

## Celllabs 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 polyclonal antibodies immobilised on the inner surface of the microwells. The test sample is added and incubated to allow the binding of adhesin present in the sample, washed to remove the unbound, and followed by adding an enzyme conjugated monoclonal antibody specific for the adhesin of *E. histolytica*. The addition of substrate solution allows the development of a blue colour complex proportionate to the bound adhesin present in the sample.

### CONTENTS OF THE KIT

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

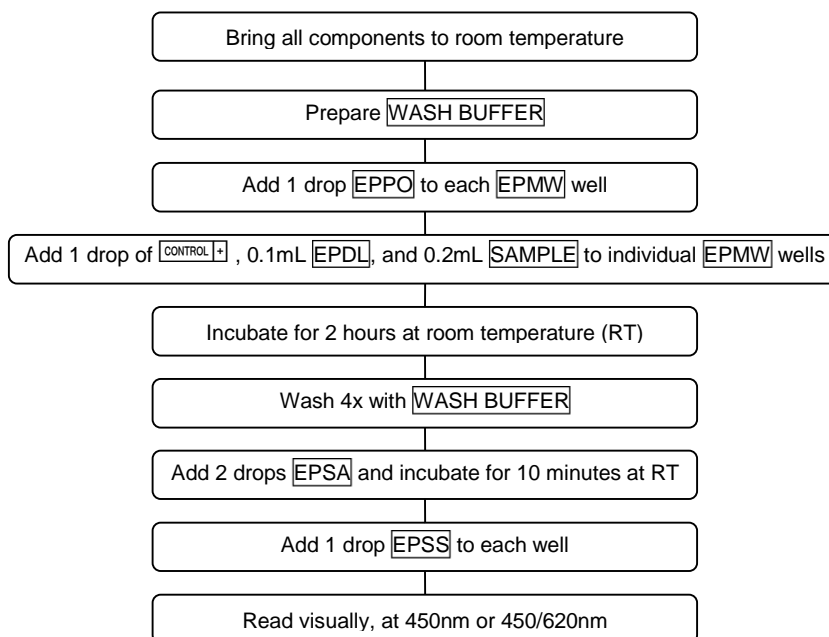
All components should be stored at 2-8°C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

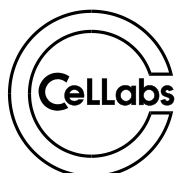
### MATERIALS REQUIRED BUT NOT PROVIDED

- 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 Celllabs 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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