

137 mm x 218 mm



Control set for immunological assay of *P. falciparum*, *P. vivax* Malaria antigen detection

SUMMARY AND INTRODUCTION

Malaria has been considered as serious, sometimes fatal parasitic disease caused by the parasite plasmodium. Five species of the Plasmodium parasites are responsible for malaria infections in human viz. *P.falciparum*, *P.vivax*, *P.ovale*, *P.malariae* and *P.knowlesi*. It is estimated there are over 500 million cases reported every year and immunological assay for Malaria antigen detection has played a crucial role to diagnose the malaria cases where the traditional microscopic examination is either impractical/ impossible or difficult to perform. Wide variations in Malaria antigen detection immunoassay product (such as RDTs) quality underscore the need for a product testing and QA that will ensure the suitability of the tests for laboratory as well as field testing use.

ParaTROL™ controls are assayed controls useful for monitoring the precision of laboratory testing, quality assurance and performance evaluation of Malaria antigen detection immunoassay.

REAGENT

ParaTROL™ is a set of lyophilized preparation of selected Malaria negative human whole blood sources spiked with *P.falciparum*, *P. vivax* specific recombinant antigens and Malarial parasite negative whole blood. During lyophilization the blood specimen is lysed. This changes the cell morphology; but however, preserves the target malarial antigen/analyte such as, Pf HRP 2, Pf pLDH and Pv pLDH. These controls can be used for on site validation / quality assurance of immunological assays for malaria antigen detection.

PRESENTATION

| ParaTROL™ | Number of vials | Control characteristics | Form | Volume |
|-----------|-----------------|-------------------------|-------------|--------|
| Vial - P | Three | Malaria Positive | Lyophilised | 0.2 ml |
| Vial - N | Three | Malaria Negative | Lyophilised | 0.2 ml |

| | |
|-----------|----------------|
| REF | 110456002 |
| Pack Size | 2 x 3 x 0.2 ml |

REAGENT STORAGE AND STABILITY

Unopened vials should be stored at 2-8°C and are stable up to the expiry date mentioned on the vial labels. After reconstitution the shelf life of the controls are 2 days at 2-8°C storage in sterile condition.

PRINCIPLE

The properties of the controls are similar to malaria positive/negative human whole blood specimen. They can be used for quality assurance and performance evaluation of malaria antigen detection immunoassay.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. NOT FOR MEDICINAL USE.
2. The source material used for preparation of the reagent is screened for HBsAg, HCV and HIV antibodies and is found to be non-reactive. However, handle the material as if it is infectious, as no known test method can assure that infectious agents are absent.

PREPARATION OF THE REAGENT

1. Bring the vial to room temperature prior to the reconstitution.
2. Reconstitute the control with exactly 0.2 ml of sterile bi-distilled water. Avoid using water containing preservatives.
3. Re-stopper the vial and allow standing for minimum 5 minutes for proper hydration and completing reconstitution.
4. Mix by gently swirling and inversion, avoiding froth formation. Do not shake.
5. Allow to stand and equilibrate for a further 10 minutes before use.
6. Reconstituted control can be stored at 2-8°C up to 2 days.

TEST PROCEDURE

1. Bring the reconstituted controls at room temperature prior to the testing.
2. Use the reconstituted **ParaTROL™** controls in the same manner as patient's whole blood specimen.
3. **ParaTROL™** control must be treated as a specimen and run strictly adhering to the instructions described by the manufacturer of reagents/test kit used for analysis.

ASSIGNED VALUES

| Vial | Characteristics | Malarial Antigen Content | Identical to biological sample parasitemia |
|------|--|---------------------------|--|
| P | <i>P. falciparum</i> & <i>P. vivax</i> Positive | Pf HRP2, Pf pLDH, Pv pLDH | >200 Parasites/ μ L |
| N | Malaria Negative | No Malarial Antigen | NIL |

REMARKS

1. This product is recommended to be used as control for quality assurance and performance evaluation of Malaria antigen detection assays specific to Pf HRP2, Pf pLDH and Pv pLDH only. Not to be used for molecular or NAT assay.
2. The relationship between parasites density and target antigen activity in clinical specimen may vary region to region/ individual to individual depending upon demography, drug history of the patient and parasite characteristics.
3. Repeated refrigeration and room temperature exposure may accelerate target antigen (i.e Pf HRP2, Pf pLDH and Pv pLDH) denaturation of the control.
4. After reconstitution the control could be diluted with known malaria negative fresh whole blood or the reconstituted negative controls could be used as diluent if dilution required.












WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Evaluating diagnostics. Nature Reviews, September 2006 pg. 534-540.
2. Journal of Clinical Microbiology 2006, Aug44(8) pg no. 2773-2778.
3. WHO, Regional office for Western Pacific: Informal Consultation on Lab methods for quality assurance of Malaria RDT Manila, Philippines, 20-22 July 2004.
4. WHO, Regional Office for Western Pacific, Malaria Rapid Diagnosis, making it work, Meeting Report 20-23 Jan 2003.
5. Malaria Journal, 2008, 7 (Suppl. 1), S1/S5.
6. Clinical Microbiology Reviews, Jan 2008 pg. no. 97-110.
7. Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

| | | | |
|--|--|---|--|
|  Temperature limitation |  Manufacturer |  Batch Number/ Lot Number |  Malaria Negative |
|  Use by |  Consult Instructions for use |  <i>In vitro</i> Diagnostic Medical Device | |
|  Date of Manufacture |  Catalogue Number |  This way up |  Malaria Positive |

 **TULIP DIAGNOSTICS (P) LTD.**

0724/VER-02

REGD. OFFICE: GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH, ALTO SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202, INDIA. E-mail: sales@tulipgroup.com
Website: www.tulipgroup.com

MANUFACTURING UNIT: PLOT NOS. 92/96, PHASE II C, VERNA IND. EST., VERNA, GOA-403 722, INDIA.