NAME AND INTENDED USE:
The Malaria *P. falciparum* Culture Panel is intended for use with *in vitro* tests for the determination of the presence or absence of *P. falciparum* based on the detection of the histidine rich protein 2 (HRP2) or assays for the quantification of HRP2. This panel is for Research Use Only and should not be used in diagnostic procedures.

SUMMARY:
The Malaria *P. falciparum* Culture Panel can be used to evaluate the analytical performance of HRP2 detecting assays. Each panel contains aliquots of a *P. falciparum* laboratory strain at seven predetermined HRP2 concentrations as well as negative aliquots. This panel can be used to evaluate the performance of assay or diagnostic test based on the detection or quantification of HRP2.

PRINCIPLES OF THE PROCEDURE:
The Malaria *P. falciparum* Culture Panel has been designed for use with *in vitro* test for detecting the presence or absence of *P. falciparum* through the detection of HRP2 and with laboratory assay for the quantification of HRP2. The Malaria *P. falciparum* Culture Panel is prepared from human and non-human components. The Malaria *P. falciparum* Culture Panel reagents should be evaluated as unknown specimens per the instructions supplied by the manufacturer of the in vitro assay being used.

REAGENTS:
The Malaria *P. falciparum* Culture Panel reagents contain culture-derived *P. falciparum* parasites diluted in human whole blood at decreasing HRP2 concentrations as follows:

1. Two vials 8,000 pg/mL (200 µL per vial).
2. Two vials 800 pg/mL (200 µL per vial).
3. Two vials 400 pg/mL (200 µL per vial).
4. Two vials 120 pg/mL (200 µL per vial).
5. Two vials 40 pg/mL (200 µL per vial).
6. Two vials 12 pg/mL (200 µL per vial).
7. Two vials 4 pg/mL (200 µL per vial).
8. Two vials Negative (200 µL per vial).

WARNINGS AND PRECAUTIONS:
1. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.
2. USE UNIVERSAL PRECAUTIONS: HANDLE AS IF CAPABLE OF TRANSMITTING INFECTIOUS AGENTS.

The Malaria *P. falciparum* Culture Panel reagents are provided for Research Use Only and should not be used in diagnostic procedures, for calibration or as primary reference preparations for any test kit.

PROCEDURE:
1. The Malaria *P. falciparum* Culture Panel reagents may be included in a test run following the procedure provided by the *in vitro* assay manufacturer for unknown specimens.
2. Allow The Malaria *P. falciparum* Culture Panel reagents to thaw on ice prior to use.
3. Mix contents by gentle swirling prior to use. Do not mix by vigorous shaking.
4. Vial should be considered for single use only. The HRP2 concentration of vials undergoing several freeze-thaw cycles cannot be ensured.

INTERPRETATION OF RESULTS:
The Malaria *P. falciparum* Culture Panel test results should be determined as recommended for unknown specimens in the package insert for each commercially available test kit and compared to the reagent predetermined HRP2 concentration.

LIMITATION OF THE PROCEDURE:
1. The Malaria *P. falciparum* Culture Panel reagents must not be substituted for the positive and negative control reagents provided with some commercially available test kits.
2. Malaria *P. falciparum* Culture Panel reagents are provided for Research Use Only and should not be used in diagnostic procedures, for calibration or as primary reference preparations for any test kit.
3. BACKUP PANEL and INTERPRETATION OF RESULTS provided in package insert of each commercially available test kit must be followed closely when testing the Malaria *P. falciparum* Culture Panel reagents. Deviations from the recommended procedures may produce unreliable results.
4. It is the responsibility of each laboratory to determine the suitability of Malaria *P. falciparum* Culture Panel reagents for its particular use. They must establish guidelines for the interpretation of results.

SPECIFIC PERFORMANCE CHARACTERISTICS:
The Malaria *P. falciparum* Culture Panel reagents were tested using commercially available test systems following the procedures provided by the manufacturer for the testing of unknown specimens. The data contained in the Panel Box Key Code is intended to be for informational use only. Each laboratory should establish its own performance characteristic.

This Product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.

ZeptoMetrix Corporation • 25 Kenwood Circle, Franklin, MA 02038 • Tel (508) 553-5800 • Fax (508) 520-1525

For Customer Support, please visit www.zeptometrix.com or email custserv@zeptometrix.com
### Malaria P. falciparum Culture Panel

**Product Code:** KZMC045  
**Strain:** PH1 (Type C)  
**Lot Number:** 1611-272-00025  
*For Research Use Only. Not for use in diagnostic procedures.*

**Product Key Code**  
Expiration Date: 01/06/2021

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This data is intended to be for informational purposes only. They are not intended to represent performance specifications.

**REFERENCES:**

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