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.

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 prepared from *P. falciparum* laboratory culture samples and human whole blood. All materials used in the preparation of The Malaria *P. falciparum* Culture Panel reagents are known to be non-reactive for HIV1/2 Ab, HBsAg and HCV Ab. However, no known test method can assure that products derived from human sources will not transmit infection. It is recommended that these reagents and all human specimens be handled in accordance with Biosafety Level 2 practices as described in the CDC NIH publication, Biosafety in Microbiological and Biomedical Laboratories (1), or other equivalent guidelines (2,3).

SAFETY PRECAUTIONS:
1. Clean any spillage immediately and thoroughly using a suitable disinfectant such as 1% bleach solution.
2. Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents (1-3).

HANDLING PRECAUTIONS:
1. Do not use Malaria *P. falciparum* Culture Panel reagents beyond the expiration date.
2. Avoid contamination of reagents when opening and dispensing.

STORAGE INSTRUCTIONS:
1. Store Malaria *P. falciparum* Culture Panel reagents long term (≥30 days) at ≤ -70°C or Short Term (≤30 days) at ≤ -10°C when not in use.
2. Vials should be stored upright to prevent leakage.
3. For single use only.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION:
1. Alterations in physical appearance may indicate instability or deterioration of Malaria *P. falciparum* Culture Panel.

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. 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. PROCEDURE 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 also 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.
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For Customer Support, please visit www.zeptometrix.com or email custserv@zeptometrix.com

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Lot Number: 1611-272-00025
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Product Key Code
Expiration Date: 01/06/2021

Variable	Values	Description	Comment
STUDY ID	**01**	Malaria specimen repository	Constant
CULUTRE PRODUCTION SITE	**06**	Supplier	N/A
STRAIN AND [HRP2]	**0036**	PH1, 8000 pg/mL	Type A
	0042	PH1, 800 pg/mL	Type A
	0021	PH1, 400 pg/mL	Type A
	0022	PH1, 120 pg/mL	Type A
	0023	PH1, 40 pg/mL	Type A
	0024	PH1, 12 pg/mL	Type A
	0025	PH1, 4 pg/mL	Type A
	0031	Negative, n/a pg/mL	N/A
TYPE OF SPECIMEN	**2**	Culture specimen	Constant
ALIQUOT ID	**001-999**	Unique identification for each aliquot	

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

REFERENCES:
1. U.S. Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. HHS Publication (NIH) 93-8395. Washington: U.S. Government Printing Office, May, 1993.
2. National Committee for Clinical Laboratory Standards. Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Second Edition, Tentative Guideline. NCCLS Document M29-T2. Villanova, PA: NCCLS, 1991.
3. National Committee for Clinical Laboratory Standards. Clinical Laboratory Waste management; Approved Guideline> NCCLS Document GP 5-A. Villanova, PA: NCCLS, 1993.

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