



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

REF 172120

PIC ID172120XW1

IVD See External Label 30°C 25 Tests

INTENDED USE

The OneStep Malaria pan-LDH Antigen RapiCard™ InstaTest is an in vitro qualitative immunochromatographic assay for the rapid detection 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 sample. This test is intended to provide an aid in the diagnosis of Malaria infection.

SIGNIFICANCE AND SUMMARY

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.

The OneStep Malaria pan-LDH Antigen RapiCard™ InstaTest contains a membrane strip, which is pre-coated with anti-pan LDH monoclonal antibody 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 via capillary flow 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.

ASSAY 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 and used within three days. 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.

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 capillary pipet, gently squeeze the pipet and, immerse the open end in the blood drop. Then gently release the pressure to draw blood into the pipet.

MATERIALS AND COMPONENTS

Materials provided with the test kit

1. Test Device
2. Assay Buffer
3. 5 µL Capillary Pipet
4. Instructions for Use

Malaria (Pan-LDH) RapiCard™	
Principle	Rapid Chromatographic Immunoassay
Detection	Qualitative
Sample	Whole Blood
Sensitivity	91%
Specificity	96%

PRODUCT FEATURES


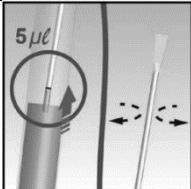
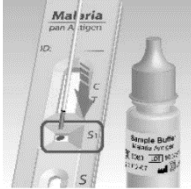
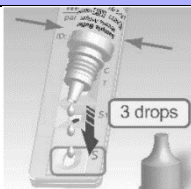
- High Sensitivity and Specificity
- Built in Internal Controls
- Simplified Workflow, Non-invasive, and Safe
- Rapid and Faster Results

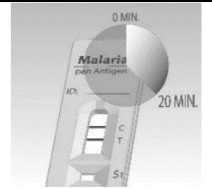


Materials required but not provided

1. Lancet
2. Timer

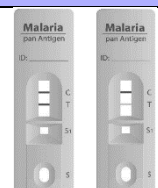
ASSAY PROCEDURE

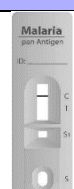
1	
	Allow test device, buffer, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2	
	Add 5 µl of whole blood into sample well [S1], the small well.
	
3	
	Add three (3) drops (approx. 80 µL) of assay buffer into developer well marked with [S].

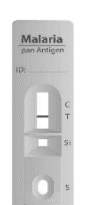
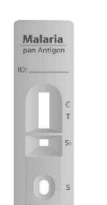
4	
	Read the test result in 20 min.

RESULTS

(Please refer to the illustrations)

POSITIVE	
	The presence of two color bands indicates a positive result for Mal. Pan-LDH.

NEGATIVE	
	The presence of only one band, "C", within the result window indicates a negative result.

INVALID	
	The test is invalid if the control line, "C" does not appear. If this occurs, the test should be repeated using a new test.
	

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 a significant level based on blood parasitemia 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 parasitemia detected by the RDT was 204 parasites/µl of blood.

LIMITATIONS OF THE PROCEDURE

1. The positive result obtained with the OneStep Malaria pan-LDH Antigen RapiCard™ InstaTest 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.
- 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.
 - Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.

STORAGE AND STABILITY



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. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

REFERENCES

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- Rodriguez-del Valle, M., et al, Detection of Antigens and Antibodies in the Urine of Humans with Plasmodium falciparum Malaria. J. Clin. Microbiol., (1991) 29:1236-1242

MANUFACTURER AND BRAND DETAILS

 <p>ISO 13485:2016</p> <p>bsi ISO 13485 Quality Management for Medical Devices CERTIFIED</p>	
 <p>Diagnostic Automation/Cortez Diagnostics, Inc. 21250 Califa St, Suite 102 and 116, Woodland Hills, California 91367 USA</p>	
Date Adopted	2025-May
Brand Name	RapiCard™ InstaTest
REF 172120	OneStep Malaria (Pan-LDH) W/B RapiCard™ InstaTest
PIC	ID172120XW1
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