

PAN MALARIA ANTIBODY CELISA

INTENDED USE AND PRINCIPLE OF THE TEST

The Pan Malaria Antibody CELISA is for the detection of specific IgG antibody against *P. falciparum*, *P. vivax*, *P. malariae* and *P. ovale in* blood, serum or plasma samples. The indirect ELISA principle is employed using microwells coated with a panel of recombinant *malaria* antigen. The test sample is added and incubated to allow the binding of the antibody-antigen complex, washed to remove any unbound then followed by adding a conjugate of enzyme labelled anti-human monoclonal antibody. The addition of a substrate solution allows the development of a colour proportional to the amount of malarial antibodies present in the serum under test.

CONTENTS OF THE KIT

Celisa Plate - 2 x 96 wells - (single use only)	2 plates
Positive Control	0.10mL
Negative Control	0.10mL
Enzyme Conjugate (200x)	0.15mL
PBS/Tween (20x)	125mL
Substrate Chromogen (20x)	1.2mL
Substrate Buffer	24mL
Stopping Solution	12mL
	Positive Control Negative Control Enzyme Conjugate (200x) PBS/Tween (20x) Substrate Chromogen (20x) Substrate Buffer

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.

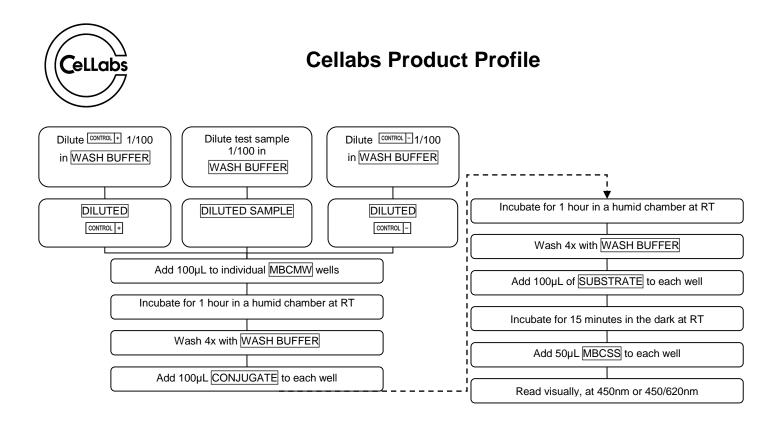
MATERIALS REQUIRED BUT NOT PROVIDED

- Micropipettes and tips
- Clean glassware or plastic containers for solutions
- Distilled water
- Humid chamber

- ELISA washer
- Spectrophotometer to read absorbances at a single wavelength of 450nm, or at dual wavelengths of 450nm and 620nm

DIAGRAM FOR USE

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





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.

PERFORMANCE DATA FOR PAN MALARIA ANTIBODY CELISA

Sensitivity/Specificity

А	n = 173 Samples. Pan Malaria CELISA (Reference test = IFAT)	Sensitivity: 94%
		Specificity: 100%

Repeatability

2 Positive samples were tested in replicates of 8, by 3 different operators. The coefficient of variation for repeatability ranged between 1.71% and 4.41%, with an average of 2.75%.

Reproducibility

2 Positive samples were tested in replicates of 8, by 3 different operators. The coefficient of variation for reproducibility ranged between 5.72% and 5.90%, with an average of 5.81%.

Cross reactivity

The Pan Malaria Antibody CELISA does not cross-react with:

Toxocara sp. *T. cruzi* Leishmania sp. *W. bancrofti* Dengue virus

For Ordering Assistance:

See Your Local Distributor:

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