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.

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 may be included in a test run following the procedure 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.
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: