

Clinical Evaluation of the *E. HISTOLYTICA* QUIK CHEK™

A Rapid Cassette Immunoassay for the Specific Detection of *E. histolytica* in Human Fecal Specimens



#1132

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Introduction

- Entamoeba histolytica* is a protozoan parasite responsible for 100 million cases of amebiasis annually, causing diarrhea, dysentery, and colitis.
- Amebiasis has also been diagnosed in 12% of travelers returning from the developing world with acute diarrhea. (1)

Methods

- The *E. HISTOLYTICA* QUIK CHEK™ test (EHQC, TechLab, Inc) and ProSpecT™ *Entamoeba histolytica* microwell ELISA (ProSpecT, Remel) were both compared to the *E. HISTOLYTICA* II ELISA (EHII, TechLab, Inc) utilizing 200 human fecal samples from Bangladesh (endemic site) and a U.S clinical reference laboratory.
- Any fecal sample that resulted in a discrepant result amongst the three diagnostics listed above were resolved by PCR for *E. histolytica*, *E. dispar*, and *E. moshkovskii*. The *E. histolytica* real-time PCR assay was performed as described by Haque et al. (2). A 2-step nested PCR was performed to detect *E. dispar* according to the protocol described by Haque et al. (3). An in house TaqMan assay was used to detect *E. moshkovskii*.
- Limit of detection was determined for the EHQC, EHII, and ProSpecT for cultured *E. histolytica* and *E. dispar*. Negative fecal samples were spiked with culture and tested on each diagnostic test at varying concentrations.
- All spiked fecal samples were also tested by real-time PCR for *E. histolytica* and *E. dispar*. The *E. histolytica* real-time PCR assay was performed as described by Haque et al. (2). The *E. dispar* real-time PCR was performed as described by Visser et al. (4).

Conclusion

- Results indicate that the rapid format, *E. HISTOLYTICA* QUIK CHEK™ test, closely correlates with the *E. HISTOLYTICA* II ELISA with an overall percent agreement of 98%.
- The ProSpecT™ *Entamoeba histolytica* microwell ELISA when compared to the *E. HISTOLYTICA* II ELISA had an overall percent agreement of 90.5%, with many of the discrepant samples confirmed to be *E. dispar* positive by PCR.
- The *E. HISTOLYTICA* II ELISA and ProSpecT™ *Entamoeba histolytica* microwell ELISA had an equivalent limit of detection for *E. histolytica*. However, the *E. HISTOLYTICA* QUIK CHEK™ test had a 4-fold lower limit of detection for *E. histolytica* indicating a more sensitive test.
- The ProSpecT™ *Entamoeba histolytica* microwell ELISA was the only test that demonstrated detection of *E. dispar*, which may lead to a false positive diagnosis of amebiasis. Both the *E. HISTOLYTICA* II ELISA and the *E. HISTOLYTICA* QUIK CHEK™ test were specific for only pathogenic *E. histolytica* and do not cross react with *E. dispar*.
- Rapid diagnostics are critical in accurately and efficiently diagnosing infectious diseases. The *E. HISTOLYTICA* QUIK CHEK™ test is the first rapid device to specifically detect *E. histolytica*.

Results

<i>E. HISTOLYTICA</i> II			
<i>E. HISTOLYTICA</i> QUIK CHEK™	N=200	+	-
	+	35	1
	-	3	161
Sensitivity		92.1%	
Specificity		99.4%	
Correlation		98.0%	

<i>E. HISTOLYTICA</i> II & PCR			
<i>E. HISTOLYTICA</i> QUIK CHEK™	N=200	+	-
	+	36	0
	-	2	162
Sensitivity		94.7%	
Specificity		100%	
Correlation		99.0%	

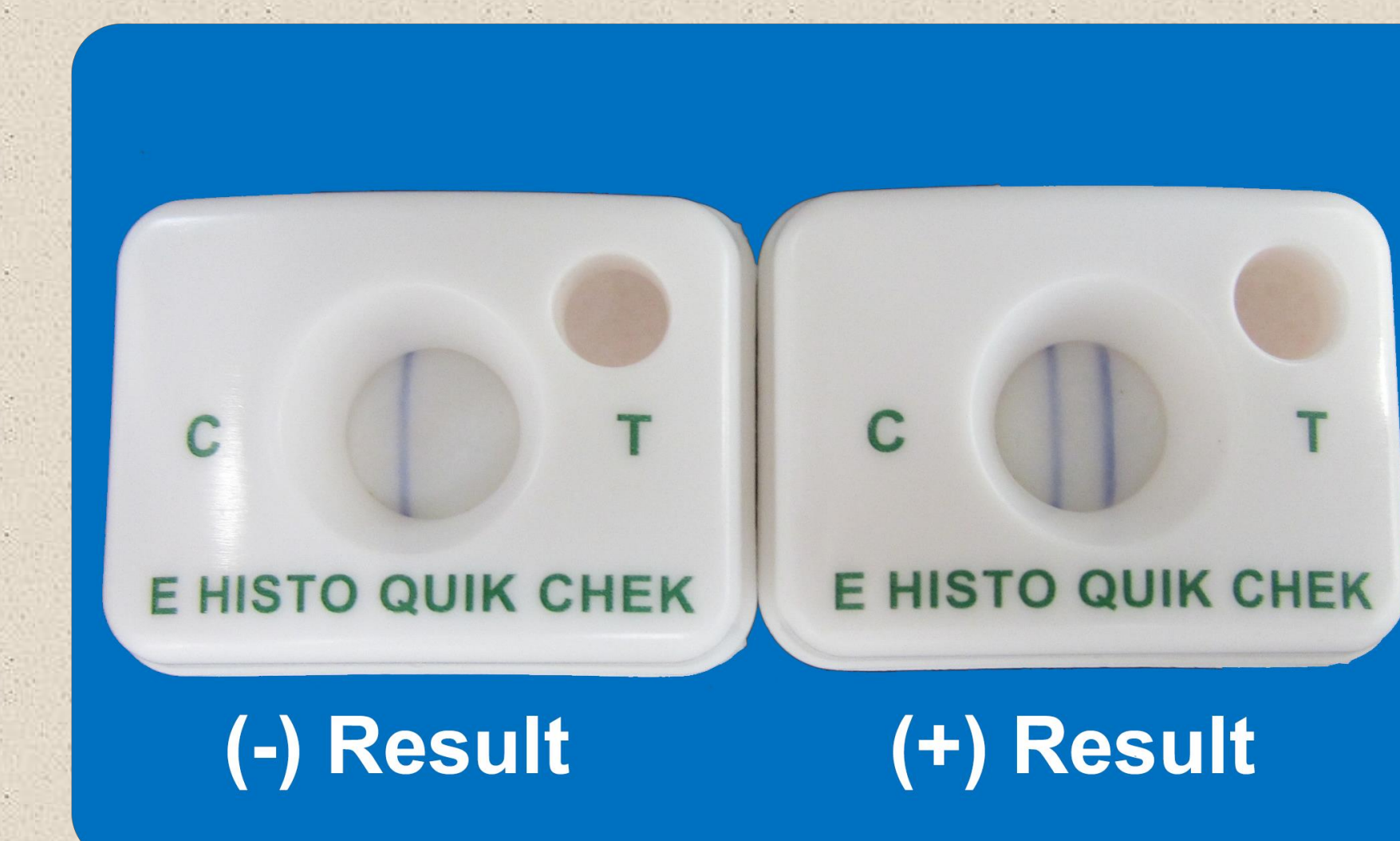
- A total of 200 fecal samples were tested on the *E. HISTOLYTICA* QUIK CHEK™ test (EHQC) and *E. HISTOLYTICA* II ELISA (EHII) that resulted in 4 discrepant results.
- The one sample that was negative by the EHII and positive by the EHQC was determined to be positive for *E. histolytica* by PCR. Of the 3 samples that were positive by the EHII and negative by the EHQC, 2 were confirmed positive for *E. histolytica* by PCR.

<i>E. HISTOLYTICA</i> II			
ProSpecT™ <i>Entamoeba histolytica</i>	N=200	+	-
	+	36	17
	-	2	145
Sensitivity		94.7%	
Specificity		89.5%	
Correlation		90.5%	

<i>E. HISTOLYTICA</i> II & PCR			
ProSpecT™ <i>Entamoeba histolytica</i>	N=200	+	-
	+	38	15
	-	1	146
Sensitivity		97.4%	
Specificity		90.7%	
Correlation		92.0%	

- A total of 200 fecal samples were tested on the ProSpecT™ *Entamoeba histolytica* microwell ELISA (ProSpecT) and *E. HISTOLYTICA* II ELISA (EHII) that resulted in 19 discrepant results.
- Of the 17 samples that were negative by the EHII and positive by ProSpecT, 13 were confirmed *E. dispar* positive by PCR and 2 *E. histolytica* positive by PCR. Of the two samples that were positive by the EHII and negative by ProSpecT, 1 was confirmed *E. histolytica* positive by PCR.

Limit of Detection				
Cultured <i>E. histolytica</i> Trophozoites (EH)	EHII	ProSpecT	EHQC	EH PCR C(t)Value
800 EH/mL of fecal	+	+	+	+ (34)
400 EH/mL of fecal	+	+	+	+ (35)
200 EH/mL of fecal	-	-	+	+ (38)
100 EH/mL of fecal	-	-	+	+ (39)
50 EH/mL of fecal	-	-	-	+ (39)
Cultured <i>E. dispar</i> Trophozoites (ED)	EHII	ProSpecT	EHQC	ED PCR C(t)Value
50,000 ED/mL of fecal	-	+	-	+ (22)
25,000 ED/mL of fecal	-	+	-	+ (23)
12,500 ED/mL of fecal	-	+	-	+ (24)
6250 ED/mL of fecal	-	+	-	+ (25)
3125 ED/mL of fecal	-	-	-	+ (28)



References

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