

EVALUATION OF *GIARDIA II* - A Fecal Diagnostic ELISA for the Detection of Human *Giardia* Infection



J. F. Herbein¹, L. S. Garcia², S. Buss¹, J. H. Boone¹, T. D. Wilkins¹

¹TECHLAB®, Inc., Blacksburg, VA, ²LSG & Associates, Santa Monica, CA

[C-241]

INTRODUCTION

Giardia is a binucleated flagellated protozoan parasite which exists in two forms: a noninfectious, pear-shaped trophozoite (9 to 20 µm) inhabiting the small intestine, and the highly infectious cyst form which is elliptical in shape and ranges in size from 8 to 12 µm. Survival outside its host varies greatly between the two forms: the trophozoite which is extremely labile, lasts only a matter of hours outside the body, while the cyst form may survive for several days in the external environment. The parasite is responsible for infections due to water contamination, and travelers have been found to contract giardiasis from endemic areas. Transmission also occurs by direct contact, especially with asymptomatic carriers and by food contamination. High-risk categories include young children, immunocompromised patients, and those without previous exposure. More recently, giardiasis has become a common sexually transmitted disease. *Giardia* has been found in all animal hosts studied and animal-based fecal contamination of water is another route of transmission in humans. Clinical manifestations of giardiasis range from asymptomatic carriage with the passing of cysts to chronic debilitating diarrhea, weight loss, and malabsorption.

METHODS

- Study Samples: 186 human fecal specimens preserved in sodium acetate formalin (SAF) or 10% formalin (dilution equalled 1 part feces to 3 parts preservative).
- Samples were analyzed for the presence of pathogenic microorganisms using routine staining and microscopic procedures. The presence of *Giardia* spp. was confirmed using parasite-specific immunofluorescence assays (IFA).
- Samples were further analyzed using the TECHLAB[®] *GIARDIA II* ELISA test and another commercially available ELISA with similar assay protocols and performance characteristics.

RESULTS

- Both displayed 98.4% correlation to IFA microscopy.
- Both displayed false-positive and false negative rates of $\leq 1\%$ compared to IFA-confirmed microscopy.
- Both tests were compatible with *Giardia*-positive and *Giardia*-negative fecal samples preserved in SAF and 10% buffered formalin (1 part feces to 3 parts preservative).
- For samples where both tests indicated a positive (79 samples), the TECHLAB[®] *GIARDIA II* test resulted in a higher OD reading compared to control for 90% of the samples (avg. increase = 0.87).
- Visual interpretation of the tests compared with spectrophotometric analysis – 100%.
- Neither test displayed cross-reactivity with other identified microorganisms including *B. hominis*, *Entamoeba* spp., *Cryptosporidium* spp., *D. fragilis*, and *Endolimax nana*.

FECAL SPECIMEN ANALYSIS <i>GIARDIA II</i> ELISA			IFA-Confirmed Microscopy	
ELISA (n=186)			Positive	Negative
TECHLAB [®] , Inc.'s	Positive		80	1
<i>GIARDIA II</i> ELISA	Negative		2	103
Sensitivity	Specificity	PPV	NPV	Correlation
97.6%	99.0%	98.8%	98.1%	98.4%

FECAL SPECIMEN ANALYSIS OTHER COMMERCIAL ELISA			IFA-Confirmed Microscopy	
ELISA (n=186)			Positive	Negative
Other Commercial	Positive		81	2
ELISA	Negative		1	102
Sensitivity	Specificity	PPV	NPV	Correlation
98.8%	98.1%	97.6%	99.0%	98.4%

CONCLUSIONS

- The TECHLAB[®] *GIARDIA II* ELISA assay is a sensitive and specific test for the presence of *Giardia* spp. in human fecal specimens.
- *GIARDIA II* test results correlate well with IFA-confirmed microscopy and is more sensitive than conventional microscopic techniques.
- The *GIARDIA II* 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 II* test results may be read visually or spectrophotometrically.
- *GIARDIA II*'s monoclonal antibody-based format yields highly specific results with no identifiable cross-reactivity with other protozoan parasites and pathogenic microorganisms.

