Malaria Pan/Syphilis Combo Rapid Test

**INTRODUCTION**

The EzDx™ Malaria Pan/Syphilis Combo Rapid Test Cassette (Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of four kinds of circulating antigens to *Plasmodium* (*P.f., P.vivax, P.ovale, P.malariae*) and Syphilis antibodies (IgG and IgM) to *Treponema Pallidum* (TP) in whole blood. For professional use in in-vitro diagnostics only.

**CLINICAL SIGNIFICANCE**

The EzDx™ Malaria Pan Rapid Test (Whole Blood) is a rapid test to qualitatively detect the presence of four kinds of circulating antigens (*P. falciparum* (*P.f*), *P. vivax* (*P.v*), *P. ovale* (*P.o*), and *P. malariae* (*P.m*)) in whole blood. Malaria is caused by a protozoan which invades human red blood cells. Malaria is one of the world’s most prevalent diseases. According to the WHO, the worldwide prevalence of the disease is estimated to be 300-500 million cases and over 1 million deaths each year. Most of these victims are infants, young children. Microscopic analysis of appropriately stained thick and thin blood smears has been the standard diagnostic technique for identifying malaria infections for more than a century. The technique is capable of accurate and reliable diagnosis, when performed by skilled microscopists using defined protocols. Although there is a logistical burden associated with performing a time-intensive, labor-intensive, and equipment-intensive procedure such as diagnostic microscopy, it is the training required to establish and sustain competent performance of microscopy that poses the greatest difficulty in employing this diagnostic technology.

The EzDx™ Syphilis Rapid Test (Whole Blood) utilizes a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilized on membrane to detect TP antibodies (IgG and IgM) qualitatively and selectively in whole blood. *Treponema Pallidum* (TP) is the causative agent of the venereal disease Syphilis. TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane. Relatively little is known about the organism in comparison with other bacterial pathogens. According to the Center for Disease Control (CDC), the number of cases of Syphilis infection has markedly increased since 1985. Some key factors that have contributed to this rise includes the crack cocaine epidemic and the high incidence of prostitution among drug users. One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis. Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary Syphilis is defined by the presence of a chancre at the site of inoculation. The antibodies response to the TP bacterium can be detected within 4 to 7 days after the chancre re-appears. The infection remains detectable until the patient receives adequate treatment.

**PRINCIPLE**

The EzDx™ Malaria Pan Rapid Test (Whole Blood) is a qualitative, membrane based immunoassay for the detection of *P.f., P.v., P.o.* and *P.m.* antigens in whole blood. The membrane is pre-coated with anti-Malaria antibodies.

During testing, the whole blood specimen reacts with the dye conjugate, which has been pre-coated on the test cassette. The mixture then migrates upward on the membrane by capillary action, reacts with anti-Malaria antibodies on the membrane on Test Line region. If the specimen contains *P.f., P.v., P.o.* and/or *P.m.* antigens, a colored line will appear in test line region. The absence of the colored line in test line region indicates that the specimen does not contain *P.f., P.v., P.o.* and/or *P.m.* antigens. To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added.

The EzDx™ Syphilis Rapid Test (Whole Blood) is a qualitative, membrane based immunoassay for the detection of TP antibodies (IgG and IgM) in whole blood. In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the test. After specimen is added to the specimen well of the cassette, it reacts with Syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized Syphilis antigen. The double antigen test format can detect both IgG and IgM in specimens. If the specimen contains TP antibodies, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a colored line will not appear in this region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**MATERIALS PROVIDED**

The EzDx™ Malaria Pan/Syphilis Combo Rapid Test Kit contains following items to perform the assay:

1. Test device individually foil pouch with a desiccant.
2. Sample applicator for malaria test.
3. Sample applicator for syphilis test.
4. Malaria Buffer solution.
5. Syphilis Buffer Solution.
INTERPRETATION OF RESULTS

<table>
<thead>
<tr>
<th>Malaria</th>
<th>Malaria</th>
<th>Syphilis</th>
<th>Syphilis</th>
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<tbody>
<tr>
<td><img src="image1.png" alt="Positive" /></td>
<td><img src="image2.png" alt="Positive" /></td>
<td><img src="image3.png" alt="Negative" /></td>
<td><img src="image4.png" alt="Negative" /></td>
</tr>
</tbody>
</table>

(Please refer to the illustration above)

**POSITIVE:**
Two distinct colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

**NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Pan-malarial antigens and/or Syphilis antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE:**
One colored line appears in the control line region (C) No line appears in the test line region (T).

**INVALID:**
Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new device.

**STORAGE AND STABILITY**
1. EzDx™ Malaria Pan/Syphilis Combo Rapid Test should be stored between 2°C to 30°C or (36 to 86°F).

**DO NOT FREEZE.**
2. Do not use the test device beyond the expiration date. The expiration date of this kit is indicated on the kit carton and on individual kit pouch as well.

**QUALITY CONTROL**
Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

**LIMITATIONS**
1. The Malaria Pan Rapid Test (Whole Blood) is for in vitro diagnostic use only. This test should be used for the detection of Pf, Pv, Pm. antigens in whole blood specimens only. Neither the quantitative value nor the rate of increase in Pf, Pv, Pm. concentration can be determined by this qualitative test.

2. The Malaria Pan Rapid Test (Whole Blood) will only indicate the presence of antigens of Plasmodium sp. (Pf, Pv,Po,Pm.) in the specimen and should not be used as the sole criteria for the diagnosis of malaria infection.

3. The Syphilis Rapid Test (Whole Blood) is for in vitro diagnostic use only. The test should be used for the detection of TP antibodies in whole blood specimens only. Neither the quantitative value nor the rate of increase in TP antibodies can be determined by this qualitative test.

4. The Syphilis Rapid Test (Whole Blood) will only indicate the presence of TP antibodies in the specimen and should not be used as the sole criteria for the diagnosis of TP infection.

5. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

6. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of malaria and/or TP infection.

**REFERENCES**
DISCLAIMER:
Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. This product is used outside of the control of the manufacturer and the distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

WARNING:
The Manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

For any complaint/query and suggestions:
Customer Care No.: + 91 - 22 - 25830326

ORDERING INFORMATION

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Product Code</th>
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</thead>
<tbody>
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<td>RK MTP 002-30</td>
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