

GIARDIA CELISA

INTENDED USE AND PRINCIPLE OF THE TEST

The Giardia CELISA kit is a qualitative *in vitro* enzyme immunoassay for the detection of *Giardia lamblia* cyst antigens in faecal specimens. The sandwich ELISA principle is employed using a monoclonal antibody to Giardia coated on the microwells. The faecal test sample is added and incubated to allow the binding of the antigen present in the sample, washed to remove the unbound, then followed by adding a conjugate of enzyme labelled polyclonal antibody. The addition of a substrate solution allows the development of a blue colour complex proportional to the Giardia antigen present in the sample.

CONTENTS OF THE KIT

GMW	Celisa Plate – 1x96 wells - (single use only)	1 plate
CONTROL +	Positive Control (Black Cap)	3.5mL
GDB	Diluent (White Cap)	40mL
GPO	Enzyme Conjugate (Red Cap)	7.0mL
GWB	Wash Buffer Concentrate (20x) (White Cap)	50mL
GSC	Substrate Solution (Blue Cap)	14.0mL
GSS	Stopping Solution (Yellow Cap)	7.0mL
	Graduated Disposable Pipettes	100
	Plastic Adhesive Sheets	1
	Resealable Bag	1

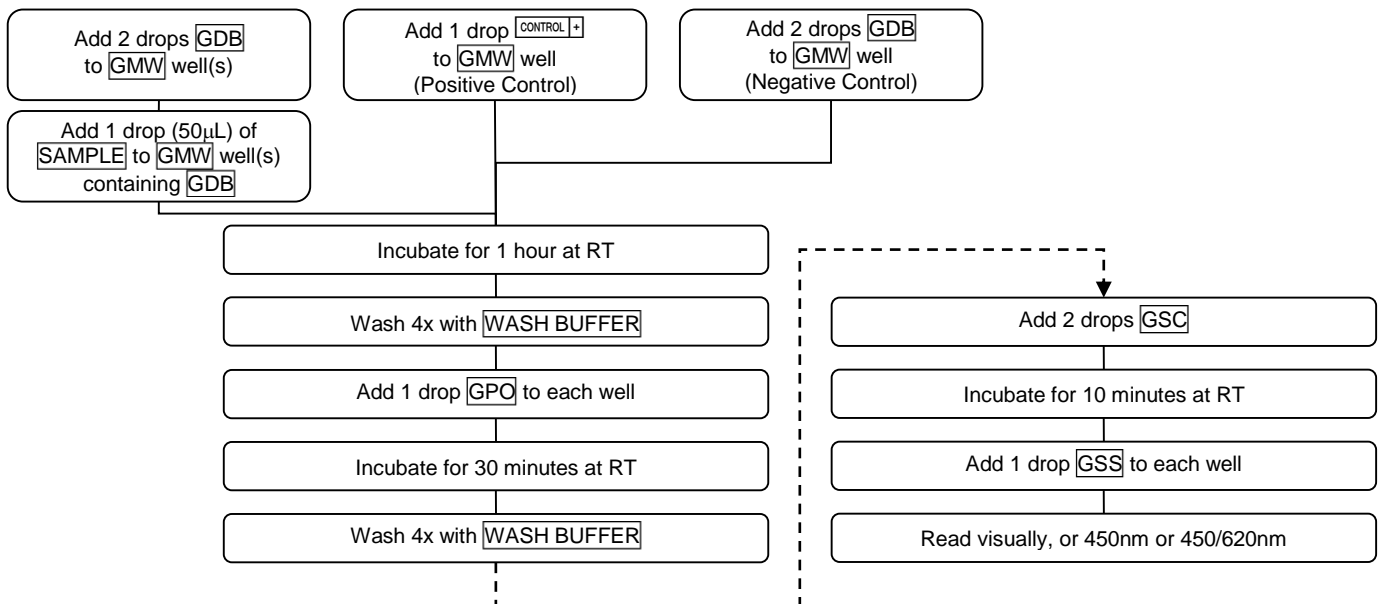
All components should be stored at 2-8°C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

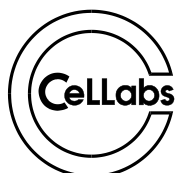
MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled water for diluting wash reagent
- 1L bottle for diluting wash reagent
- Squirt bottle for wash reagent
- Test tubes
- Applicator sticks
- Micropipettes with disposable tips
- Vortex mixer
- Timer
- Discard container and absorbent paper
- Spectrophotometer capable of reading absorbance of EIA plates at 450nm or 450/620nm

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.





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.

PERFORMANCE DATA FOR GIARDIA CELISA

Sensitivity/Specificity

A	n = 203 faecal specimens in 10% formalin. Giardia CELISA versus microscopy.	Sensitivity: 100% Specificity: 100%
B	n = 128 faecal specimens. Giardia CELISA versus another commercial ELISA.	Sensitivity: 97.7% Specificity: 100%

Repeatability

The intra-assay variation was determined by analysing four positive and four negative specimens in 12 wells each. The average intra-assay coefficient of variation (CV) for positive specimens was 7.1% with a range of 2.9% to 11.4%. The negative specimens had an average CV of 22.8% with a range of 7.9% to 36.9%.

Reproducibility

The inter-assay variation was determined by analysing four positive and four negative specimens five times over a five day period. The average inter-assay coefficient of variation (CV) for positive specimens was 5.2% with a range of 3.5% to 8.0%. The negative specimens had an average CV of 8.3% with a range of 3.4% to 14.9%.

Cross reactivity

The Giardia CELISA does not cross-react with:

Ascaris tumbricoides
Blastocystis hominis
Clonorchis
Chilomastix mesnili
Cryptosporidium parvum
Dientamoeba fragilis

Endolimax nana
Entamoeba coli
Entamoeba hartmanii
Entamoeba histolytica
Hookworm
Iodamoeba butchlii

Isospora belli
Rotavirus
Schistosoma mansoni
Strongyloides stercoratis
Trichuris trichiura

For Ordering Assistance:

See Your Local Distributor:

OR

Cellabs Pty Ltd
Unit 7, 27 Dale Street
Brookvale, NSW 2100 Australia
Tel: +61 2 9905 0133 Fax: +61 2 9905 6426
Web: <http://www.cellabs.com.au>
Email: sales@cellabs.com.au



Authorised Representative in the European Community:

WMDE
Bergerweg 18
6085 AT Horn
The Netherlands