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Malaria Rapid Test Using BinaxNOW™ Malaria Test Kit

Introduction

- 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 is not intended for use in screening asymptomatic populations.
- The test targets the histidine-rich protein II (HRPII) antigen specific to *Plasmodium falciparum (P. falciparum)* and a pan-malarial antigen common to all four malaria species capable of infecting humans: *P. falciparum*, *Plasmodium vivax (P. vivax)*, *Plasmodium ovale (P. ovale)*, and *Plasmodium malariae (P. malariae)*. It is intended to aid in the rapid diagnosis of human malaria infections and to aid in the differential diagnosis of *P. falciparum* infections from other less virulent malarial infections.

Scope

The intended users of this document include Medical Laboratory Technicians (MLT), Clinical Laboratory Scientists (CLS), and Managers handling BinaxNOW® Malaria Test samples, issues, or concerns.
The BinaxNOW Malaria test is classified as CLIA moderate complexity.

Policy

Whole blood specimens from patients suspected of having a malarial infection will be screened at the local Area Medical Center Laboratory using the Binax NOW® Malaria Test Kit. All results will be confirmed by thin/thick smear microscopy. Thin/thick smears will be prepared from the whole blood (refer to *Preparing Blood Films for Malaria and Other Blood Parasites – Medical Centers* procedure for instructions).

Principle

- The BinaxNOW® Malaria Test is an immunochromatographic membrane assay that uses monoclonal antibodies to detect *P. 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 control antibodies are immobilized on a membrane support as three distinct lines, and are combined with a simple pad impregnated with visualizing particles conjugated to control and anti-malarial antibodies, to create a test strip. This test strip is mounted on a book-shaped, hinged test device along with wash and absorbent pads intended to aid in the cleaning of the membrane when the device is closed.
- 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 a Control line. A negative test result will produce only a Control line, indicating that malarial antigens were not detected in the sample. Failure of the Control line to appear, whether or not a Test Line is present, indicates an invalid run.

Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Specimen Sources

- Venous whole blood
- Capillary whole blood

Specimen Collection

- Venous whole blood: Collect venous blood by the standard venipuncture procedure, into an EDTA tube.
- Capillary whole blood: To obtain capillary blood via puncture of 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 perform the test immediately.

Specimen Transport

- Deliver the specimen to the testing laboratory immediately after collection.

Specimen Storage

- Capillary whole blood: Must be tested immediately, and the blood film slides must also be prepared immediately (refer to the *Preparing Blood Films for Malaria and Other Blood Parasites – Medical Centers* procedure for instructions).
- Test venous blood samples as soon as possible on the day of collection*.

  ** Warning!*
  Blood film slides must be prepared from venous blood within one hour after collection (refer to the Preparing Blood Films for Malaria and Other Blood Parasites – Medical Centers procedure).

- It is not clinically appropriate to delay testing a malaria specimen.

Specimen Rejection

The following conditions will lead to cancelation of the test:

- Sources other than capillary or venous whole blood
- Specimens received in biohazardous condition.
- Specimens received with name or identification discrepancies.
- Unlabeled specimens
- Improperly collected or transported specimens

Continued on next page

Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Materials Provided

- BinaxNOW® Malaria Test Kit 25 test (Catalog # 665025)
- BinaxNOW® Malaria Test Kit 12 test (Catalog # 665000)
  - Test Device: A cardboard, book-shaped, hinged test device containing the test strip
  - Reagent A: Tris buffer containing detergent and sodium azide
  - Capillary Tubes: EDTA capillary tubes used to transfer whole blood samples obtained via fingerstick

Materials and Equipment Required but Not Provided

- BinaxNOW® Malaria Positive Control Kit (Catalog # 665010)
- Negative Control (for a Negative Control, a pool of equal volumes of EDTA whole blood samples from 3 to 5 presumed malaria negative individuals can be used. The blood samples should be no more than 3 days old and should not have been frozen. If bloods are refrigerated, allow them to come to room temperature (15-30°C) prior to use. Test the Negative Control as you would a patient sample, following the test procedure instructions as written.)
- Lancets, sterile wipes, or pads
- Timer or stopwatch
- 15 µL calibrated pipette

Kit and Reagent Storage and Stability

- BinaxNOW® Malaria Test Kit: Store at 2-37°C. The kit and reagents are stable until the expiration dates marked on their outer packaging and containers when stored as specified.
- BinaxNOW® Malaria Positive Control Kit:
  - Store lyophilized BinaxNOW® Malaria Positive Control in its foil pouch at 2-8°C. The lyophilized Positive Control is stable until the expiration date marked on its outer packaging when stored as specified.
  - Store aliquots of reconstituted BinaxNOW® Malaria Positive Control frozen (≤ -20°C) in a non-frost free freezer, using the cardboard cryovial rack provided. Once reconstituted and when stored as specified, the aliquotted control is stable for the number of months indicated on the label located on the rack.

Safety Precautions

Observe standard precautions when collecting blood. Follow blood collection protocols and procedures. Wear personal protective equipment, as required. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Refer to the safety manual for additional information.

Continued on next page

Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Quality Control

- **Internal Procedural Controls:**
  - Internal positive and internal negative controls are assessed for acceptability prior to release of patient results.
  - A **pink to purple** band appearing at the Control Line (C) serves as a procedural internal control and indicates the test has been performed correctly, that proper flow occurred, and that the test reagents were active at the time of use.
  - A clean background around the Control or Test lines also serves as a procedural control. Control or Test lines that are obscured by heavy background color may invalidate the test and may be an indication of reagent deterioration, use of an inappropriate sample, or improper test performance.
- **External Controls:**
  - External positive and negative controls are used to monitor reagent reactivity each day of testing, and are parallel tested with each new shipment and each new lot of the BinaxNOW® Malaria Test Kit.
  - Refer to the *Preparing BinaxNOW® Malaria Positive and Negative Controls – Medical Centers* procedure for instructions on how to prepare the external positive and negative controls.
- Document the results according to your local procedure. If controls are invalid, patient results are not to be released and the assay must be repeated.

Warning!
Readings are only valid if the results are read within one minute of the end of the 15-minute incubation.

Precautions

- For *in vitro* diagnostic use.
- Perform the test using a Biosafety Cabinet, if available, or use a face shield.
- Do not use the test kit beyond its expiration date.
- Do not mix components from different kit lots.
- Leave test device sealed in its foil pouch until just before use.
- Do not use test devices from pouches that have holes, where the pouch has not been completely sealed, or where the desiccant indicator has changed from blue to pink. The change in the desiccant color is an indicator the Test Device has been exposed to moisture. **False-negative reactions may result if Test Device is exposed to moisture.**
- If using blood obtained via fingerstick, use the capillary tubes supplied in the test kit to deliver the blood to the test device, and fill the entire volume of the tube.
- If using venous blood, mix sample by tapping the tube or vial gently, and before sampling, prime the pipette tip by drawing the sample into the tip and expelling it two times.

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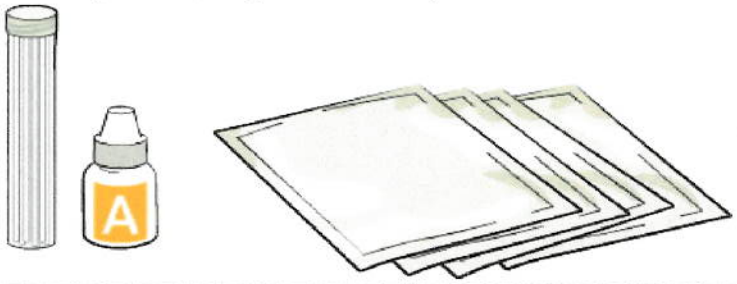
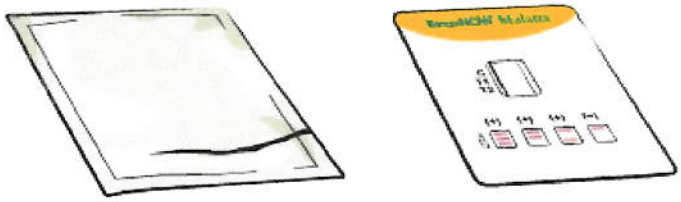
Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Precautions, continued

- Excessive air circulation (e.g., air conditioning, fans, etc.) can slow the flow of the sample. During testing, protecting the devices from excessive air flow is recommended.
- When interpreting test results, use bright, unfiltered light.
- All capillary tubes and pipette tips are single use items – do not use with multiple specimens. Contamination of dispensing equipment, containers or reagents can lead to inaccurate results.
- Reagent A contains sodium azide as a preservative. Sodium azide is toxic and should 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.

Procedure

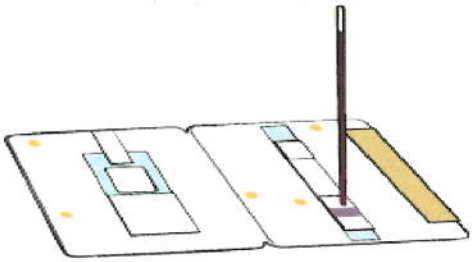
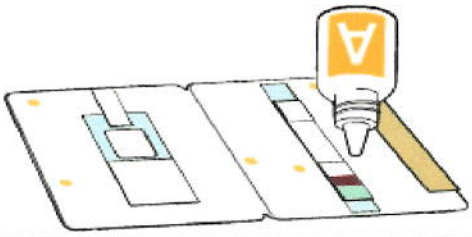
- Follow these steps to test patient samples using the BinaxNOW® Malaria Test Kit.
- Ensure that all blood samples are at ambient temperature prior to use.

Step	Action
1	Assemble all test components, reagents and samples. 
2	Tear the pouch along the notched to open and remove test device 
3	Open the Test Device and lay flat on the work surface: For ease of use, familiarize yourself with the contents of the test device: • **Purple** sample pad (right side) • Reagent pad 1 (below the purple sample pad) • Reagent pad 2 (top left)

Continued on next page

Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Procedure, continued

Step	Action
4	Prime the pipette tip by drawing up sample and expelling it a couple of times. Then slowly add 15 uL of EDTA blood sample to the bottom half of the PURPLE sample pad. ***Warning!*** ***Incorrect addition of sample may lead to an invalid or uninterpretable test.*** Slowly transfer blood to the **purple** sample pad. 
5	• There is a white pad immediately below the purple sample pad. • Hold the Reagent A vial in a vertical position ½ - 1 inch above the pads and slowly 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. • Allow the sample to run up to 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. If this occurs, repeat the test. ***Note:*** ***If the blood flow up the 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).*** 

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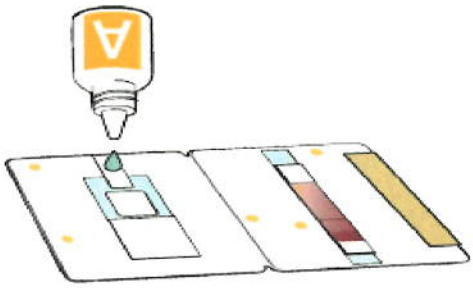
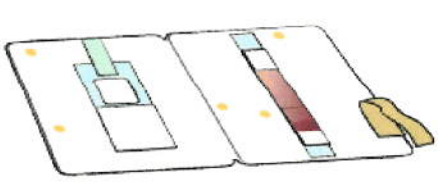
Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Procedure, continued

Step	Action
6	**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 left-hand side of the test device, allowing each drop to absorb into the pad before adding the next.** ***Note:*** ***The third and fourth drops may not completely absorb into the pad.*** 
7	When the sample just reaches the base of the absorbent pad at the **top** of the 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 strip. ***Note:*** ***To ensure good device closure and test flow, press very firmly along the entire edge of the right of the result window.***  
8	Set the Timer for **15 minutes**.
9	• **Immediately** after 15 minutes, and with the device closed, look through window to view and interpret the results. • When reading test results, tilt the device to reduce glare on the results window, if necessary. ***Warning!*** ***Results read before or after 15 minutes may be inaccurate.***

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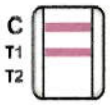
Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Interpretation of Results

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 band, **even when very faint**, indicates a positive result.

Result	Description/Interpretation
No T1 or T2 Lines	• A **pink to purple** line is present at the Control Line position. • No lines are present at the T1 and T2 positions.  **NEGATIVE** – Negative result (no malaria antigens were detected)
T1 Positive	A **pink to purple** line is present at the **Control** position and a **pink to purple** line is present at the **T1** position. ***Note:*** • ***The color of the Test Line can be lighter than that of the Control Line.*** • ***A Weak-positive Test Line should be interpreted with caution since weakly positive test results may represent false-positive tests.***  **T1 POSITIVE** – Positive result for ***P. falciparum*** **(P.f.)**
T2 Positive	A **pink to purple** line is present at the **Control** position and a **pink to purple** line is present at the **T2** position. ***Note:*** • ***The color of the Test Line can be lighter than that of the Control Line.*** • ***A Weak-positive Test Line should be interpreted with caution since weakly positive test results may represent false-positive tests.***  **T2 POSITIVE** – Positive result for ***P. vivax*** **(P.v.)**, ***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.

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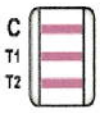
Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Interpretation of Results, continued

Result	Description/Interpretation
T1 and T2 Positive	A **pink to purple** line is present at the **Control** position and **pink to purple** lines are present at the **T1** and **T2** positions. ***Note: In some cases the appearance of both the T1 and T2 lines may indicate a mixed infection of P. falciparum with other species.***  **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 with another species
Invalid or Uninterpretable Test Results	• The test is invalid if the **Control Line** does not appear, whether or not one or both **Test Lines** are present. • The test is invalid if a band of any color other than **pink to purple** appears (bands with colors other than **pink to purple** may indicate reagent deterioration). • 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. ***Warning!*** ***A false positive reaction may occur if the test is incubated too long.*** A test is **INVALID** if the Control Line does not appear whether a Test Line(s) is present or not. A test is **UNINTERPRETABLE** if the background color hinders reading of the test result at 15 minutes.  • If an invalid or uninterpretable result is obtained, repeat the test using a new device. • If the result is still invalid or uninterpretable after repeat testing, proceed to Reporting Results on Page 13 of this procedure.. • If results are questionable, consult a Manager.

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Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Method Performance Specifications

The following information was taken from the BinaxNOW® Malaria Test Kit Product Insert, with additional data provided by the manufacturer:

- Analytic Sensitivity: 99.7% *(P. falciparum)*; 93.5% *(P. vivax)*
  - The performance of the BinaxNOW® test was compared to Giemsa malaria microscopy in a multi-center prospective study conducted in 2001 outside the U.S., in regions considered endemic for malaria. A total of 4,122 whole blood specimens collected from patients presenting with malaria-like symptoms were evaluated on the BinaxNOW® test. Microscopy was considered positive only when asexual malaria forms were detected, since asexual forms (not gametocytes) are indicative of active infection. Forty-four percent (1,796/4,122) of the tested population was microscopy positive for malaria, including 557 patients with *P. falciparum* and 1,187 with *P. vivax*. Fifty-nine percent of patients were male, 41% female, 19% pediatric (<18 yrs) and 81% adult (≥18 yrs).
    - Sensitivity was evaluated based on the levels of parasitemia (parasites per µL) observed in microscopy.
    - No differences in BinaxNOW® Malaria Test performance were observed based on patient age or gender.
    - BinaxNOW® Malaria test performance on samples with low hematocrit and with high hematocrit values was equivalent to its performance on the overall study population.
    - Thirty-four samples were both *P. falciparum* and *P. vivax* positive by microscopy, based on the detection of asexual forms of both species. The BinaxNOW® test detected 32 of these samples by generating both test lines, for a sensitivity of 94.1% (95% CI of 81-98%).
  - Limits of Detection: In the study above, the BinaxNOW® Malaria test clinical limit of detection (LOD) for *Plasmodium falciparum*, defined as the parasitemia level in infected blood that produces positive BinaxNOW® test results approximately 95% of the time, was determined to be 1001-1500 parasites per µL and the clinical LOD for *Plasmodium vivax* was determined to be 5001-5500 parasites per µL.
- Analytic Specificity: 94.2% *(P. falciparum)*; 99.8% *(P. vivax)*
  - The performance of the BinaxNOW® test was compared to Giemsa malaria microscopy in a prospective study conducted in the eastern US in 2006-2007. One hundred (100) whole blood specimens collected from febrile patients were evaluated on the BinaxNOW® test and on microscopy. All 100 samples were negative for malaria on microscopy, and 99 of these samples generated negative BinaxNOW® test results, yielding a specificity of 99% (99/100) in this low incidence population.

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Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Method Performance Specifications, continued

- Interfering Substances:
  - Exogenous Blood Components: Selected substances, e.g., antibiotics, were evaluated in the BinaxNOW® Malaria Test at the concentrations listed in the Product Insert, and were found not to affect test performance.
  - Endogenous Blood Components: The BinaxNOW® Malaria Test was evaluated for possible interference from high levels of endogenous blood components, based on guidelines described in CLSI EP7. EDTA whole blood samples were tested that contained hemoglobin, protein, bilirubin (conjugated and unconjugated) or triglycerides at concentrations above physiological levels. None of the endogenous blood components affected test performance. Interference from Unrelated Medical Conditions: To assess the impact of unrelated medical conditions on the specificity of the BinaxNOW® Malaria Test, 116 specimens from subjects with a variety of medical conditions unrelated to malaria were tested. Only five (5) of the 116 specimens tested produced a false positive result on the BinaxNOW® Test, four (4) from subjects known to be positive for rheumatoid factor and one (1) from a subject with a positive human anti-mouse antibody (HAMA) titer.
- Clinical Performance
  - Analytical Reactivity: The four species of malaria that infect humans, *P. falciparum*, *P. vivax*, *P. ovale*, and *P. malariae* tested positive in the BinaxNOW® Malaria Test at the concentrations listed in the Product Insert.
  - Cross Reactivity: To determine the analytical specificity of the BinaxNOW Malaria Test, 28 pathogenic microorganisms (7 bacteria, e.g. *Borrelia burgdorferi* (N40 strain); 5 protists, e.g. *Leishmania donovani*; and 16 viruses, e.g., Cytomegalovirus [CMVAD169]) that may be present in whole blood were tested. All were negative when tested at the concentrations listed in the Product Insert.
  - Reproducibility: A blind study of the BinaxNOW® Malaria Test was conducted at 3 separate sites using panels of blind coded specimens containing negative, limit of detection, and low positive *P. falciparum* and *P. vivax* samples. Participants tested each sample multiple times on 3 different days. There was 97% (140/144) agreement with expected test results, with no significant differences within run (replicates tested by one operator), between run (3 different days), between sites (3 sites), or between operators (6 operators).

Reference Range

Negative

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Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Reporting Results

Test Result	Group Coded Response Mnemonic	Group Coded Response Description	Action Taken	Result Message in KP HealthConnect
T1 Positive	MRTT1POS	Malaria Rapid T1 Positive	Report result. Call critical value. Submit smears for microscopy.	Positive for *P. falciparum* protein antigen only. Refer to confirmatory smear result.
T2 Positive	MRTT2POS	Malaria Rapid (T2 Positive)	Report result. Call critical value. Submit smears for microscopy.	Positive for malaria protein antigen, representing *P. vivax* or *P. malariae* or *P. ovale* or a mix of these. Differentiation of the species is not possible with this test. Refer to confirmatory smear result.
T1 and T2 Positive	MRTT1T2POS	Malaria Rapid (T1 and T2 Positive)	Report result. Call critical value. Submit smears for microscopy.	Positive for *P. falciparum* protein antigen or a mix of *P. falciparum* antigen and other *Plasmodium* protein antigens. Differentiation of the species is not possible with this test. Refer to confirmatory smear result.
Negative	MRTNEG	Malaria Rapid (Negative)	Report Result. Submit smears for microscopy.	Presumptive negative for malaria antigens. Infection due to malaria cannot be ruled out. Refer to confirmatory smear result.
Invalid or Uninterpretable	MRTINV	Malaria Rapid (Invalid)	Report Result. Submit smears for microscopy.	Invalid or uninterpretable test. Refer to confirmatory smear result.

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Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Limitations

- 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.
- 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.
- 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.
- 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.
- Analytical reactivity testing demonstrates that the pan malarial test line (T2) on the BinaxNOW® test is capable of detecting all four malaria species *(P. falciparum, P. vivax, P. ovale,* and *P. malariae).* However, during clinical trials, insufficient data was generated to support clinical performance claims for the detection of *P. malariae* or *P. ovale.* Clinical performance claims for this test are made for *P. falciparum* and *P. vivax* detection only.
- The test is not intended for use in screening asymptomatic populations.

Controlled Documents

- The following controlled documents support this procedure. Locally approved versions will have different document numbers

Document Number	Title
SCPMG-PPP-0008	Preparing Blood Films for Malaria and Other Blood Parasites – Medical Centers
SCPMG-PPP-0007	Preparing BinaxNOW® Malaria Positive and Negative Controls – Medical Centers
SCPMG-Form-0002	Parallel Testing Form: BinaxNOW Malaria Test Kit
SCPMG-Form-0004	Parallel Testing Form: BinaxNOW Malaria Test Positive Control
SCPMG-Form-0005	Control Log: BinaxNOW Malaria Test

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Malaria Rapid Test Using BinaxNOW® Malaria Test Kit, Continued

Non-Controlled Documents

The following non-controlled documents support this procedure:

- *Laboratory Diagnosis of Blood-borne Parasitic Diseases: Approved Guideline.* CLSI Document M15-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2000.
- Laboratory Procedures for Diagnosis of Blood-Borne Parasitic Diseases (Cumitech 46, 2008); ASM Press, Washington, D.C.
- BinaxNOW Malaria Test Kit (Moderate) Procedure and Documents Packet, SCRMKT-0018 Rev.6 01/2023, Abbott Diagnostics Scarborough, Inc. Scarborough, Maine, USA.
- BinaxNOW Malaria Test Kit Product Instructions PN IN665000, Rev.7.4 10/25/2019, Abbott.
- BinaxNOW Malaria Procedure Card, PN IN665001 Rev.6.4 11/6/2019, Abbott.

Author(s)

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Signature Manifest

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All dates and times are in Pacific Standard Time.

Microbiology Regional Documents

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
Annaleah Raymond (Q741709)	Laboratory Operations Director	20 Mar 2024, 05:02:41 PM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Mark Taira (P161328)	CLIA Director	22 Mar 2024, 08:06:37 AM	Approved