Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

OneStep Malaria (Pan-LDH) Whole Blood RapiCard™ InstaTest

REF 172120-25-23

IVD See external Label 4-30°C Σ 25 Tests

Specificity	**96%**
Sensitivity	**91%**

INTENDED USE

For the rapid qualitative determination of one or more of the known Malaria species; *P. falciparum P. vivax*, *P. ovale*, and/or *P. malariae* by detecting lactate dehydrogenase (LDH) in human blood.

SUMMARY AND EXPLANATION

Malaria is a serious parasitic disease characterized by **fever**, chills, and anemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes.
There are four kinds of malaria that can infect humans: *Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale,* and *Plasmodium malariae.* In humans, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites. The disease now occurs in more than 90 countries worldwide, and it is estimated that there are over 500 million clinical cases and 2.7 million malaria-caused deaths per year. At the present, malaria is diagnosed by looking for the parasites in a drop of blood. Blood will be put onto a microscope slide and stained so that the parasites will be visible under a microscope.

DAI Malaria pan-LDH Antigen Test Antigen Test contains a membrane strip, which is pre-coated with anti-pan LDH monoclonal antibodies on the test line region of the strip. When a Whole Blood specimen is applied at one end of the membrane and following the application of the assay buffer, it reacts with the colloidal gold-anti-pan LDH antibody that have already been applied to the specimen pad. The mixture then migrates chromate-graphically towards the other end of the membrane and reacts with the monoclonal antibodies previously placed on the test line region. If the blood contains one or more of the four Malaria species, a colored line will appear in the test line region, showing a positive result. The absence of the colored line in the test region indicates a negative result therefore the whole blood does not contain detectable levels of any of the Malaria species. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly. This control line serves to validate the performance of the test.

TEST PRINCIPLE

This test is an aid in the diagnosis of Malaria infection.

SPECIMEN COLLECTION AND PREPARATION

Collection by venipuncture

1. Collect whole blood into a collection tube (containing EDTA, citrate or heparin) by venipuncture.
2. If specimens are not immediately tested, they should be refrigerated at 2 ~ 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen after long-term storage of more than three days can cause non- specific reaction.
3. When stored at 4 ~ 8°C, the whole blood sample should be used within three days.

Collection using a lancet

1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with a sterile lancet provided.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Using a 5 µL calibrated dropper tube, while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the dropper.

MATERIALS AND COMPONENTS

Materials provided with the test kits

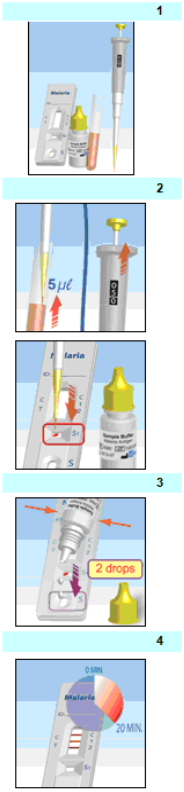
1. Test Device.
2. Assay Buffer.
3. Instructions for Use.

Materials required but not provided

1. Calibrated Pipette.
2. Lancet.
3. Timer.
4. Alcohol swab.

ASSAY PROCEDURE

1. Allow test device, buffer, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Add 5 µl of whole blood into sample well [S1], the small well.
3. Add three drops (approx. 80 µL) of assay buffer into developer well marked with [S]
4. Read the test result in 20 min.



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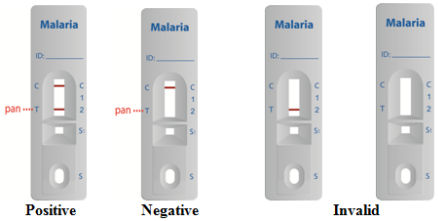
RESULTS

- **Positive:** The presence of two color bands indicates a positive result for Malaria. T
- **Negative:** The presence of only one band in the control region of the result window indicates a negative result.
- **Invalid:** The test is invalid if the control line does not appear. If this occurs, the test should be repeated using a new device.

Positive sample may show positive results within a few minutes after the sample is added. However, to confirm a negative result, please wait until 20 minutes.



PERFORMANCE CHARACTERISTICS

248 patients with suspected uncomplicated malaria were recruited. Blood samples were tested with the rapid malaria pan-LDH antigen test and compared with the gold standard in malaria diagnosis–slide microscopy. The patient sample was assessed as positive or negative by slide microscopy with significant level based on blood parasiteamia of 100 parasites/µl of blood determined by expert microscopists/parasitologists.

The test showed true positive in 68 patients, false positive in 7, true negative in 166 and false negative in 7. Sensitivity was 91 %(69/75) and specificity 96 %(166/173). The positive predictive value (PPV) was 91 %(68/75) and the negative predictive value (NPV) 96 % (166/173).

Of all positive samples with rapid malaria pan-LDH test (75), 37(49.3%) was P.falciparum alone, 32(42.7%) was mixed infection and 6(8.0%) was positive for non-P.falciparum malaria. The lowest level of parasiteamia detected by the RDT was 204parasites/µl of blood.

LIMITATIONS OF PROCEDURE

1. The positive result obtained with Cortez Malaria pan-LDH Antigen Test alone cannot be the final diagnosis of malaria infection. Any positive result must be interpreted in conjunction with the patient clinical history and other laboratory testing results.
2. Negative results do not rule out the possibility of malaria exposure or infection.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. The kit can be stored at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch.
6. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.**
7. Does not use beyond the expiration date.

ISO 13485
ISO 9001

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Date Adopted	2016-02-03
REF 172120-25-23	CORTEZ- OneStep Malaria (Pan-LDH) W/B RapiCard™ InstaTest
Revision Date: 2011-06-22	