Evaluation and comparative analysis of a rapid diagnostic assay for *E. histolytica*

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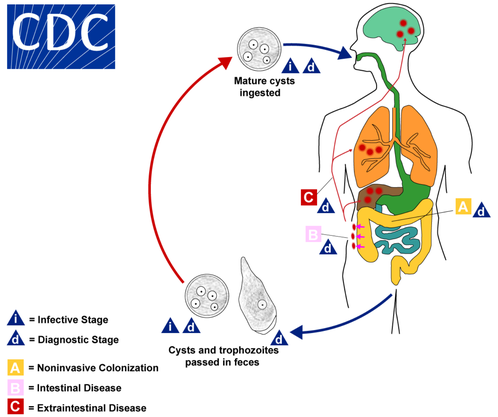
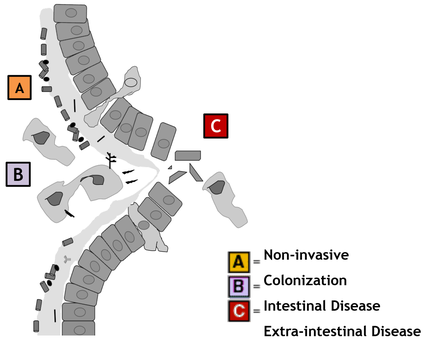
What is Amebiasis?



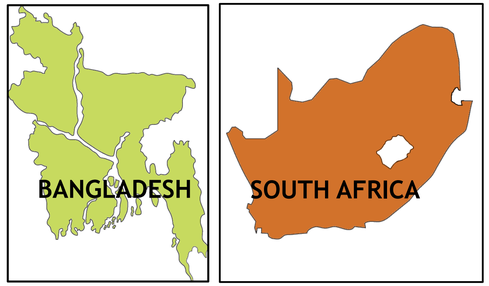
Intestinal invasion by *E. histolytica* trophozoites



Importance of *E. histolytica* diagnostics

- Intestinal colonization by the protozoan parasite *Entamoeba histolytica* is an important cause of diarrheal disease globally, particularly in the developing world.
- Diagnostics targeting protozoan parasites are important tools for surveillance and determination of appropriate therapeutic intervention in clinical settings.
- False positive results lead to inappropriate treatments with added risk to the patient and wasted cost for the health care system.
- In the developing world, limited resources and transitory populations make sensitive and rapid diagnosis of infectious diseases essential for early and effective intervention.

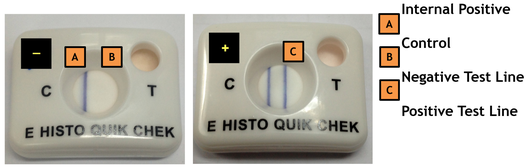
Multi-site evaluation of the *E. HISTOLYTICA QUIK CHEK* (TECHLAB®)



309 fecal specimens from Bangladesh

140 fecal specimens from South Africa

E. HISTOLYTICA QUIK CHEK (TECHLAB®)



RAPID:	Results in less than 30 minutes
SIMPLE:	Minimal training required Fresh or frozen samples
CONTROL:	Internal positive control in every cassette

E. HISTOLYTICA QUIK CHEK Evaluation Workflow

Fecal Specimens from South Africa and Bangladesh Suspected to Contain *Entamoeba* spp.

ProSpecT *E. histolytica* Microplate Assay Remel Lenexa, KS	*E. HISTOLYTICA QUIK CHEK* TECHLAB®, Inc. Blacksburg, VA	*E. HISTOLYTICA II* ELISA TECHLAB®, Inc. Blacksburg, VA

Comparison of results from 3 assays

PCR for *E. histolytica*, *dispar*, and *moshkovskii* on discrepant samples

Results

449 Total Fecal Specimens were tested

Remel ProSpecT *E. histolytica* Assay	*E. HISTOLYTICA QUIK CHEK*	*E. HISTOLYTICA II* ELISA
337 Negative	352 Negative	349 Negative
112 Positive	97 Positive	100 Positive

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Results, Continued

	Discrepant Results (N=38)					
	PCR for *E. histolytica, E. dispar, and E. moshkovskii* for discrepant samples					
	ProSpecT ELISA discrepant		*EH QUIK CHEK* discrepant		*EH II* ELISA discrepant	
	31 Samples		3 Samples		4 Samples	
PCR Result	22 +	9 -	0 +	3 -	1 +	3 -
EH	0	9	0	3	0	3
ED	13	0	0	0	0	0
EM	0	0	0	0	0	0

PCR for *E. histolytica*, *E. dispar*, and *E. moshkovskii* was performed on 38 discrepant results.

QUIK CHEK	*E. HISTOLYTICA II* ELISA PCR	
	Positive	Negative
Positive	97	0
Negative	3	349
	PPA 97%	NPA 100%

ProSpecT	*E. HISTOLYTICA II* ELISA or PCR	
	Positive	Negative
Positive	91	21
Negative	9	328
	PPA 91%	NPA 94%

Results Summary:

- 85 samples tested positive by all three assays
- 327 tested negative by all three assays
- 38 discrepant samples were identified and tested by PCR for *E. histolytica* and other *Entamoeba* spp.
- The *E. HISTOLYTICA QUIK CHEK* exhibited a positive percent agreement (PPA) of 97% and a negative percent agreement (NPA) of 100%
- The ProSpecT™ ELISA exhibited a PPA of 91% and NPA of 94%

Conclusions:

- Our results indicate that the *E. HISTOLYTICA QUIK CHEK* outperforms the ProSpecT ™ ELISA in sensitive and specific detection of *E. histolytica* in clinical isolates from the developing world.
- Our analysis of discrepant results suggests that the use of specific antibodies targeting the *E. histolytica* adhesin in the *QUIK CHEK* enables *Entamoeba* species discrimination—reducing the frequency of false positive results.
- This assay represents a strong candidate for rapid diagnosis of *E. histolytica* infection.

Funding and Conflict of Interest

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