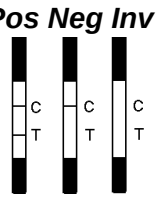
Code 341-025 Malaria Quick Test
25 Individual poached cassettes
1 vial Reaction buffer
25 Lancets
25 Capillaries

CYPRESS DIAGNOSTICS



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Malaria Quick Test

Rapid test for qualitative screening of Plasmodium falciparum malaria in whole blood

Intended Use:

The Cypress Malaria Quick Test is designed as a simple, rapid, qualitative and cost effective method for testing, *in vitro*, the presence of *Plasmodium falciparum* malaria in whole blood. The test is an antigen-capture assay detecting presence of a specific soluble protein, histidine-rich protein II (PfHRP-II), which is present in, and released from, infected red blood cells. The assay is intended for use with whole blood and does not require additional instruments.

Principle of the Test:

A capture monoclonal antibody is immobilized on the nitrocellulose strip. The red blood cells are lysed releasing PfHRP-II which binds selectively to this antibody as the blood is wicked up the strip. The signal reagent is coated with specific antibodies which bind with the antibody-antigen complex, producing a red line. The presence of an upper red line (the procedural control line) demonstrates the test has been performed correctly.

Limitations of the Test:

Definitive clinical diagnosis should not be made until the physician has evaluated the result in combination with other clinical and laboratory findings
Good Laboratory Practice includes the use of an external positive and negative control specimen to ensure proper kit performance.

Materials required but not provided:

-Sterile wipes

Specimen Collection and Storage:

Either capillary or venous blood may be used. Clean skin thoroughly with antiseptic and allow to air dry before collection of sample. In the case of venous blood being used, it should be treated with anticoagulants such as EDTA or Heparin, as neither of these has been shown to interact with the test.

Precautions:

Standard safety precautions in the handling of bioharzardous material should be observed in specimen handling. Dispose of used lancets, capillary tubes and cassettes in designated biohazard disposal containers.

Test Kit Storage and Stability:

Refer to expiration date printed on box of cassettes. This date refers to stability of the reagents when stored at 18-28 °C.
Store strips at 4 to 28 °C. DO NOT FREEZE.

Performance Characteristics:

The following data was generated from previously frozen whole blood samples, and was determined by correlation to standard thick and thin smear microscopic examination with discrepants evaluated via PCR.

Retrospective study results are summarized below:

	Pos.	Neg.	Test Pos.	Test Neg.
Samples	273	317	262 (96.0%)	316(99.7%)

The Cypress Malaria Quick Test did not cross-react with any of the following species of malaria: P.malariae, P.ovale, and P.vivax

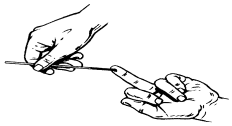
Procedure:

1. Shortly prior to use, remove the device from the foil bag.

2. Select the finger for puncture, usually the side of the third or fourth finger. Clean with antiseptic and allow to air dry.

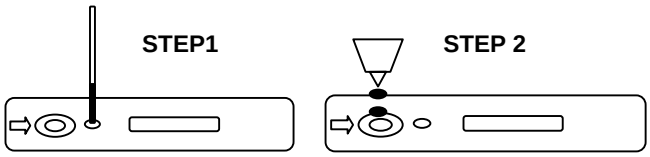
3. Puncture the finger with a sterile lancet. Blood will well to the surface. Redo procedure on another finger if necessary.

4. Touch the collection capillary to the blood spot and allow the blood to fill up to the FIRST line (5µl).



INSTRUCTIONS

1. **Transfer blood (5 µl) to the test strip by gently touching the nozzle to the well.**
2. **Place 4 drops of reaction buffer into the well.**
3. **Time for 15 minutes**
4. **Read and record the results and dispose of the cassette.**
5. **Some tests may develop a faint line upon drying. Results have to be read within 30 minutes.**



Interpretation of results:

Positive: **Both the test and the control lines are observed, demonstrating that P.falciparum antigen is present.**
Negative: **The control line is present but not the test line, demonstrating the test was performed correctly but no P.falciparum antigen is present.**
Invalid: **Either no lines are observable or a test line without a control line. Improper test procedure was carried out or reagents have deteriorated. In this case, a retest is required.**

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www.diagnostics.be
Langdorpsesteenweg 160 • 3201 Langdorp • Belgium • Tel: ++ 32 16 44 63 89 • Fax: ++ 32 16 44 77 62 • e-mail: cypress@diagnostics.be