
Lab Dept: Hematology

Test Name: MALARIA, RAPID ANTIGEN TEST

General Information

Lab Order Codes: RMAL

Synonyms: BinaxNOW® Malaria Test; Malaria Antigen test; Rapid test for Plasmodium; Rapid Antigen Test for Malaria

CPT Codes: 87899 – Plasmodium falciparum
87899 – Plasmodium vivax

Test Includes: Antigen testing for Plasmodium falciparum as well as pan-malarial antigen that is shared by other Plasmodium species causing human malaria.

Logistics

Test Indications: Useful for providing a rapid result in diagnosing malaria.

Lab Testing Sections: Hematology

Phone Numbers: MIN Lab: 612-813-6280

STP Lab: 651-220-6550

Test Availability: 7 days a week, 24 hours per day

Turnaround Time: 1 hour after receipt in the laboratory

Special Instructions: Rapid antigen testing should be followed up with examination of thick and thin peripheral blood smear.

Specimen

Specimen Type: Whole blood

Container: Lavender (EDTA) top tube , Lavender (EDTA) Microtainer®.

Draw Volume: 2 mL blood in a 2 mL Lavender top tube
OR
0.5 mL in a EDTA Microtainer®

Processed Volume: Same as Draw Volume

Collection: Fill to mark on tube or Microtainer®. Mix thoroughly by gentle inversion.

Special Processing:	Lab Staff: Do Not centrifuge
Patient Preparation:	None
Sample Rejection:	Improper tube; clotted sample; underfilled tube; mislabeled or unlabeled specimens

Interpretive

Reference Range: Negative for Plasmodium antigen
Positives will be called

Critical Values: N/A

Limitations: A negative test does not exclude infection with malaria, particularly at low levels of parasitemia. As is often done in serial microscopy another sample can be collected and retested.

Positive test results should also be verified by examination of thick and thin peripheral blood smears.

Methodology: The BinaxNOW® Malaria Test is an immunochromatographic membrane assay that uses monoclonal antibodies to detect Plasmodium falciparum antigen and pan – malarial (an antigen shared by Plasmodium species causing human malaria) in venous and capillary whole blood specimens.

Contraindications: This test has not been established for monitoring the treatment of malaria. Residual plasmodium antigen may be detected for several days following the elimination of the parasite by anti-malaria treatment.

This test is not intended for use in screening asymptomatic populations.

References: Brenan, J.G., M.S. Alilio, and A. Mills. Conquering the intolerable burden of malaria: what's new, whats needed: a summary. American J. of Tropical Medicine and Hygiene, 2004;71 (Suppl 2);1-15

Centers for Disease Control (CDC). Treatment of Malaria (Guidelines for Clinicians), June 28, 2004

Manual of Clinical Microbiology, 8th Edition (2003) Plasmodium and Babesia, pp1944-59.

Tijtra, Emiliana, S. Suprianto, J. McBoon, B.J. Currie, and N.M. Antsey. Persistent ICT Malaria P.f./ P.v. Panmalarial and HRP2 Antigen Reactivity after treatment of Plasmodium falciparum Malaria Is Associated with Gametocytemia and Results in False-Positive Diagnoses of Plasmodium vivax in Convalescence. J. of Clinical Microbiology, March 2001;39: 1025-1031

Moody, Anthony. Rapid Diagnostic Tests for Malaria Parasites. Clinical Microbiology Reviews, Jan,2002; 15: 66-78

Iqbal, J.,A. Sher and A. Rab. Plasmodium falciparum Histidine-Rich Protein 2- Based Immunocapture Diagnostic Assay for Malaria: Cross-Reactivity with Rheumatoid Factors. J. of Clinical Microbiology, March 2000; 38:1184-1186

Review Criteria for Assessment of Rheumatoid Factor (Rf) IN Vitro Diagnostic Devices Using Enzyme-Linked Immunoassay (EIA), Enzyme Linked Immunosorbent Assay (ELISA), Particle Agglutination Tests, and Laser and Rate Nephelometry. FDA Guidance Document; February 21, 1997

Lysenko, A. JA. And A.E. Beljaev. An analysis of the Geographical Distribution of Plasmodium ovale. World Health Organization Bulletin, 1969; 40:383-394

Collins, W.E. and G.M. Jeffrey. Plasmodium ovale. Parasite and Disease. Clinical Microbiology Reviews, July 2005; 18:570-581

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