



Terms of Reference/Technical Specification Clauses

Code: FOR/043

Edition: 01

Implementation date: 24/04/2018

Item Name: CAPTIA™ Malaria EIA

I- Specifications:

This kit is intended for use for the qualitative and semi-quantitative detection of antibodies to *Plasmodium falciparum* (P. falciparum), *Plasmodium vivax* (P. vivax), *Plasmodium ovale* (P. ovale) and *Plasmodium malariae* (P. malariae) in human serum and plasma.

Captia™ Malaria is designed to detect antibodies occurring in subjects infected with P. falciparum, P. vivax, P. ovale and P. malariae. Captia™ Malaria EIA uses four recombinant antigens in a sandwich test to produce a test that is both highly specific and sensitive.

The antigens will detect P falciparum, P. vivax, P. ovale and P. malariae-specific IgG, IgM, and IgA, enabling the test to detect antibodies during all stages of infection.

The procedure uses undiluted samples and standard volumes for ease of both manual and automated use.

The assay can be used with both serum and plasma.

The plastic wells are coated with a mixture of P. falciparum and P. vivax recombinant antigens. The antigenic similarity between *Plasmodium* species means that antibodies to all species can be detected.

Specific antibodies in serum or plasma specimens combine with these antigens and with the same antigens conjugated to horseradish peroxidase, when conjugate is added to a well in which the specimen has been incubated.

After unreacted material has been removed by washing, the presence of bound enzyme indicating the presence in the specimen of specific antibodies is revealed by a colour change in the substrate/chromogen mixture.

The intensity of the color is compared to that in control wells to determine the presence or absence of specific antibody.

REAGENT DESCRIPTION

R1: Plate Polystyrene coated with recombinant antigens. 96 wells in 12 strips of 8. 1 plate per 96 test kit and 5 plates per 480 test kit.

R2: Positive control Positive human serum. 1.5 mL. Red.

R3: Negative control Negative human serum. 2 mL. Yellow.

R4: Conjugate 11x concentrate. Recombinant antigens conjugated to horseradish peroxidase. Blue/Colorless. 0.8 mL per 96 test kit and 3 mL per 480 test kit.

R5: Conjugate Buffer Buffered saline containing surfactant and stabilisers. Green. 8 mL per buffer 96 test kit and 30 mL per 480 test kit.

R6: Substrate Urea peroxide and tetramethyl benzidine. Pink. 7 mL per 96 Test kit and 30 mL per 480 test kit.

R7: Wash 20x concentrated. Saline containing surfactant. Colorless. 125 mL per 96 test kit and 2x 125 mL per 480 test kit.



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R8: Stop solution 0.5 M H₂SO₄. Colorless. 7 mL per 96 test kit and 30 mL per 480 test kit.

Instructions for Use.

Bag for storing unused wells.

II- Training:

Upon Delivery.

III- Documents to be delivered:

- Compliance certificate
- User Manual.
- Test Validation (if available).

IV- Accessories required:

- Any additional material should be mentioned and provided by the company.

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