



Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Rapid Malaria Test - OptiMAL-IT		
Applies To:	All Hematology Staff		
Preparation Date:	January 06, 2025	Index No:	LB-IPP-059
Approval Date:	January 20, 2025	Version :	2
Effective Date:	February 20, 2025	Replacement No.:	LB-IPP-059 (1)
Review Date:	February 20, 2028	No. of Pages:	03

1. PURPOSE:

- 1.1 To provide Hematology Technologists with a standard methodology for performing Rapid Malaria Test.

2. DEFINITIONS:

N/A

3. POLICY:

- 3.1 DiaMed OptiMAL-IT is an immuno-chromatographic test, using monoclonal antibodies against the metabolic enzyme PLDH (parasite lactate dehydrogenase) of Plasmodium spp. These monoclonal antibodies are classified in two groups:
 - 3.1.1 One specific for Plasmodium falciparum.
 - 3.1.2 And the other is a pan-specific monoclonal antibody which reacts with all four species of Plasmodium
- 3.2 In case of presence of Plasmodium spp. in the blood sample, the PLDH captured by the conjugate reacts with the specific antibodies against Plasmodium falciparum and/or Plasmodium spp.
- 3.3 Specificity: OptiMAL-IT detects the presence of PLDH, an enzyme produced by both sexual and asexual form of the parasite. There is no cross-reaction with human LDH or Rheumatoid factor. The "lysis and dilution" buffer avoids also non-specific reactions due to heterophiles antibodies
- 3.4 Sensitivity: OptiMAL-IT can detect peripheral parasitaemia levels of 0.001-0.002% (50-100 parasites per ul of blood). This sensitivity can be compared to microscopic observation of a thin blood smear using a X 100 immersion objective, for a period of approx. 30 minutes, by a well-trained technician
- 3.5 Fast and easy: The result is obtained in 20 minutes. OptiMAL-IT provides all necessary materials to perform a test.
- 3.6 Monitoring of treatment with OptiMAL-IT: the test is only positive when live parasites are present in the blood. A repeat test becomes negative generally within 2-4 days following the beginning of successful treatment. Thus OptiMAL-IT is suitable to verify the effectiveness of therapy, underlining possible resistant strains of Plasmodium spp.

4. PROCEDURE:

4.1 Sample Material:

- 4.1.1 Capillary blood collected from fingertip
- 4.1.2 Whole blood collected by venipuncture, using EDTA sample tubes.

4.2 Test procedure:

- 4.2.1 Tear open the aluminium package and take out all the material. Important: Do not leave the material exposed to humidity and high temperature. In tropical conditions use the test within 15 minutes after opening the aluminium package.
- 4.2.2 Take the device, place it horizontally on a flat surface, write the patient's name or number on the lab.

- 4.2.3 Tear open the ampoule of buffer, add 1 drop of buffer to the first well (conjugate well, marked with a red line), and 4 drops to the second well (wash well). Allow to stand for 1 minute.
- 4.2.4 For finger prick blood: clean the fingertip with the swab, let dry, remove the lancet from its envelope, and prick the finger. Take the pipette, squeeze it, place the open tip into the blood drop, release pressure and draw up blood to the black line. Discard used swab and lancet into a suitable waste container. When using venous blood, draw blood from the tube into the pipette in the same manner.
- 4.2.5 Add the entire volume of blood by squeezing the pipette gently, to the first well (conjugate well, marked with a red line).
- 4.2.6 Gently with the upper end of the pipette and allow to stand for 1 minute. Discard the pipette into a suitable waste container.
- 4.2.7 Pull the IT device apart: hold the device with the wells between thumb and forefinger and, with the other hand, pull out the dipstick holder (with the label). Place the wells back on the table; insert the legs of the dipstick holder into the holes beside the conjugate well (with red line) so that the dipstick end reaches the bottom of the conjugate well. Allow to stand for 10 minutes. The blood/conjugate mixture should then be completely soaked up.
- 4.2.8 Transfer the dipstick to the second well (wash well) and allow to stand for 10 minutes. The reaction field should then be completely cleared of blood. The control band must be clearly visible.
- 4.2.9 Remove the dipstick from the wash well and click it back into the clear plastic piece. Close the wells with the well cover, break them off, and break the two legs off from the clear plastic piece. Discard them into a suitable waste container.
- 4.2.10 Read the reaction and interpret the results (see: Interpretation). The dipstick slide should be kept for future reference and for comparison in case of further tests for monitoring the efficiency of treatment.

4.3 Interpretation of results:

- 4.3.1 DiaMed OptiMAL-IT is a rapid detection test using a dipstick coated with monoclonal antibodies against the metabolic enzyme PLDH (parasite lactate dehydrogenase).
- 4.3.2 In case of presence of Plasmodium in the blood sample, the PLDH captured by the conjugate reacts with the specific antibodies against Plasmodium falciparum and/or Plasmodium spp.
- 4.3.3 The reactions are demonstrated by the appearance of dark purple bands on the dip.

5. MATERIALS AND EQUIPMENT:

5.1 OptiMAL-IT, Individual Rapid Malaria test each single test package contains:

- 5.1.1 Device with dipstick,
- 5.1.2 Conjugate well
- 5.1.3 Wash well/ well cover
- 5.1.4 Dropper ampoule with buffer
- 5.1.5 Lancet
- 5.1.6 Disinfecting swab
- 5.1.7 Pipette (printed mark for 10 ul) / 1 schematic test procedure
- 5.1.8 Sample Material either:
 - 5.1.8.1 Capillary blood collected from fingertip
 - 5.1.8.2 Whole blood collected by venipuncture, using EDTA sample tubes
- 5.1.9 Positive Control (separately available)

5.2 Note:

- 5.2.1 Stability: See expiry date on aluminium foil. Do not freeze.
- 5.2.2 Important: When transporting or storing the packages, avoid exposure to high temperature (over 40°C) for a period longer than 1 day. Avoid an exposure to 60°C and higher (the reagents may be damaged).
- 5.2.3 When used as directed, OptiMAL-IT reagents present no risk to the user.

6. RESPONSIBILITIES:

- 6.1 This policy applies to all Hematology technologists involved in this special Hematology test.

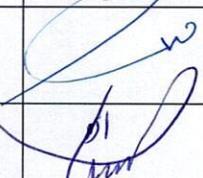
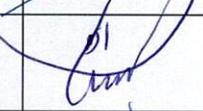
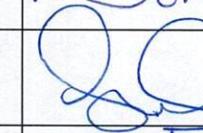
7. APPENDICES:

N/A

8. REFERENCES:

- 8.1 Practical hematology ;Dacie Lewis, 7th edition 1991(p286)
- 8.2 Lactate Dehydrogenase and the Diagnosis of Malaria. Makler M.T., Piper R.C., & Milhous. Parasitology Today, 14(191.376-377.
- 8.3 Performance of the OptiMAL malaria antigen capture dipstick for malaria diagnosis and treatment monitoring at the Hospital for Tropical Diseases, London. Moody A.H., Hunt Cooke A., Gabbett E. and Chodini P. Br.J.Haematol., 109.891.894.2000.
- 8.4 Malaria diagnosis and treatment;relevance of laboratory support from the rapid immunochromatographic tests of ICT-Malaria IP.t/P.vl and OptiMAL. Tarimo DS, Minjas IN, Bvqbjerg IC. Ann. Trop. Med.Parasit. 95(551. 437-444. 2001.
- 8.5 Rapid Diagnostic Tests for Malaria Parasites. A. Moody. Clin. Microbiol. Rev. 15 (11. 66-78, 2002.

9. APPROVALS:

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