Special Hematology/ 107 BinaxNOW MALARIA TEST

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Comments for version 1.0
Initial version

Approval and Periodic Review Signatures

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Periodic review	Medical Pathologist	3/22/2024	1.0	Lekidule Taddesse-Heath	
Approval	Lab Director	8/15/2021	1.0	Ali Mousa Ramadan	
Approval	Laboratory Operations Manager	8/13/2021	1.0	Wendell McMillan	
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Version History

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1.0	Approved and Current	Initial version	7/22/2021	8/15/2021	Indefinite

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL

Special Hematology/107 **BinaxNOW Malaria test**

Purpose

The BinaxNOW® Malaria Test is an in vitro immunochromatographic assay for the qualitative detection of Plasmodium antigens circulating in human venous and capillary EDTA whole blood of individuals with signs and symptoms of malarial infection. The test targets the histidine-rich protein II (HRPII) antigen specific to Plasmodium falciparum (P.f.) and a pan-malarial antigen, common to all four malaria species capable of infecting humans - P. falciparum, P. vivax (P.v.), P. ovale (P.o.), and P. malariae (P.m.). It is intended to aid in the rapid diagnosis of human malaria infections and to aid in the differential diagnosis of Plasmodium falciparum (P.f.) infections from other less virulent malarial infections. Negative results must be confirmed by thin / thick smear microscopy.

The dual line format allows for detection of malaria parasites and for differentiation of Plasmodium falciparum (P.f.) from other less virulent malaria species. The test cannot distinguish a single species malaria infection from a mixed species infection. Good clinical practice warrants that microscopy be performed to make this determination, as well as to differentiate among the non-falciparum Plasmodium species.

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

Principle

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

These antibodies, and a control antibody, are immobilized on a membrane support as three distinct lines and are combined with a sample pad, which is impregnated with visualizing particles conjugated to control and anti-malaria antibodies, to create a test strip. This test strip is mounted in a book-shaped, hinged test device, along with wash and absorbent pads, intended to aid in the clearing of the membrane when the device is closed.

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL

Special Hematology/107 **BinaxNOW Malaria test**

To perform the test, whole blood is applied to the sample pad. Malarial antigen present in the sample reacts to bind the anti-malaria conjugated antibody. Reagent A is added to the bottom of the test strip and allows the antigen-conjugate complexes to migrate along the test strip, where they are captured by the immobilized antibodies, forming the Test Line(s). Immobilized control antibody captures control conjugate, forming the Control Line. Once the blood sample has migrated the length of the test strip, the device is closed, allowing Reagent A that has been added to the wash pad to clear the test strip of excess blood.

Test results are interpreted by the presence or absence of visually detectable pink-to-purple colored lines. A positive test result, read in 15 minutes, will include the detection of both a Test Line (and Test Lines) and a Control Line. A negative test result, read in 15 minutes, will produce only a Control Line, indicating that malarial antigens were not detected in the sample. Failure of the Control Line to appear, whether the Test Line(s) is present or not, indicates an invalid result.

Reagents

Materials Provided

BinaxNOW® Malaria Test Kit:

Test Devices: A cardboard, book-shaped, hinged test device containing the test strip

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL

Reagent A: Tris buffer containing detergent and sodium azide

MATERIALS REQUIRED BUT NOT PROVIDED

BinaxNOW® Malaria Positive Control Kit (665-010)

Negative Quality Control (pool of 3 – 5 EDTA whole blood samples) Lancets, sterile wipes or pads, clock, timer or stopwatch

STORAGE

Store kit at 2-37°C (36-98.6°F). The BinaxNOW® Malaria Test Kit and reagents are stable until the expiration dates marked on their outer packaging and containers when stored as specified.

QUALITY CONTOL

- The BinaxNOW® Malaria Test has built-in procedural controls.
- External positive and negative controls are run with each day of patient testing
- positive and negative controls be run with each new shipment or lot
- For a negative control, a pool of 3 - 5 EDTA whole blood samples from presumed malaria negative individuals can be used.
- For a positive control, use the BinaxNOW® Malaria Positive Control Kit (665-010); for complete instructions for use, see the package insert included in that kit. BinaxNOW Malaria Positive Control kit insert

Preparation of negative control:

- Equal volumes of EDTA whole blood sample from 3 to 5 presumed malaria negative individuals
- Blood should be no more than 3days old and should not have been frozen
- Refrigerated blood should come to room temperature

- Negative control pool can be used to dilute the BinaxNOW Malaria positive control to a working concentration

Preparation of reconstituted positive control stock aliquots:

- Reconstitute a vial of lyophilized BinaxNOW Malaria positive control with 500µL deionized water
- Vortex to ensure complete mixing
- Aliquot the positive control into the cryovials provided. Dispense 50ul into each vial for the total of 9-10aliquotes
- Use one aliquot to prepare a working dilution of the positive control and freeze the remaining aliquots at ≤-20°C for future use. it is stable for the months indicated on the label located on the card board rack

  Note: each aliquot should be used once to prepare the working positive control

Preparation of working positive control:

- Combine 25µl of the liquid positive control stock with 100µl of the negative blood pool to make a 1:5 dilution of the reconstituted positive control
- Vortex to ensure control is uniform
- Test the malaria positive control as you would patient sample

  Note: once diluted in presumed negative whole blood, the BinaxNOW Malaria positive control can be used only for one day of testing

Procedural Controls:

A. The pink-to-purple line at the "C" (Control) position in a tested device can be considered an internal positive procedural control. If the sample flows and the reagents work, this line will always appear.

B. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white at 15 minutes. Background color should not hinder reading of the test.

Note: If the correct control results are not obtained, do not report patient results. Contact Technical Service during normal business hours.

SPECIMEN

- Collect venous blood, by the standard venipuncture procedure, into an EDTA tube.
- Test whole blood samples as soon as possible after collection.
- If the test cannot be performed immediately, the blood may be stored for up to three days at 2° to 30°C (36-86°F).
- If blood is refrigerated, allow it to come to room temperature (15-30°C) prior to testing.
- Mix gently before testing.
- If microscopy confirmation of a BinaxNOW® negative test result is necessary on a venous blood sample that has been stored, appropriate criteria for the handling of samples used for microscopy should be followed. In some cases, it may be necessary to obtain a fresh sample from the patient.
- To obtain capillary blood via puncture of a finger, cleanse the area with a sterile wipe or pad and dry. Use a lancet to puncture the skin and collect the blood directly into the EDTA capillary tube provided in the test kit. Fill the entire capillary tube with blood and use immediately.

PROCEDURE

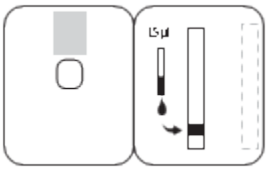
Remove test device from pouch just prior to use. Open the device and lay it flat on the work surface.

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL

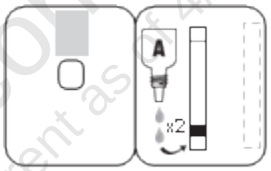
Special Hematology/107 **BinaxNOW Malaria test**

1. If using a venous blood sample, prime the pipette tip by drawing up sample and expelling it a couple of times. Then slowly add 15 µl of blood to the bottom half of the PURPLE sample pad. Go to Step 2.



Note: Incorrect addition of sample may lead to an invalid or uninterpretable test.

2. There is a white pad immediately below the purple sample pad. Hold the Reagent A bottle vertically and add two (2) free-falling drops of Reagent A to this white pad. Allow the first drop to absorb into the pad before adding the second drop. Do not add Reagent A directly to the purple pad.

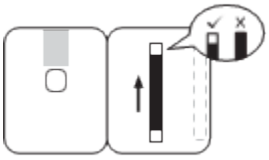


3. Allow the blood sample to run up the full length of the test strip. Do not allow the blood to run into or under the absorbent pad at the top of the strip, as doing so will hinder optimal washing (clearance) of the test strip.

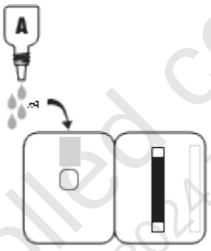
Note: If blood flow up the test strip appears to stall or is less than halfway up the strip after one (1) minute, add one (1) additional drop of Reagent A to the white pad at the bottom of the test strip (below the sample pad where the blood was added).

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL



4. Just before the blood sample reaches the base of the white absorbent pad located at the top of the test strip, SLOWLY add four (4) free-falling drops of Reagent A to the wash pad on the top left-hand side of the test device, allowing each drop to absorb into the pad before adding the next. Note that the third and fourth drops may not completely absorb into the pad.



5. When the sample just reaches the base of the white absorbent pad at the top of the test strip, remove the adhesive liner from the right edge of the device, and close the device. This allows the Reagent A to wash (clear) the blood sample off the test strip. To ensure good device closure and test flow, press very firmly along the entire edge to the right of the result window.

6. Read the test result through the viewing window 15 minutes after closing the test device. Results read before or after 15 minutes may be inaccurate.

Note: When reading test results, tilt the device to reduce glare on the result window, if necessary

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

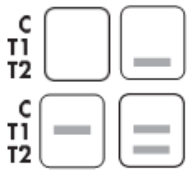
STANDARD OPERATING POLICY AND PROCEDURE MANUAL

Special Hematology/107 **BinaxNOW Malaria test**

RESULT

Valid Test Results

The Control Line (C) will appear on all valid tests and, when it is present, test results are interpreted as follows. Note that the appearance of any Test Line, even when very faint, indicates a positive result.

TEST	RESULTS	DESCRIPTION / INTERPRETATION
T1 Positive		Positive result for *P. falciparum* (P.f.)
T2 Positive		Positive result for *P. vivax* (P.v.) or *P. malariae* (P.m.) or *P. ovale* (P.o.) In some cases the appearance of only the T2 Line may indicate a mixed infection with two or more of P.v., P.m., and P.o.
T1 + T2 Positive		Positive result for *P. falciparum* (P.f.) In some cases the appearance of both the T1 and T2 Lines may indicate a mixed infection of P.f. with another species.
No T1 or T2 Lines		Negative result (no malaria antigens were detected)
Invalid and/or Uninterpretable Test Results		The test is invalid if the Control (C) Line does not appear, whether a Test Line(s) is present or not. The test is uninterpretable if the background color hinders reading of the test result at 15 minutes. Invalid or uninterpretable tests can occur due to improper sample or Reagent A addition. Consult the Test Procedure section and Precaution # 5 before repeating testing with a new device. Call Technical Service if the problem persists.

Positive result requires a blood smear for review and Identification

Negative smear requires a blood smear for review

Limitations

1. A negative test result does not exclude infection with malaria, particularly at low levels of parasitemia. Therefore, the results obtained with the BinaxNOW® Malaria Test should be

used in conjunction with other laboratory and clinical findings to make an accurate diagnosis. As is often done in serial microscopy testing, another sample can be collected and retested.

2. The BinaxNOW® Malaria Test detects antigen from both viable and non-viable malaria organisms, including gametocytes and sequestered P. falciparum parasites. Test performance depends on antigen load in the specimen and may not directly correlate with microscopy performed on the same specimen.
3. Performance of the BinaxNOW® Malaria Test has not been established for monitoring treatment of malaria. Residual plasmodium antigen may be detected for several days following elimination of the parasite by anti-malarial treatment.
4. Samples with positive rheumatoid factor (Rf) titers may produce false positive results in the BinaxNOW® Malaria Test. Rheumatoid factors are autoantibodies, and positive Rf titers are associated with acute autoimmune disorders, such as rheumatoid arthritis, as well as with chronic viral infections (such as hepatitis C) and parasitic infections. In addition, positive Rf titers are present in 1 to 4% of the general population. Like other rapid malaria antigen detection tests, the BinaxNOW® test has been shown to generate false positive results in samples of some individuals with positive Rf titers
5. Analytical reactivity testing demonstrates that the pan malarial test line (T2) on the BinaxNOW® test is capable of detecting all four malaria species (P.f., P.v., P.o., or P.m.). However, during clinical trials, insufficient data was generated to support clinical performance claims for the detection of P.m. or P.o. Clinical performance claims for this test are made for P.f. and P.v. detection only.
6. The test is not intended for use in screening asymptomatic populations**.**

For performance characteristics refer to the product insert

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL

Special Hematology/107 **BinaxNOW Malaria test**

Reference

- BinaxNOW test kit. Test kit product instruction. Alere Scarborough, Inc. IN665000 Rev. 5 2012/11

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

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

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL

Special Hematology/107 **BinaxNOW Malaria test**

Replaces Core lab/special Hematology/318/2010. Approval and revision of documentation maintained electronically