

MALARIA ANTIGEN CELISA

INTENDED USE AND PRINCIPLE OF THE TEST

The Malaria Ag CELISA™ kit has been designed as a confirmatory test for *falciparum* malaria in situations where traditional diagnosis is unclear, for screening blood transfusion products, or to confirm cases of travel-related infection. It is not intended to replace the conventional blood film diagnosis. The sandwich ELISA principle is employed using microwells pre-coated with anti-*P. falciparum* monoclonal capture antibody. An enzyme labelled anti-*P. falciparum* monoclonal antibody is prepared and used as the detector antibody. The user adds a blood sample to the coated wells and if *P. falciparum* malaria antigen is present it binds to the coated well. All other blood components are removed by a washing step. The horse radish peroxidase enzyme labelled anti-malaria monoclonal indicator antibody conjugate is then added. It binds to any *falciparum* malaria antigen that has been captured on the well surface. The strip is then washed and the enzyme substrate solution is then added to the test wells and incubated. Colour generated indicates that *P. falciparum* malarial antigen in the test sample.

CONTENTS OF THE KIT

		Standard	Bulk
MAMW	Celisa Plate – 1x96 wells - (single use only)	2 plates	10 plates
CONTROL +	Positive Control	1 x 0.5mL	1 x 1.0mL
CONTROL -	Negative Control	1 x 2.5mL	1 x 5.0mL
MAPO	Enzyme Conjugate (x200)	1 x 0.12mL	1 x 1.2mL
MACD	Conjugate Diluent	1 x 24mL	1 x 120mL
MAPT	PBS/Tween (x20)	1 x 125mL	1 x 650mL
MASC	Substrate Chromogen (TMB) (20x)	1 x 1.2mL	1 x 7.5mL
MASB	Substrate Buffer	1 x 24mL	1 x 125mL
MASS	Stopping Solution	1 x 12mL	2 x 30mL

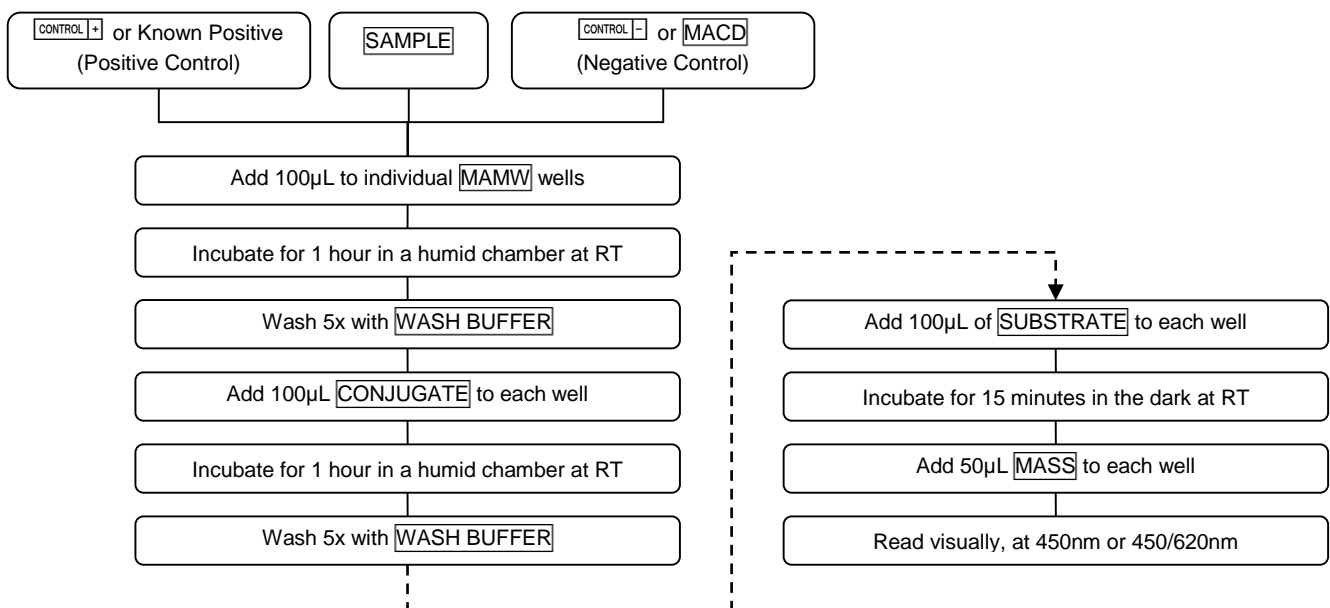
All components should be stored at 2-8°C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

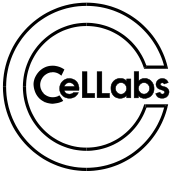
MATERIALS REQUIRED BUT NOT PROVIDED

- Malaria positive blood samples
- Micropipettes and tips
- Clean glassware or plastic containers for solutions.
- Humid chamber
- ELISA washer
- Spectrophotometer to read absorbances at 450nm or 450/620nm

DIAGRAM FOR USE

Use Celllabs Instructions for Use Insert contained in kit when performing test, and refer to Material Safety Data Sheet (MSDS) for further information.



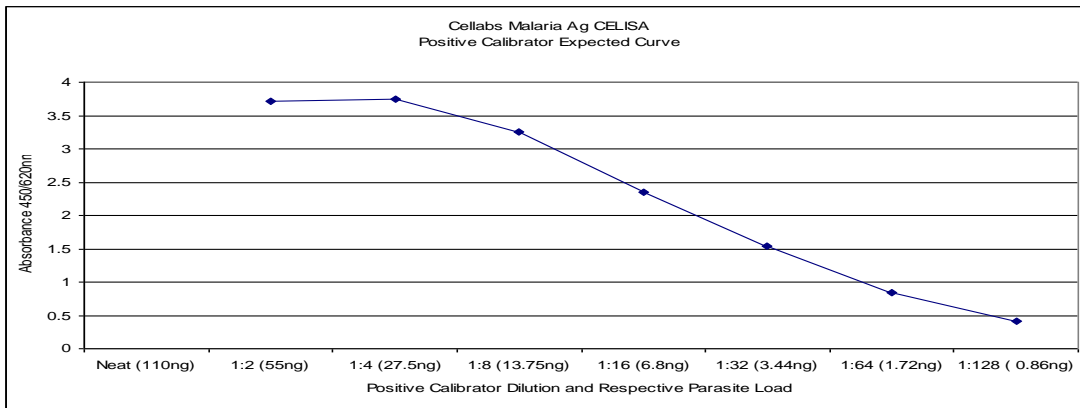


Cellabs Product Profile

READING AND INTERPRETATION OF RESULTS AND DIAGNOSIS

Samples may be read visually or photometrically. Visually, samples giving the same or less colour than the negative control are considered negative. Samples giving colour greater than the negative control, similar to the positive control, are considered positive. Using a spectrophotometer, negative samples should give an optical density below a certain level and positive samples should give an optical density above a certain level. Please refer to the kit insert for detailed information.

Typical standard curve and equivalent parasite load using the kit positive control



PERFORMANCE DATA FOR MALARIA ANTIGEN CELISA

Sensitivity/Specificity

A	n = 207 samples. Malaria Ag CELISA versus blood film.	Sensitivity: 98.1% Specificity: 96.2%
B	n = 100 samples. Malaria Ag CELISA versus blood film.	Sensitivity: 98% Specificity: 96%

Repeatability & Reproducibility

2 Positive samples were tested in replicates of 8, by 3 different operators. The coefficient of variation for repeatability ranged between 4.25% and 8.16%, with an average of 5.65%. The coefficient of variation for reproducibility ranged between 9.15% and 10.28%, with an average of 9.72%.

For Ordering Assistance:

See Your Local Distributor:

OR

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