

## A New Diagnostic Test for the Detection of *Giardia* and *Cryptosporidium* in Feces

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### INTRODUCTION

*Cryptosporidium* spp. and *Giardia* spp. are highly-infectious protozoan parasites that cause debilitating diarrhea, weight loss and malabsorption in humans and animal species. Both pathogens are transmitted through direct contact with infected individuals and via fecal contamination of water, and both cause opportunistic infections in immunocompromised individuals. Here we report results of the clinical evaluation of TECHLAB's *GIARDIA*/CRYPTOSPORIDIUM CHEK, an ELISA for the qualitative detection of *Cryptosporidium* oocysts and *Giardia* cysts in human fecal specimens.

Preserved fecal specimens (218) were tested and results were compared with microscopy. Another equivalent commercial ELISA was also evaluated. Discrepant samples were reevaluated using immunofluorescence antibody detection specific for *Cryptosporidium* and *Giardia*.

The *GIARDIA*/CRYPTOSPORIDIUM CHEK ELISA is a new reliable assay for the detection of *Giardia* and *Cryptosporidium* antigen in human fecal specimens. It is an ideal assay for bench-top or large-scale screening. Its multi-parasite format eliminates screening large numbers of negative samples on two ELISA tests.

### METHODS

- Study Samples: Human fecal specimens submitted for routine parasitological screening preserved in sodium acetate formalin (SAF) or 10% buffered formalin at a 1:4 dilution (1 part sample to 3 parts preservative).
- Samples were analyzed for pathogenic microorganisms using routine staining and microscopic procedures. The presence of *Giardia* spp. or *Cryptosporidium* spp. was confirmed using immunofluorescence assay (IFA) microscopy.
- Samples were further analyzed using the TECHLAB<sup>®</sup>, Inc. *GIARDIA*/CRYPTOSPORIDIUM CHEK ELISA test and another commercially available ELISA test with similar assay protocols and performance characteristics. Both tests utilize a single assay well per sample, and indicate a positive result with samples containing either *Giardia* spp. antigen or *Cryptosporidium* antigen.



### Comparison of the *GIARDIA*/CRYPTOSPORIDIUM CHEK ELISA and Another Commercial ELISA to IFA-Confirmed Microscopy

ELISA Assays	Microscopy		Sens	Spec	PPV	NPV	Corr	
	Pos	Neg						
TECHLAB <sup>®</sup> G/C CHEK ELISA (n = 218)	Pos	121	0	96.8%	100%	100%	95.9%	98.2%
	Neg	4	93					
Other Commercial ELISA (n = 185)	Pos	115	0	96.6%	100%	100%	94.3%	97.8%
	Neg	4	66					

### RESULTS

- Both ELISA tests correlated well with IFA-confirmed microscopy.
- Neither test displayed false-positive results.
- The false-negative results for both tests were with samples containing fewer than 5 *Cryptosporidium* oocysts per well (as identified by IFA microscopy). There were no false-negative readings with *Giardia*-positive samples.
- Both tests were compatible with positive and negative fecal samples preserved in SAF and 10% formalin (dilution equalled 1 part feces to 3 parts preservative).
- Visual interpretation compared well with spectrophotometric analysis.
- Neither test displayed cross-reactivity with other microorganisms including *Blastocystis hominis*, *Entamoeba* spp., *Dientamoeba fragilis*, & *Endolimax nana*.

### CONCLUSIONS

- The TECHLAB<sup>®</sup> *GIARDIA*/CRYPTOSPORIDIUM CHEK ELISA assay is a sensitive and specific test for the presence of *Giardia* and *Cryptosporidium* in human fecal specimens.
- *GIARDIA*/CRYPTOSPORIDIUM CHEK test results correlate well with IFA-confirmed microscopy and the test is more sensitive than conventional microscopic techniques.
- The *GIARDIA*/CRYPTOSPORIDIUM CHEK test requires less sample preparation and assay time compared to complete microscopic analysis:
  1. Specimen concentration is not required.
  2. Specimens maintained in SAF, 10% formalin, or Cary Blair medium may be added directly to the assay well.
  3. Fresh and frozen specimens require a simple one-step dilution - neither filtering nor centrifugation are required.
  4. The test utilizes a two-step direct assay format with a 60-minute sample incubation, 30-minute conjugate incubation, and a 10-minute development step.
- *GIARDIA*/CRYPTOSPORIDIUM CHEK test results may be read visually.
- *GIARDIA*/CRYPTOSPORIDIUM CHEK's monoclonal antibody-based format yields highly specific results with no identifiable cross-reactivity with other protozoan parasites.

