

Symbol key

Only the internationally recognized symbols in use:

Symbol	Explanation	Symbol	Explanation
	In vitro diagnostic medical device		Catalogue number
	Contains sufficient for < n > tests		Consult instructions for use
	Batch code or Lot number		Use by YYYY-MM-(DD)
	Date of manufacture YYYY-MM-(DD)		Manufacture
	Do not reuse		Do not use if package is damaged
	Temperature limitation		Sterile
	Irritant		Biological risks
	Keep away from sunlight		Keep dry

Storage Conditions

Kits stored between 4 - 40°C will have a shelf-life of 24 months after manufacture. Do not freeze.

Expected Results

Shown below are 2 comparative results to blood samples, previously evaluated with microscopy based on 200 Parasites/ml and an *International Laboratory evaluated against PCR.

Sample	# Pos.	# Neg.	CT Malaria Dual Pos.	ICT Malaria Dual Neg.
Total non-<i>P.f.</i> malaria specimens	35 *28	317 *10	33 (94.3%) *28 (100%)	316 (99.7%) *10 (100%)
Total <i>P.f.</i> specimens	273 *28	317 *10	262 (96.0%) *28 (100%)	316 (99.7%) *10 (100%)

Sensitivity (Non-*P.f.* malaria): 61/63 (96.8%)
Sensitivity (*P.f.* Malaria): 290/301 (96.3%)
Specificity: 326/327 (99.7%)

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Manufactured under: ISO 13485:2016

Ordering Information: Ref: ML03 25 TEST KIT

ICT MALARIA DUAL Test
Malaria Pf/PAN Antigen RDT
(HRPII/pLDH)
ML03 (25 Tests)
for in vitro diagnostic usage only

Intended Use

The qualitative detection of *Plasmodium falciparum* (*P.f.*), *Plasmodium vivax* (*P.v.*), *Plasmodium malariae* (*P.m.*) and *Plasmodium ovale* (*P.o.*) antigens in whole blood (1). For the differential diagnosis of Malaria. Using an in vitro immunochromatographic assay.

Principle of the Test

Two capture monoclonal antibodies (anti HRPII for *P.f.* and anti pLDH for PAN) are immobilized on the nitrocellulose strip. The red blood cells are lysed releasing plasmodium specific antigens which bind selectively to these antibodies as the blood is wicked up the strip. The signal reagent is coated with specific antibodies which bind with the antibody-antigen complexes so formed, producing a red line. The presence of an upper red line (the procedural control line) demonstrates the test has been performed correctly (2).

Specimen Collection

Use the collection device provided to collect 5µl of capillary blood, or venous blood collected into EDTA tubes.

- A) To obtain capillary blood via puncture of a finger, heel or other appropriate site, cleanse the area with a sterile swab and dry with a sterile pad. Use a lancet to puncture the skin and collect the blood using the collection device. **Use the blood immediately.**
- B) Collect venous blood, by the standard venipuncture procedure, into an EDTA tube. If the test cannot be performed immediately, the blood may be stored for up to three days at 2°C - 8°C. *Use of an automated pipette is prescribed for transferring blood volumes from EDTA tubes.*

Precautions and Warnings

- Optimal results will be obtained by strict adherence to this protocol. Reagents must be added carefully to maintain precision and accuracy. Treat used cassettes as biohazardous. Do not reuse cassettes.
- Biological contamination of dispensing equipment, containers or reagents can lead to false results. Observe established precautions against microbiological and serological hazards in specimen handling, disposal and throughout all procedures.

- Do not use kits beyond their expiration date. Keep storage boxes dry.
- Store kits at 4°C - 40°C. DO NOT FREEZE.
- Buffer contains sodium azide as a preservative. Sodium azide is toxic and should, therefore, be handled carefully, avoiding ingestion or skin contact
- Do not mix reagents from different kit lots.
- Do not use if damaged.
- Do not use if dessicant colour has reached saturation.

Limitations of Procedure

- A negative test result does not exclude infection with malaria, particularly at low levels of parasitemia. When indicated, perform the reference method (microscopical examination of thick and thin blood films).
- Certain HRPII mutations may not be picked-up (false negative result).
- This test has not been evaluated for monitoring treatment of malaria. Malaria antigens can still be detected for several days after elimination of the parasite by antimalarial treatment. This is especially the case for HRPII.
- Patients with rheumatoid factors, with chronic viral infections (such as hepatitis B or C) or parasitic infections (such as schistosomiasis and trypanosomiasis) may have false positive results.
- Lipaemic and icteric samples can impair the results.
- The pan species test line is capable of detecting all four malaria species. However, there is a low sensitivity for detecting malaria caused by *non-falciparum*, in particular *P. ovale* and *P. malariae*.
- The internal control (control line) only validates the migration of the test. It does not guarantee that the correct sample was used, that the sample was applied correctly or that the sample was correctly stored.

Kit Contents

- Individually packaged cassettes.
- 5µl collection device (for blood collection).
- Buffer bottle.
- Product insert.
- Lancets.
- Sterile swab.

Materials Required but not Included

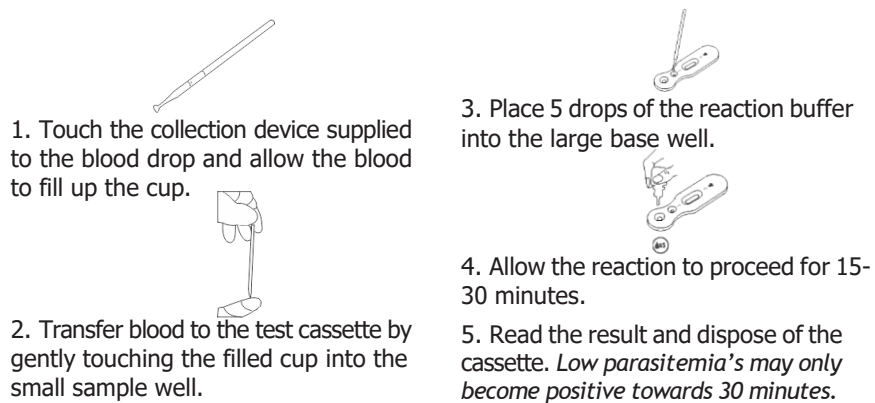
- Timer
- Gloves
- Biohazard Container

Malaria Test Procedure

Prior to use, open the foil bag to be used, exposing the cassette.

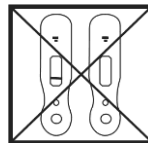
Ensure that all components are at room temperature.

Select the finger for puncture, usually the side of the third or fourth finger. Clean with antiseptic and allow to air dry. Puncture the finger with a sterile lancet. Blood will well to the surface. Redo procedure on another finger if necessary.

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1. Touch the collection device supplied to the blood drop and allow the blood to fill up the cup.
 2. Transfer blood to the test cassette by gently touching the filled cup into the small sample well.
 3. Place 5 drops of the reaction buffer into the large base well.
 4. Allow the reaction to proceed for 15-30 minutes.
 5. Read the result and dispose of the cassette. *Low parasitemia's may only become positive towards 30 minutes.*

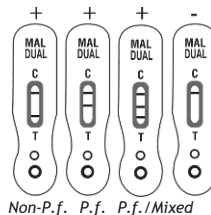
Interpretation of results

Invalid: Either no lines are observable or test line without a control line. Improper test procedure was carried out or reagents have deteriorated. Re-test.



P.f. Positive: The middle and top (control) lines, or all three lines are evident. All three lines may also show in a mixed infection.

Non P.f. Positive: The bottom and top (control) lines are evident.



Negative: The control line is present but not either test line, demonstrating the test was performed correctly but no malarial antigens are present.

References

- 1 Wilson, M. (2012). Malaria Rapid Diagnostic Tests. Clin Infect Dis. (2012) 54 (11): 1637-1641
- 2 Arai, M. Ishii, A. Matsuoka, H. (2004). Laboratory evaluation of the ict malaria *P.f./P.v.* immunochromatographic test for detecting the panmalarial antigen using a rodent malaria model. Am J Trop Med Hyg. 2004 Feb;70(2):139-43
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- 3 Gillet P, Scheirlinck A, Stokx J, De Weggeleire A, Chauque H, Canhanga O, Tadeu B, Mosse C, Tiagö A, Mabunda S, Bruggeman C, Bottieau E, Jacobs J: Prozone in malaria rapid diagnostics tests: how many cases are missed? *Malar J* 2011, 10:166. 9:215
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- 5 Maltha J, Gillet P, Cnops L, Van Den Ende J, Van Esbroeck M, Jacobs J: Malaria rapid diagnostic tests: *Plasmodium falciparum* infections with high parasite densities may generate false positive *Plasmodium vivax* pLDH lines. *Malar J* 2010, 9:198
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- 6 Maltha J, Gillet P, Jacobs J. REVIEW: Malaria rapid diagnostic tests in endemic settings. *Clin Microbial Infect* 2013; 19: 399-407.
<http://onlinelibrary.wiley.com/doi/10.1111/1469-0691.12151/pdf>