Detection of P.v. Infection
BinaxNOW test sensitivity and specificity for detection of P.v. vs. microscopy is presented below. Sensitivity was evaluated based on the levels of parasitemia (parasites per µl) observed in microscopy. There were 68 samples generating two BinaxNOW test lines that were microscopy positive for P.v. only. When these samples are included in the true positive calculation, BinaxNOW test sensitivity for overall detection of P.v. increases from 68.9% to 74.6% (886/1,187).

BinaxNOW™ Malaria Test Sensitivity and Specificity for P.v. vs. Microscopy

SENSITIVITY for P.v.

Parasitemia Level	% Sensitivity	95%CI
> 5000	93.5% (462 / 494)	91 – 96%
1000 – 5000	81.0% (277 / 342)	76 – 85%
500 – 1000	47.4% (37 / 78)	36 – 59%
100 – 500	23.6% (34 / 144)	17 – 31%
0 – 100	6.2% (8 / 129)	3 – 12%
Overall	68.9% (818 / 1187)	66 – 72%

SPECIFICITY for P.v.

% Specificity	95%CI
99.8% (2863 / 2870)	99 – 100%

Detection of P.m. and P.o. Infection
BinaxNOW test sensitivity was 43.8% (7/16) for detection of P.m. and 50% (1/2) for detection of P.o. When five P.m. microscopy positive samples that generated two test lines in the BinaxNOW test are included in the true positive calculation, BinaxNOW test sensitivity for P.m. increases from 43.8% to 75.0% (12/16).

Detection of Mixed P.f./P.v. Infection
Thirty-four samples were both P.f. and P.v. 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%).

P.f. and P.v. Limits of Detection:
In the study described above, BinaxNOW test clinical limit of detection (LOD) for P.f., 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 P.v. was determined to be 5001-5500 parasites per µl.

Clinical Sample Performance - BinaxNOW™ Malaria Test Sensitivity & Specificity using Venous Draw and Fingerstick Samples – Endemic Population:
The performance of the BinaxNOW test on both venous draw and fingerstick samples was compared to Giemsa malaria microscopy in a prospective study conducted in 2003 outside the U.S. in a region considered endemic for malaria. Whole blood specimens, collected by both venipuncture and fingerstick from 787 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.

Samples that were microscopy positive for P.m. or P.o. and those that were a mix of P.f. and P.v. by microscopy were excluded from the analysis. BinaxNOW test sensitivity and specificity for detection of P.f. and P.v. versus microscopy is presented below for the remaining 782 samples collected via venipuncture and the remaining 784 samples collected via fingerstick.

BinaxNOW™ Malaria Test Sensitivity and Specificity for P.f. and P.v. vs. Microscopy in Venous Draw and Fingerstick Samples

	Venous Draw Samples				Fingerstick Samples			
	% Sens	95% CI	% Spec	95% CI	% Sens	95% CI	% Spec	95% CI
P. f.	100% (81/81)	96 – 100%	94.7% (664/701)	93 – 96%	98.8% (82/83)	94 – 100%	90.4% (634/701)	88 – 92%
P.v.	81.6% (102/125)	74 – 87%	99.7% (655/657)	99 – 100%	80.6% (104/129)	73 – 87%	99.5% (652/655)	99 – 100%

Clinical Sample Performance - BinaxNOW™ Malaria Test Specificity – Non-Endemic Population:
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. BinaxNOW test specificity versus microscopy is presented below.

BinaxNOW™ Malaria Test Specificity vs. Microscopy

	- / -	+ / -	% Spec	95% CI
P.f.	100	0	100%	96 – 100%
P.v., P.o., P.m.	99	1	99%	95 – 100%

Analytical Reactivity:
The four species of malaria that infect humans, ***Plasmodium falciparum*** (P.f.), ***Plasmodium vivax*** (P.v.), ***Plasmodium ovale*** (P.o.) and ***Plasmodium malariae*** (P.m.), tested positive in the BinaxNOW Malaria Test at the concentrations listed below.

Species	Concentration in Parasites per µl Whole Blood
P. falciparum	310
P. vivax	50 – 500
P. ovale	820
P. malariae	50

Analytical Specificity (Cross-Reactivity):
To determine the analytical specificity of the BinaxNOW Malaria Test, 28 pathogenic microorganisms (7 bacteria, 5 protists and 16 viruses) that may be present in whole blood were tested. All were negative when tested at the concentrations listed below.

Type	Pathogen Tested	Concentration Tested
Bacteria	*Borrelia burgdorferi* (N40 strain)	2.3 x 10^6 organisms/ml
	Leptospira interrogans (icterohaemorrhagiae)	1.0 x 10^7 organisms/ml
	Leptospira biflexa (andamana)	1.0 x 10^7 organisms/ml
	Treponema pallidum	1.0 x 10^5 organisms/ml
	Rickettsia conorii (Malish 7)	1.0 x 10^7 organisms/ml
	Rickettsia typhi (Wilmington)	1.0 x 10^7 organisms/ml
	Orientia tsutsugamushi - Rickettsia (Karp)	1.0 x 10^7 organisms/ml
Protists	*Babesia microti* (RMNS strain)	4.4 x 10^7 parasites/ml
	Trypanosoma cruzi (Y strain)	1.3 x 10^6 parasites/ml
	Leishmania donovani	1.0 x 10^6 parasites/ml
	Leishmania infantum	1.0 x 10^6 parasites/ml
	Leishmania chagasi	1.0 x 10^6 parasites/ml
Viruses	Cytomegalovirus (CMV) (AD169)	1.2 x 10^5 PFU/ml
	Epstein-Barr virus (EBV)	1.1 x 10^4 copies/ml
	Dengue virus – West Pac 74	1.2 x 10^5 PFU/ml
	Dengue virus – S16803	3.9 x 10^4 PFU/ml
	Dengue virus – CH53489	1.3 x 10^4 PFU/ml
	Dengue virus – TVP360	1.4 x 10^5 PFU/ml
	Yellow Fever virus	7.9 x 10^6 PFU/ml
	West Nile virus	1.6 x 10^5 PFU/ml
	Chikungunya virus	4.0 x 10^5 PFU/ml
	Ross-River virus	1.0 x 10^6 PFU/ml
	Influenza A – Bayern/7/95	2.5 x 10^7 $TCID_{50}$/ml
	Influenza B – Victoria/2/87	1.0 x 10^7 $TCID_{50}$/ml
	HIV-1 (Subtype B)	1.4 x 10^5 copies/ml
	Hepatitis B	2.0 x 10^5 IU/ml
	Hepatitis C	1.9 x 10^5 IU/ml
	Rubella virus	≥ 2.0 x 10^2 $TCID_{50}$/ml

Interference from Exogenous Blood Components:
The following substances that may be artificially introduced into whole blood were evaluated in the BinaxNOW Malaria Test at the concentrations listed and were found not to affect test performance. ***Note:*** *The analytical effects of these drugs on the BinaxNOW test were studied by taking whole blood and spiking it with quantities at high therapeutic concentrations and then testing these samples. The effects of the clinical metabolites of these drugs on the test were not studied.*

Substance Type	Substance	Concentration
Anti-malarial drugs (prevention)	Mefloquine (Lariam®)	1 mg/ml
	Doxycycline* (Vibramycin®)	1 mg/ml
	Chloroquine	1 mg/ml
	Hydroxychloroquine sulfate	1 mg/ml
	Paludrine® (Proguanil)	1 mg/ml
	Primaquine	1 mg/ml
	Quinine	1 mg/ml
	Sulfadoxine and Pyrimethamine (Fansidar®)	1 mg/ml
Antibiotic (treatment)	Amoxicillin (Trimox®)	0.1 mg/ml
	Cephalexin	0.1 mg/ml
	Ciprofloxacin	0.1 mg/ml
	Erythromycin	0.1 mg/ml
Anti-Inflammatory Drugs (treatment)	Aspirin	1 mg/ml
	Acetaminophen	1 mg/ml
	Ibuprofen (NSAID)	1 mg/ml

* Doxycycline is also used as an antibiotic, typically at a lower dose than that tested in this study.

Interference from 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.

Medical Condition	Number of Samples Tested	BinaxNOW™ Test Negative Results	BinaxNOW™ Test Positive Results
Rheumatoid Factor	50	46	4
Human Anti-mouse Antibody (HAMA)	29	28	1
Anti-nuclear Antibody (ANA)	30	30	0
Systemic Lupus Erythematosus (SLE)	7	7	0

In addition, 20 blood samples, with elevated leukocyte levels ranging from 24 x 10^6 – 87 x 10^6 white blood cells per ml, were evaluated in the BinaxNOW Malaria Test and were found not to affect test performance.

Reproducibility Study
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.f. and P.v. 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). The overall percent detection of each sample type is summarized below.

Overall Percent Detection of P.f. and P.v. Samples

Sample Type	% Detection
P.f. Low Positive	94% (17/18)
P.f. LOD	97% (35/36)
P.v. Low Positive	94% (17/18)
P.v. LOD	100% (36/36)
Negative	3% (1/36)*

* One operator called a negative sample a P.f. positive.

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ORDERING and CONTACT INFORMATION

Reorder number:

#665-000:	BinaxNOW Malaria 12 Test Kit
#665-025:	BinaxNOW Malaria 25 Test kit
#665-010:	BinaxNOW Malaria Positive Control Kit
US	1 877 441 7440

Technical Support

Advice Line
Further information can be obtained from your distributor, or by contacting Abbott Technical Support on:

+1 877 866 9341 TS.SCR@abbott.com

SYMBOLS

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IN665000 Rev. 7 2019/10

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BinaxNOW™ MALARIA TEST KIT
PRODUCT INSTRUCTIONS

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INTENDED USE

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.

Clinical performance has not been adequately established for ***P. ovale*** (P.o.) and ***P. malariae*** (P.m.). The user must establish performance characteristics of this test with these ***Plasmodium*** species.

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

SUMMARY and EXPLANATION of the TEST

Malaria is a major parasitic disease, which is endemic in many countries in various areas of the world. Each year it causes up to 3 million deaths and close to 5 billion cases of clinical illness worldwide.[1]

Diagnosis of malaria using traditional microscopy methods can be difficult and requires precise and meticulous microscopy. Thin and thick smears for malaria detection are labor-intensive and require skilled handling. An experienced technologist is required for interpretation. Even under ideal conditions, microscopic examination of stained blood smears is less than 100% sensitive.

The BinaxNOW Malaria Test is a simple, rapid test for the diagnosis of malaria using whole blood collected by finger stick or venous draw. 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.

It is important that physicians be aware that empiric treatment is required for ***P. falciparum*** if signs and symptoms of individuals warrant immediate therapy.[2] Life threatening end-organ damage can result if treatment is delayed.

PRINCIPLES of the PROCEDURE

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.

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 (or 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 and MATERIALS

Materials Provided

BinaxNOW™ Malaria Test Kit:

Test Devices: 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 to the test devices

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

Note: *When pipetting sample, use a calibrated pipette capable of delivering a 15 µl volume*

PRECAUTIONS

1. For ***in vitro*** diagnostic use.
2. Leave test device sealed in its foil pouch until just before use.
3. Do not use kit past its expiration date.
4. Do not mix components from different kit lots.
5. Samples and Reagent A must be added as described in the test procedure to obtain optimal sample flow and test performance. The following precautions should be taken when adding Reagent A to the test device.
   a. To ensure delivery of the appropriate volume of Reagent A to both pads on the test device, hold the vial vertically, ½ - 1 inch above the pads and slowly add free falling drops.
   b. When adding Reagent A to the white pad directly below the purple sample pad, allow the first drop to absorb completely into the pad before adding the second drop. A third drop of Reagent A may be added to this pad if necessary – see Test Procedure, Step 3.
6. 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 a couple of times.
7. 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.
8. Patient samples and test devices should be handled as though they are capable of transmitting disease. Observe established precautions against bloodborne pathogens. Do not reopen or reuse test cards.
9. Excessive air circulation (i.e. air conditioners, fans, etc.) can slow the flow of the sample. During testing, protecting the devices from excessive air flow is recommended.
10. When interpreting test results, use a bright, unfiltered light.
11. 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.
12. 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.
13. Reagent A also contains Triton® X-100. Warning, causes serious eye irritation. ⚠
14. Safety Data Sheets for this product are available upon request.
15. Follow your national, regional, and local ordinances accordingly for waste disposal regulations.

STORAGE and STABILITY

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 CONTROL

Daily Quality Control:
The BinaxNOW Malaria Test has built-in procedural controls. For daily quality control, the manufacturer recommends that you record these controls for each test run.

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.

External Positive and Negative Controls:
Good laboratory practice recommends that positive and negative controls be run with each new shipment or lot to ensure that:

- test reagents are working, and
- the test is being correctly performed.

For training purposes, it is recommended that all first time users of the test perform external control testing prior to running patient samples.

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); sold separately. For complete instructions for use, see the package insert included in that kit.

Other controls must be tested in order to conform with:

- local, state and/or federal regulations,
- accrediting groups, and/or,
- your laboratory's standard Quality Control procedures.

Refer to 42 CFR 493.1256 for guidance on proper QC practices (U.S. customers only).

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

SPECIMEN COLLECTION and HANDLING

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.

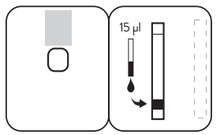
To obtain capillary blood via puncture of a finger, cleanse the area with a sterile wipe or pad and dry. Use a lancet to puncture the skin and collect the blood directly into the EDTA capillary tube provided in the test kit. Fill the entire capillary tube with blood and use immediately.

TEST PROCEDURE

See the Specimen Collection and Handling section for information regarding sample collection. Ensure that all blood samples are warmed to room temperature prior to use.

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

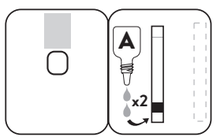
1. If using a capillary blood sample, slowly apply blood from the capillary tube to cover the entire **PURPLE** sample pad on the right side of the device. This is done by holding the capillary tube vertically and gently touching the end of it to the middle of the pad. Once the pad is saturated, properly discard the capillary tube. The test may not require all of the blood that has been collected into the capillary tube. Go to Step 2.



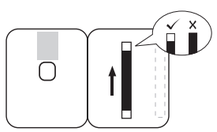
   If using a venous blood sample, prime the pipette tip by drawing up sample and expelling it a couple of times. Then **slowly** add 15 µl of blood to the bottom half of the **PURPLE** sample pad. Go to Step 2.

IMPORTANT: 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.

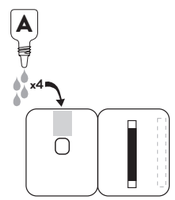


3. Allow the blood sample to run up the full length of the test strip. **Do not** allow the blood to run into or under the absorbent pad at the top of the strip, as doing so will hinder optimal washing (clearance) of the test strip.



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).*

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.*

RESULT INTERPRETATION

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	C T1 T2	Positive result for ***P. falciparum*** (P.f.)
T2 Positive	C T1 T2	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	C T1 T2	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	C T1 T2	Negative result (no malaria antigens were detected)
Invalid and/or Uninterpretable Test Results	C T1 T2	The test is invalid if the Control (C) Line does not appear, whether a Test Line(s) is present or not.
	C T1 T2	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.

REPORTING of RESULTS

Result	Suggested Report
T1 Positive	Positive for ***P. falciparum*** protein antigen only
T2 Positive	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.
T1 and T2 Positive	Positive for ***P. falciparum*** protein antigen. In some cases this may represent a mix of ***P. falciparum*** antigen with ***P. vivax***, ***P. malariae***, or ***P. ovale*** protein antigen. Differentiation between a P.f. only infection and a mixed infection containing P.f. and another malaria species is not possible with this test. Microscopy must be performed to make this determination, as well as to differentiate among the non-falciparum ***Plasmodium*** species.
Negative	Presumptive negative for malaria antigens. Infection due to malaria cannot be ruled out. Malaria antigen in the sample may be below the detection limit of the test. Negative results must be confirmed by thin / thick smear microscopy.

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.[3]

The BinaxNOW Malaria Test detects antigen from both viable and non-viable malaria organisms, including gametocytes[4] and sequestered ***P. falciparum*** parasites[5]. 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.[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.[6] In addition, positive Rf titers are present in 1 to 4% of the general population.[7] Like other rapid malaria antigen detection tests[6], the BinaxNOW test has been shown to generate false positive results in samples of some individuals with positive Rf titers (see Performance Characteristics section).

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.

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

EXPECTED VALUES

Malaria is a serious parasitic disease and is a major health problem in much of the tropics and subtropics. The rate of positive results found in malaria testing is dependent on many factors including the method of specimen collection, the test method used, geographic location, and the disease prevalence in specific localities. ***P. falciparum*** infection is considered to be the most serious and is often fatal, while infections with the other species such as ***P. vivax*** are typically less fatal.[2]

In a clinical study conducted in 2001 in areas considered to be endemic for malaria, the average prevalence of ***P. falciparum*** (as determined by microscopy) in symptomatic patients was 14%, and the average prevalence of ***P. vivax*** was 29%. The prevalence of ***P. ovale***, ***P. malariae***, and mixed infections of P.f. and P.v. was significantly less, totaling less than 2% in the population tested. When only the pan malarial (T2) line appears in the result window of the BinaxNOW Malaria Test, it is likely that the infection is due to the presence of P.v., rather than P.m. or P.o., given the relatively low incidence of these two species in most areas of the world. Areas of West Africa, where P.o. is common, and P.v. is rare, may be an exception to this general rule.[8,9]

In a multi-site study conducted in the eastern US in 2005-2006, 217 whole blood specimens, collected from adult hospitalized patients and outpatients with fever or history of fever, were tested in the BinaxNOW Malaria Test. Two hundred and sixteen (216 – 99.5%) of these presumed negative patients, who were living in areas with a low incidence of malaria, produced negative BinaxNOW test results.

PERFORMANCE CHARACTERISTICS

Clinical Sample Performance - BinaxNOW™ Malaria Test Sensitivity & Specificity – Endemic Population:

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.f., 1,187 with P.v., 16 with P.m., 2 with P.o., and 34 with mixed P.f./P.v. infections. Fifty-nine percent of patients were male, 41% female, 19% pediatric (<18 years) and 81% adult (>18 years). BinaxNOW test performance for detection of the individual malaria species and for mixed P.f./P.v. infections is summarized below.

No differences in BinaxNOW Malaria Test performance were observed based on patient age or gender. BinaxNOW test specificity for P.f. trends slightly lower (89.4%) in the 5% of patients who were on anti-malarial drug therapy, than in patients not receiving therapy (94.4%), but does not achieve statistical significance.

BinaxNOW Malaria test performance on samples with low hematocrit and with high hematocrit values was equivalent to its performance on the overall study population.

Detection of P.f. Infection
BinaxNOW test sensitivity and specificity for detection of P.f. vs. microscopy is presented below. Sensitivity was evaluated based on the levels of parasitemia (parasites per µl) observed in microscopy.

BinaxNOW™ Malaria Test Sensitivity and Specificity for P.f. vs. Microscopy

SENSITIVITY FOR P.f.

Parasitemia Level	% Sensitivity	95%CI
> 5000	99.7% (326 / 327)	98 – 100%
1000 – 5000	99.2% (126 / 127)	96 – 100%
500 – 1000	92.6% (25 / 27)	76 – 99%
100 – 500	89.2% (33 / 37)	75 – 97%
0 – 100	53.9% (21 / 39)	37 – 70%
Overall	95.3% (531 / 557)	93 – 97%

SPECIFICITY FOR P.f.

% Specificity	95%CI
94.2% (3297 / 3500)	93 – 95%

Abbott
BinaxNOW
Malaria

PI - US

Size:
17.0 in. x 11.0 in.

Printed Colors

Black

PN: IN665000
Rev: 7

Date of Last Revision:
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