

Cellabs Product Profile

ENTAMOEBA CELISA PATH

INTENDED USE AND PRINCIPLE OF THE TEST

The Entamoeba CELISA Path test is an enzyme immunoassay for the rapid detection of the adhesin of *E. histolytica* in human faecal specimens. The Entamoeba CELISA Path test uses antibodies to the adhesin of the organism. The microtitre wells in the kit contain immobilised polyclonal antibody that binds adhesin. The conjugate is a monoclonal antibody specific for the adhesin of *E. histolytica*. In the assay an aliquot of a faecal specimen is emulsified in the diluent and the diluted specimen is transferred to a microtitre well. If adhesin is present in the specimen, it binds to the conjugate and immobilised polyclonal antibody during the incubation phase. Any unbound material is removed during the washing steps. Following the addition of substrate, a colour is detected due to the enzyme-antibody-antigen complexes that form in the presence of adhesin.

CONTENTS OF THE KIT

EPMW	Celisa Plate – 1x96 wells - (single use only)		1 plate
EPPC	Positive Control	(Black Cap)	3.5mL
EPDL	Diluent	(White Cap)	40mL
EPPO	Enzyme Conjugate	(Red Cap)	7.0mL
EPWB	Wash Buffer Concentrate (20x)	(White Cap)	50mL
EPSA	Substrate	(Blue Cap)	14.0mL
EPSS	Stopping Solution	(Yellow Cap)	7.0mL
	Plastic Adhesive Sheets		1
	Resealable Bag		1

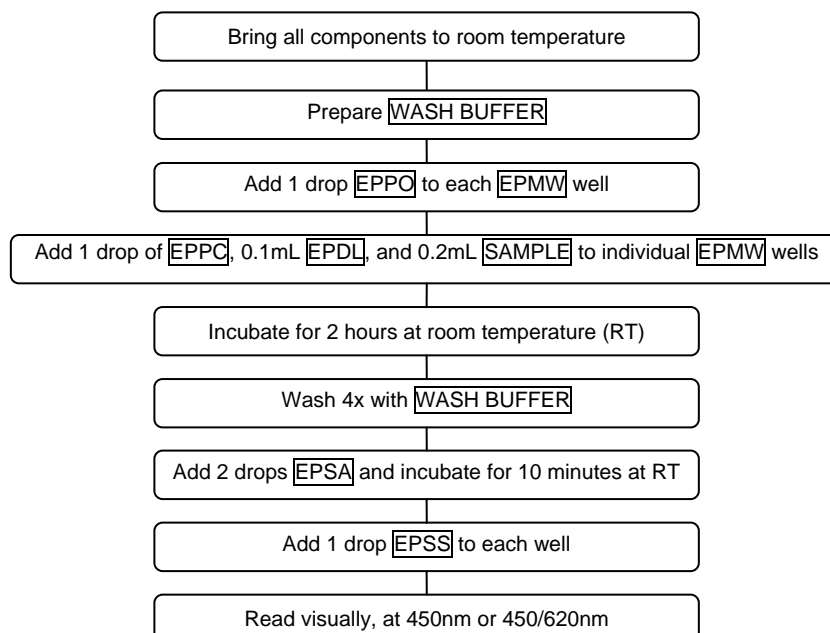
All components should be stored at 2-8°C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

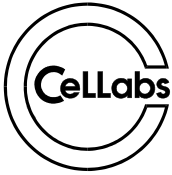
MATERIALS REQUIRED BUT NOT PROVIDED

- 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
- 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.





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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 ENTAMOEBA CELISA PATH

Sensitivity/Specificity

A	n = 60 faecal specimens. Entamoeba CELISA Path versus culture/Zymodeme.	Sensitivity: 96.9% Specificity: 100%
B	n = 757 faecal specimens. Entamoeba CELISA Path versus culture/Zymodeme.	Sensitivity: 100% Specificity: 94.7%
C	n = 44 faecal specimens. Entamoeba CELISA Path versus culture/Zymodeme.	Sensitivity: 93% Specificity: 97%
D	n = 202 faecal specimens. Entamoeba CELISA Path versus Zymodeme.	Sensitivity: 95% Specificity: 93%
E	Analytical Sensitivity: The Entamoeba CELISA Path detects approximately 0.2 to 0.4ng of adhesin per well.	

Repeatability

The intra-assay variation was determined by testing four positive specimens and four negative specimens in 12 wells per sample. The average intra-assay coefficient of variation for positive specimens was 4.728%.

Reproducibility

The inter-assay variation was determined by evaluating the three positive specimens and three negative specimens over five consecutive days. The average inter-assay coefficient of variation for positive specimens was 13.811%

Cross reactivity

The Entamoeba CELISA Path does not cross react with:

Ascaris lumbricoides
Blastocystis hominis
Clostridium difficile
Cryptosporidium sp.

Endolimax sp.
Entamoeba coli
Escherichia coli
Giardia lamblia

Rotavirus
Salmonella typhimurium
Shigella sonnei
Trichuris trichura

For Ordering Assistance:

See Your Local Distributor:

OR

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