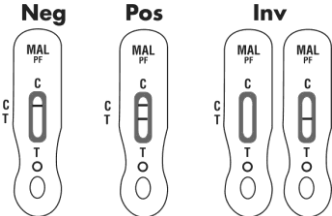


Symbol key

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

Results Interpretation



Control Line: A control line will form in the window if the test was performed correctly.
Negative: For a negative sample, a pink - purple Control line (C) will form. No other line will appear.
Positive: For a positive sample, a pink - purple Control line (C) and a pink - purple coloured Sample Line (T) will appear below the Control Line (C).
Invalid: If no lines are visible, or if no Control Line (C) forms, whether or not a Sample Line (T) appears, the assay is invalid and should be repeated with a new sample and cassette.

Ordering Information: Ref: ML01 25 TEST KIT

Contact Information: ICT International.
10 Fleur de Lage, Sovereign Rd, Johannesburg, South Africa.
Technical Support Tel: +27 (73) 955 0524; E-mail: info@ictdiagnostics.co.za
www.ictdiagnostics.co.za
Manufactured under: ISO: 13485:2016

References:

- M H Craig, B L Bredenkamp, C H Vaughan Williams, E J Rossouw, V J Kelly, I Kleinschmidt, A Martineau and G F J Harry. Field and Laboratory comparative evaluation of ten rapid malaria diagnostic tests. Transactions of the Royal Society of Tropical Medicine and Hygiene (2002) 96, 1-8.
- Gillet P, Scheirlinck A, Stokx J, De Weggeleire A, Chaque H, Canhang 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.
<http://www.malariajournal.com/content/10/1/166>
- Gillet P, Mori M, Van Den Ende J, Jacobs J: Buffer substitution in malaria rapid diagnostic tests causes false-positive results. Malar J 2010, 9:215
<http://www.malariajournal.com/content/9/1/215>
- 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>

ICT MALARIA *P.f.* ANTIGEN RDT
(HRP II)

For the qualitative detection of
Plasmodium falciparum (*P.f.*) antigens in whole blood. In-vitro diagnostic test in immunogromatographic strip format ML01 (25 Tests)

Test Principle

Intended Use:
For diagnostic use with human whole blood.

Intended User:
The test is intended to be performed by a trained user.

The ICT Malaria *P.f.* cassette is a rapid, in vitro diagnostic test for the detection of circulating Plasmodium falciparum antigens. The test uses one antibody specific to histidine-rich protein II antigen of *P.f.* HRPII that has been immobilized across the test strip. A procedural control line is also immobilized across the test strip and will always appear if the test has been performed correctly.

5µl of whole blood is applied to the sample well. Running buffer is then added to the large base well which lyses the whole blood and allows migrations across the membrane. The conjugate pad contains colloidal gold conjugated antibodies that are directed against HRPII. When a positive sample is applied *P.f.* antigens bind to the gold conjugated antibodies. The antibody/antigen complex continues migration along the test strip where they are captured by immobilized antibodies. When capture occurs a pink-purple control line and a pink-purple test line will form in the window. When a negative sample is applied only the control line will appear.

Specimen Collection

Use the sampling 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 directly into the pipette. 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.

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.
- Store kits at 4°C - 40°C. **DO NOT FREEZE.**
- Running Buffer contains sodium azide as a preservative. Sodium azide is toxic and should, therefore, be handled carefully, avoiding ingestion or skin contact. It may react with lead or copper plumbing to form explosive metal azides. Flush with a liberal volume of water when disposing of unwanted reagent.
- Do not mix reagents from different kit lots, or use kits beyond expiry date.
- Do not use if damaged.
- Do not use if devices colour has reached saturation.

Limitations of Procedure

- The test is able to identify an infection caused by Plasmodium falciparum (*P.f.*)
- Diagnosis should be made using results of this test together with other clinical and laboratory findings.
- 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 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.

Sensitivity and Specificity

Numerous evaluations carried out by independent laboratories showed a 100% sensitivity and specificity when tested against their 200 parasites/ml standard.

Kit Contents

- | | |
|--|--|
| • Individually packaged cassettes. | • Product insert. |
| • 5µl sampling devices (for blood collection). | • Lancets. |
| • Buffer. | • Sterile swab (for blood collection). |

Materials Required but not Included

- | | |
|-----------------------|----------|
| • Timer | • Gloves |
| • Biohazard Container | |

Test Procedure

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

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.



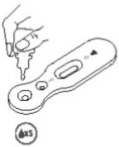
1. Touch the sampling device supplied to the blood drop and allow the blood to fill up the cup.



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 minutes.
5. Read the result and dispose of the cassette.