Cellabs Product Profile

FILARIASIS ANTIBODY CELISA

INTENDED USE AND PRINCIPLE OF THE TEST

The Filariasis Antibody CELISA is for the detection of specific IgG4 antibody to filarial antigen. The indirect ELISA principle is employed using microwells coated with the recombinant Bm14 antigen. The test sample (serum, plasma or blood spot eluate) is added and incubated to allow the binding of the antibody to the antigen, washed to remove any unbound then followed by adding a conjugate of enzyme labelled anti-IgG4 monoclonal antibody for increased sensitivity and specificity. The addition of a substrate solution allows the development of a colour proportional to the amount of antibodies present in the test sample.

CONTENTS OF THE KIT

FAMW	Celisa Plate - 5 x 96 wells - (single use only)	5 plates
CONTROL +	Positive Control	0.05mL
CONTROL -	Negative Control	0.05mL
FASD	Sample Diluent	60mL
FAPO	Enzyme Conjugate (100x)	0.2mL
FACD	Conjugate Diluent	60mL
FAPT	PBS/Tween (20x)	250mL
FASC	Substrate Chromogen (20x)	3.0mL
FASB	Substrate Buffer	60mL
FASS	Stopping Solution	2 x 30mL

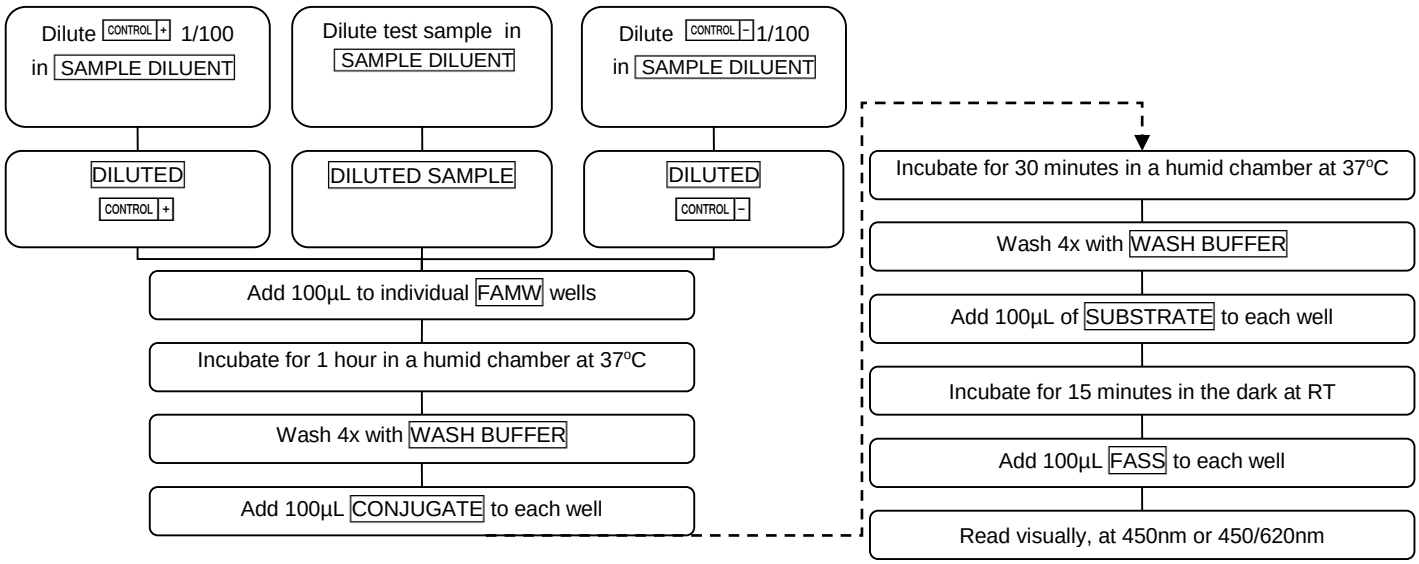
All components should be stored at 2-8^{O}C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

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.



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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

*A	n = 35 samples (*B.malayi* and *B.timori* microfilaria (mf) positive samples) n = 98 samples (*W.bancrofti* microfilaria (mf) positive samples) n = 20 samples (non-endemic samples)	Sensitivity: 91% Sensitivity : 98% Specificity: 100%

**Weil, GJ et al, , A multicentre evaluation of a new antibody test kit for lymphatic filariasis employing recombinant Brugia malayi antigen, Acta Trop (2010)*

Repeatability and Reproducibility

81 Samples were shared between four laboratories with a mean coefficient of variation (CV) of 0.16 (SD 0.15).

Cross reactivity
The Filariasis Antibody CELISA does not cross-react with:

Strongyloides
Malaria
Schistosomiasis
Dengue
Chagas
Toxoplasmosis

The Filariasis Antibody CELISA cross reacts with:

Onchocerciasis
Loa Loa

For Ordering Assistance:

See Your Local Distributor:

OR

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