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MALARIA (P.f.) Rapid InstaTest

Catalog #:172101-1

(for in vitro diagnostic usage only)

Intended Use

The Malaria Test is designed as a simple, rapid, qualitative and cost effective method for testing, *in vitro*, the presence of *Plasmodium falciparum* malaria in 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

Reagents and Materials

Provided in the kit

25 Tests	Component	Description
25	Strips	Pf malaria strips
1	Reaction Buffer	Pink label-used to lyse blood and run strip
25	Capillaries	Heparinized capillaries

Materials required but not provided:

Sterile wipes, Lancets
10 x 75mm test tubes

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 biohazardous material should be observed in specimen handling. Dispose of used lancets, capillary tubes and cassettes in designated biohazard disposal containers.

Additional User Quality Control

Good Laboratory Practice includes the use of an external positive and negative control specimen to ensure proper kit performance. These may be ordered separately.

Test Kit Storage and Stability

Refer to expiration date printed on box of strips. This date refers to stability of the reagents when stored at 18-28 °C. Store strips at 4 to 28 °C. DO NOT FREEZE. Remove the foil cover from the strip just prior to use. Do not use strip past expiry date.

Performance Characteristics

The following data was generated by from previously frozen whole blood samples, and was determined by correlation to standard thick and thin smear microscopic examination with discrepant evaluated via PCR. Retrospective study results are summarized below:

Site	# Pos.	# Neg.	Test Pos.	Test Neg.
India	82	99	79(96.3%)	99(100%)
Senegal	7	6	7(100%)	6(100%)
Varied Origin	50	52	46(92.0%)	51(98.0%)
South Africa	134	160	130(97.7%)	160(100%)
TOTAL	273	317	262 (96.0%)	316(99.7%)

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

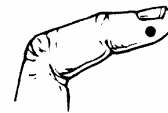
Malaria Test Procedure

Prior to use, remove the foil tab cover to be used, exposing the strip. Check that the dessicant is still blue, demonstrating the packaging is intact.

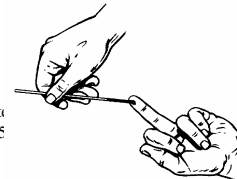


Select the finger for puncture, usually the side of the third or fourth finger. Clean with antiseptic and allow to air dry.

Puncture the finger with a sterile lancet. Blood will well to the surface. Redo



procedure on another finger if necessary.



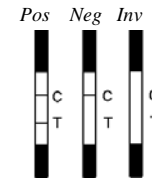
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Touch the collection capillary to the blood spot and allow the blood to fill up to the line.

1. Transfer the blood to the test strip by gently touching the nozzle to the absorbent paper end. (5µl to 10µl may be used)
2. Place 4 drops of reaction buffer into a test tube and then place the strip into the tube (blood end first).
3. Allow the buffer to migrate up the strip (+-3-7 minutes)
4. Read and record the results and dispose of the strip and tube. NB: SOME RAPID TESTS MAY DEVELOP A FAINT LINE UPON DRYING. RESULTS ARE BEST 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. Re-test.

References:

1. Howard,R.J et al. Secretion of a malarial histidine-rich protein 2 (Pf HRP11) from Plasmodium falciparum infected erythrocytes. J.Cell Bio.,103;1269-1277 (1968)
2. Parra,M.E et al. Identification of plasmodium falciparum histidine rich protein 2 in the plasma of humans with malaria. J.Clinical Microbiol,28;1629-1634
3. Multicentre Field Evaluation of a rapid immunochromatographic test for the diagnosis of P.falciparum Malaria (unpublished document)



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