Evaluation of a Diagnostic Screening ELISA for the Detection of *Giardia* spp., *Cryptosporidium* spp. and *E. histolytica* in Human Fecal Specimens

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Janice D. Hencke[1], William A. Petri, Jr.[2], Rashidul Haque[3], and Joel F. Herbein[1]
[1]TECHLAB, Inc., Blacksburg, VA; [2]University of Virginia, Charlottesville, VA; [3]ICDDR,B, Dhaka, Bangladesh

OBJECTIVE

Develop an ELISA test to screen for the three most prevalent enteric protozoan parasites.

INTRODUCTION

The *TRI-COMBO PARASITE SCREEN* test is a diagnostic ELISA for the detection of *Giardia* spp., *Cryptosporidium* spp. and *Entamoeba histolytica* in human fecal specimens to aid in diagnosis of giardiasis, cryptosporidiosis and amebiasis. Identification of these parasites, the three most common enteric protozoan parasites worldwide, often involves microscopy which is labor-intensive, time-consuming and requires advanced training. Here we report results of a clinical evaluation of the *TRI-COMBO PARASITE SCREEN* test, a qualitative ELISA which offers a simple, highly sensitive and specific method of screening fecal specimens to identify those specimens positive for one or more of these parasites, eliminating the need for expensive, time-consuming diagnostic methods on the majority of specimens. Positive results are indicated by the presence of a yellow color in the wells that can be interpreted visually or analyzed spectrophotometrically. A positive result indicates the presence of cysts or antigen from *Giardia* spp., *Cryptosporidium* spp., and/or *E. histolytica*. For labs that receive large numbers of specimens requiring parasitology screening, negative specimens can be easily and efficiently eliminated from the pool requiring further testing by using the *TRI-COMBO* test to identify only positive specimens which require follow-up testing such as microscopy, individual ELISA or fluorescent assay. Because of the labor- and cost-intensive nature of microscopy, in particular the necessity of testing multiple specimens from a single patient for a definitive diagnosis, using the *TRI-COMBO* test as a first step will result in significant savings in time and cost.

Individual ELISA Tests

TRI-COMBO PARASITE SCREEN	+	-
+	80	0
-	0	177

Sensitivity =	100.0%
Specificity =	100.0%
PPV =	100.0%
NPV =	100.0%
Correlation =	100.0%
Total specimens =	257

GIARDIA II

TRI-COMBO PARASITE SCREEN	+	-
+	51	0
-	0	177

CRYPTOSPORIDIUM II

TRI-COMBO PARASITE SCREEN	+	-
+	15	0
-	0	177

E. HISTOLYTICA II

TRI-COMBO PARASITE SCREEN	+	-
+	14	0
-	0	177

METHODS

257 specimens were tested in this study. All specimens were tested on the *TRI-COMBO PARASITE SCREEN* test and on FDA-cleared commercial ELISA tests specific for each parasite: *GIARDIA II*, *CRYPTOSPORIDIUM II* and *E. HISTOLYTIC II* tests. Specimens were tested fresh or upon thawing after frozen storage. Specimens were from children and adults and varied in consistency, being solid, semi-solid or liquid. 45% were from males and 55% were from females.

RESULTS

80 specimens were found to be positive on the *TRI-COMBO* test and on the corresponding individual test (51 for Giardia, 15 for Cryptosporidium and 14 for E. histolytica), and 177 specimens were found to be negative on all tests. Sensitivity, specificity, positive predictive value, negative predictive value and correlation for the *TRI-COMBO* test compared to the individual tests were 100%.

CONCLUSIONS

The *TRI-COMBO* test is a highly sensitive and specific ELISA that can be used as a cost-effective screening assay to eliminate negative specimens and identify positive specimens for *Giardia*, *Cryptosporidium* and/or *E. histolytica* requiring further parasitological analysis.

Relative workload for 100 specimens tested by ELISA

Prevalence rate	Without the *TRI-COMBO* test	With the *TRI-COMBO* test
10%	300 individual tests run	130 total tests (100 on TC + 30 individual tests)
20%	300 individual tests run	160 total tests (100 on TC + 60 individual tests)
50%	300 individual tests run	250 total tests (100 on TC + 150 individual tests)

Contact info: Janice Hencke - jhencke@techlab.com Joel Herbein - jherbein@techlab.com