5%	24months 1~40°C
05FK50	Malaria Ag P.f	P.f (HRP-II)	Whole Blood	Device	99.7%	99.5%	24months 1~40°C
05FK60	Malaria Ag P.f/Pan	P.f (HRP-II) P.pan (pLDH)	Whole Blood	Device	P.f : 99.7% P.pan : 95.5%	99.5%	24months 1~40°C
05FK80	Malaria Ag P.f/P.v	P.f (HRP-II) P.v (pLDH)	Whole Blood	Device	P.f : 99.7% P.v : 95.5%	99.5%	24months 1~40°C
05FK30	Malaria P.f/P.v Ab	P.f / P.v (IgG, IgM, IgA)	Serum, Plasma, Whole Blood	Device	P.f : 88.2% P.v : 91.3%	98.5%	18months 2~30°C

Logistic Information

Cat. No.	Pack Size	Kits per Carton	Carton Size (cm)	Carton G/Weight (kg)
05FK40/05FK50 /05FK60/05FK80	1T x 25/Kit	45 Kits	56 x 40 x 38	12kg
05FK30	1T x 25/Kit	45 Kits	56 x 40 x 38	13kg