One Step Malaria Antigen Strip Test

Revised on 01/2007

1. Introduction:

Malaria is a serious, sometimes fatal, 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, P. vivax, P. ovale, and P. 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 IND Diagnostic One Step Malaria Antigen Test contains a membrane strip, which is pre-coated with two monoclonal antibodies as two separate lines on the test region and polyclonal antibodies on the control region. Conjugate wells are pre-coated with monoclonal anti-pLDH antibodies, which is pan specific to the lactate dehydrogenase of *Plasmodium species.*

The IND Diagnostic One Step Malaria Antigen Test in designed for the differential diagnosis between *Plasmodium falciparum* and the other *Plasmodium species.*

2. Intended Use:

The IND Diagnostic One Step Malaria Antigen Test is a rapid, qualitative test for the detection of presence of Plasmodium lactate dehydrogenase (pLDH), and enzyme produced both in the sexual and asexual forms of parasite. The IND Diagnostic One Step Malaria Antigen Test is intended for professional use, only for an initial screening test and reactive samples should be confirmed by a supplemental assay such as microscopic examination of thin blood smear. The IND Diagnostic One Step Malaria Antigen Test is for in vitro diagnostic use only.

3. Materials provided/ Active ingredients of main components

The IND Diagnostic One Step Malaria Antigen Test contains following items to perform the assay:

24 tests/kits contain

Test Strips……	24 strips
Conjugate Wells……	3 X8 wells
Washing Wells which have been fixed on the Micro plate……..	24 wells
Assay Buffer……	1 vial of 4mL
Capillary pipette	30
Lancet ……....	30

4. Precautions / Storage and Kit Stability

In order to obtain reproducible results, the following rules must be observed:

1) The IND Diagnostic One Step Malaria Antigen Test should be stored at 2-30°C. Do not store in freezer.
2) The test strips and conjugate wells are sensitive to humidity as well as heat.
3) Perform the test immediately after removing the test reagents from the foil pouch or container.
4) Do not use it beyond the expiration date.
5) The shelf-life of the kit is as indicated on the outer package.
6) Do not use the test kit if the pouch/or container is damaged or seal is broken.
7) When transporting or storing the packages, avoid exposure to high temperature (over 45ºC) for a period longer than 1 week.

5. Warnings:

1) For in vitro diagnostic use only. DO NOT RE-USE Test strip, Conjugate well and Washing well.
2) The instruction must be followed exactly to get accurate results. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
3) Do not eat or smoke while handling specimens.
4) Use disposable gloves while handling potentially infectious material and performing the assay. Wash hands thoroughly afterwards
5) Avoid splashing or aerosol formation.
6) Clean up spills thoroughly using an appropriate disinfectant.
7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
8) When used as directed, The IND Diagnostic One Step Malaria Antigen Test reagents present no risk to the user.
9) Do not pipette by mouth.
10) Do not mix and interchange different specimen.
11) Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.
12) As known relevant interference: rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.
13) Use separate disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause errorneous results.

IND DIAGNOSTIC INC.
1629 Fosters Way, Delta, BC V3M 6S7, Canada
604-522-6331
www.ind.ca
sales@ind.ca
Tel: 604-522-1619
Fax:
Email:

One Step Malaria Antigen Strip Test

Revised on 01/2007

6. Specimen Collection, Storage and Precaution

Collection by venipuncture

1) Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by venipuncture.
2) If specimens are not immediately tested, they should be refrigerated at 2~8ºC.
3) When storage at 2~8ºC, the whole blood sample should be used within three days.
4) Using the specimen longer than three days can cause non-specific reaction.

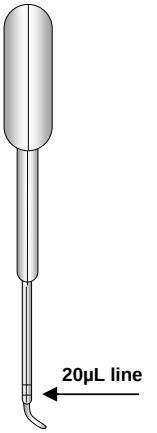
Collection using a lancet

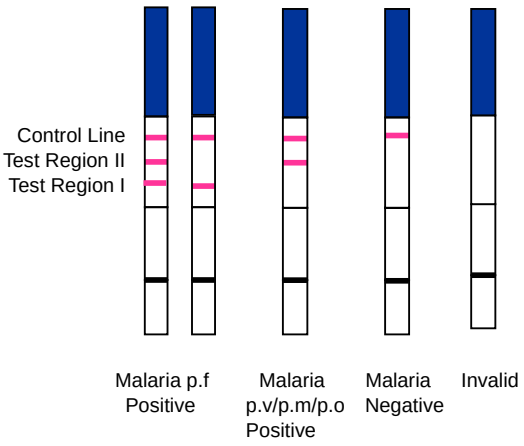
1) Clean the area to be lanceted with an alcohol swab.
2) Squeeze the end of the fingertip and pierce with a sterile lancet provided.
3) Wipe away the first drop of blood with sterile gauze or cotton.
4) Take a capillary pipette provide, while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the Capillary pipette to the first line to the tip.

7. Test Procedure

Remove the test strip from the strip can and use it as soon as possible. The instruction must be followed exactly to get accurate results.

1) Insert the Conjugate Wells into the micro plate frame provided.
2) Dispense 1 drop (about 30 µL) of Assay Buffer into the Conjugate Well and 3 drops (about 90 µL) of Assay Buffer into the Washing Well.
3) Add the entire volume of blood (about 20µL) by squeezing the pipette gently into the Conjugate Wells. Mix gently with the flat head of the same capillary pipette. Allow to stand for 1 minute.
4) Place the Test Strip vertically into the conjugate Well with mixture specimen and leave it in the well for 5 minutes.
5) Transfer the Test Strip from the Conjugate Well to the Washing Well and leave it until the Test Strip is cleared of blood and the procedure control band becomes clearly visible (~10 minutes).
6) Remove the Test Strip from the Washing Well and leave it on a flat surface wait for 3 minutes to read the results for strong positive. Normally It's better to read the results in 10-15 minutes.





8. Interpretation of the test

Negative:

Only one color band appears on the control region. No apparent band on the test region.

p.v/p.o/p.m Positive:

In addition to a pink colored control band, a distinct pink colored band will also appear in the test region II.

p.f positive:

In addition to a pink colored control band, two distinct pink colored bands will also appear in the test region I and II; or one distinct pink color band appears in the test region I.

Invalid

The test is invalid if the control Line does not appear. If this occurs, the test should be repeated using a new strip.

9. Limitations and Interferences

1) The test procedure, precautions and interpretation of results for this test must be followed when testing.
2) Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.
3) This test kit detects Plasmodium lactate dehydrogenase in patient whole blood and is useful as a screening procedure of malaria diagnosis.
4) Do not mix reagent of different lots.
5) The test is limited to the detection of antigen to Malaria *Plasmodium sp.* Although the test is very accurate in detecting

IND DIAGNOSTIC INC.
1629 Fosters Way, Delta, BC V3M 6S7, Canada
604-522-6331
www.ind.ca
sales@ind.ca

Tel: 604-522-1619
Fax:
Email:

pLDH, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. 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.

10. Internal Quality Control

The IND Diagnostic One Step Malaria Antigen Test strip has "Test Lines" and "Control Line" on the surface of the strip. Both the Test Lines and Control Line in result window are not visible before applying any sample. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.

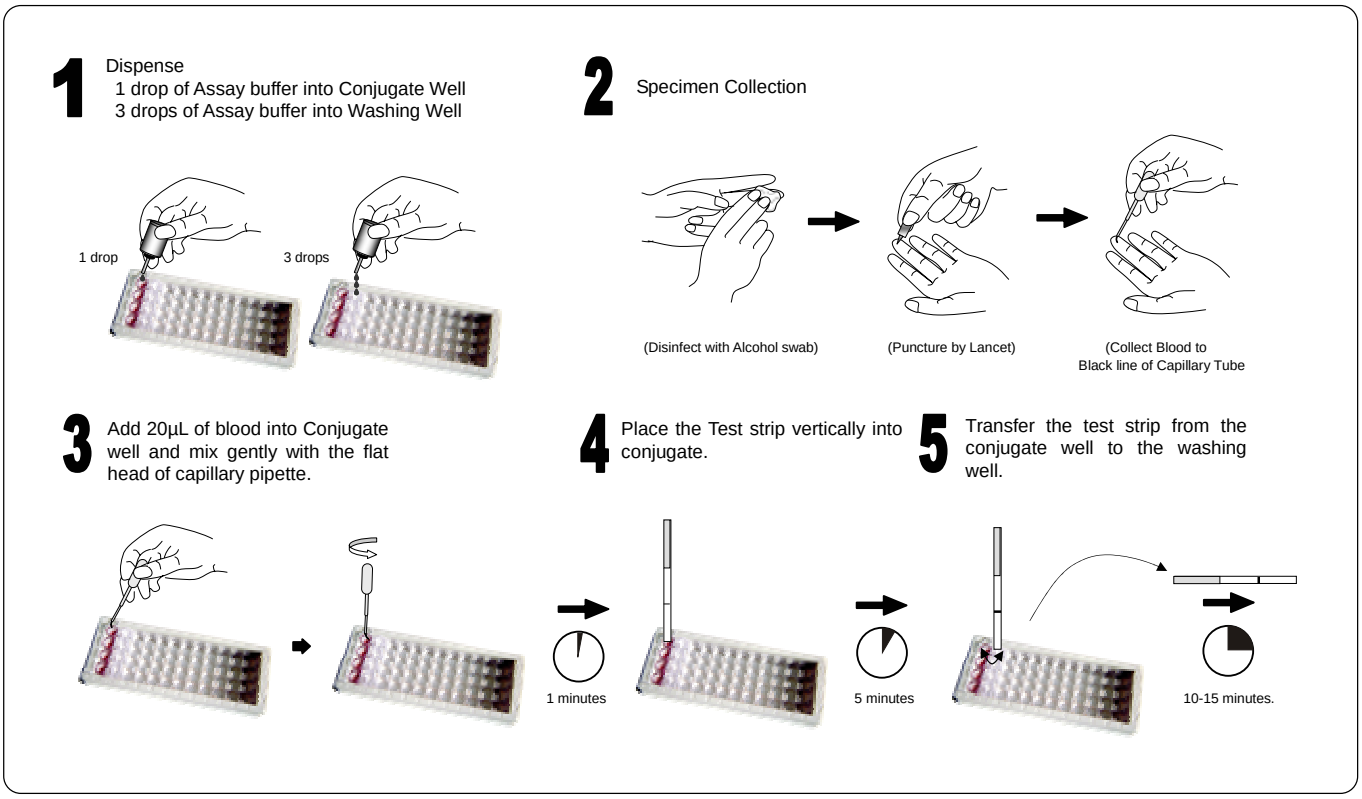
11. References

1) Leonard K. Basco, Frederique Marquet, Michael M. Makler, and Jacques Le Bras. : Plasmodium *falciparum* and *Plasmodium vivax*: Lactate Dehydrogenase Activity and its Application for in vitro Drug Susceptibility Assay. Experimental Parasitology 80, 260-271 (1995)

2) David L. Vander Jagt, Lucy A. Hunsaker and John E. Heidrich : Partial Purification an dCharacterization of Lactate Dehydrogenase from *Plasmodium falciparum*. Molecular and Biochemical Parasitology, 4 (1981) 255-264.

3) David J. Bzik, Barbara A, Fox and Kenneth Gonyer : Expression of *Plasmodium falciparum* lactate dehydrogenase in *Escherichia coli* Molecular and Biochemical Parasitology, 59 (1993) 155-166

4) Cameron R. Dunn, Mark J. Banfield, John J. Barker, Christopher W. Highm, Kathleen M. Moreton, Dilek Turgut-Balik, R. Leo Brady and J.John Holbrook. The Structure of lactate dehydrogenase from *Plasmodium falciparum* reveals a new target for anti-malarial design. Nature Structural Biology 3(11)1996, 912-915



IND DIAGNOSTIC INC.
1629 Fosters Way, Delta, BC V3M 6S7, Canada
604-522-6331
www.ind.ca
sales@ind.ca

Tel: 604-522-1619
Fax:
Email: