The BinaxNOW Malaria Test is an in vitro immunochromatographic assay for the qualitative detection of Plasmodium antigens circulating in human red blood cells (HRBC) whole blood. The BinaxNOW Malaria Test can aid in the clearing of the membrane when the device is closed. Life threatening end-organ damage can result if treatment is delayed. If signs and symptoms of individuals warrant further evaluation, it is recommended that malaria-species-specific assays be used for definitive diagnosis.

The BinaxNOW Malaria Test is not a substitute for microscopy, which remains the most valuable means of confirming a suspected diagnosis. The BinaxNOW Malaria Test is not intended to replace microscopy. Because many Plasmodium species have a range of clinical symptoms and many species can cause a variety of presentations, the test result should be considered in the broader context of patient presentation.

The BinaxNOW Malaria Test is intended for use in in vitro diagnostic procedures by laboratory technicians skilled in blood testing and interpretation. Laboratory technicians interpreting test results must have received instruction on the use of the BinaxNOW Malaria Test and use appropriate personal protective equipment (PPE) when handling blood samples or HRBC.

The BinaxNOW Malaria Test can be used with whole blood,uffy-coat blood, or EDTA blood. For best results, the sample should be processed within 4 hours of collection at room temperature (20-25°C) and no earlier than 12 hours post-sampling. The sample should not be refrigerated. The BinaxNOW Malaria Test kit is intended for use in adults and children 9 years of age and older. The test does not require a laboratory setting for detection of malaria parasites. The BinaxNOW Malaria Test should be used with a variety of medical conditions unrelated to malaria. The BinaxNOW Malaria Test is intended to be used in a low-risk malaria-endemic population. The BinaxNOW Malaria Test is not intended to be used in populations at risk for other serious infections (such as leishmaniasis or visceral leishmaniasis).
If using a capillary blood sample, slowly apply blood from the capillary

95.3% (531 / 557)

Presumptive negative for malaria antigens. Infection due to malaria cannot be ruled out. Malaria

RESULTS

Just before the blood sample reaches the base of the white absorbent pad

98 – 100%

The BinaxNOW Malaria Test Kit detects antigen from both viable and non-viable malaria organisms, including gametocytes

SPECIMEN COLLECTION AND HANDLING

See the Specimen Collection and Handling section for information regarding sample collection. Ensure all samples collected are used fresh. It is highly recommended not to store whole blood samples for more than 15 minutes.

TEST PROCEDURE

Remove test device from package just prior to use. Open the device and lay flat for the entire work surface.

1. If using a capillary blood sample, apply blood from the capillary tube to the sample pad. Malarial antigen present in the sample reacts to bind the anti-malaria antibody, causing the Test Line(s) to form. Immobilized control antibody captures uncombined Reagent A. If a Test Line(s) develops, the test is positive.

5. Experimental procedures for the BinaxNOW Malaria Test Kit, 2014, USA, Biomedical Technology, Inc., 2121 Warren St., Madison, WI 53713. The manufacturer declares the following distance between the Test Line(s) and Control Line(s): (a) 10-100 µm for P. falciparum, (b) 100-1000 µm for P. vivax, P. ovale, and P. malariae, and (c) 250-2000 µm for mixed infections.

6. BinaxNOW Malaria Test Kit and reagents are stable until the expiration dates marked on their containers. If the reagents or the test device are within their appropriate storage conditions, the test results are valid for the time period marked on the label. The expiration date is based on the day the reagents were formulated, not the date of shipment.

LIMITATIONS

A negative test result does not exclude infection with malaria, particularly at low levels of parasitemia. Therefore, the results obtained from the BinaxNOW Malaria Test should not be the sole basis for treatment decisions.

PRECAUTIONS

1. Use the test device on one occasion only.
2. Leave test device sealed in its foil pouch until just before use.
3. Open the test device and place it flat on a clean, non-porous surface.
4. To ensure proper functioning of the test, position the test device as shown in the Directions for Use section. When testing a capillary, position the test as shown in the Directions for Use section. When testing a capillary, position the test as shown in the Directions for Use section.

46. This product is not intended for sale to non-United States parties. The manufacturer reserves the right to change the information in this document without notice.

DESCRIPTION / INTERPRETATION

RESULT INTERPRETATION

Collected versus blinded, the standard procedure recommended, rates on an EDTA tube. While whole blood samples are as useful as possible for detection of Plasmodium, it is of note that the sensitivities of the BinaxNOW Malaria Test Kit and reagents are not significantly different.

A negative test result does not exclude infection with malaria. If a negative result is obtained, the sample should be retested.

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, pool a series of EDTA whole blood samples from presumed malaria negative individuals in equal volumes. For a positive control, use the Neg Control Pool (421-003), distributed every time BinaxNOW Material Control is used, or a complete series of known samples, as was the package pre-tested at the time of use.

14. Safety Data Sheets for this product are available upon request.

2. Leave test device sealed in its foil pouch until just before use.

RESULTS

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