

Evaluation of a New Rapid Diagnostic Test for the Detection of *Giardia* spp. and *Cryptosporidium* spp. in Human Fecal Specimens

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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 animals. 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 the performance evaluation results of the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK* (TechLab®, Inc.), a rapid membrane enzyme immunoassay for the simultaneous qualitative detection and differentiation of *Giardia* cyst antigen and *Cryptosporidium* oocyst antigen in a single test device.

This evaluation included 791 samples: 431 preserved specimens (215 10% formalin and 216 SAF), and 360 unpreserved specimens (220 fresh and 140 frozen). The test utilizes a device with immobilized capture antibodies on a membrane and soluble peroxidase-conjugated antibodies that are incubated with the specimen. A simple specimen dilution is required and the total assay time is less than 30 minutes at room temperature. The results are reported visually as a line for positive results and the absence of a line for negative results. A positive “control” reaction, indicated by a vertical dotted blue line under the “C” portion of the *Reaction Window*, confirms that the test is working properly and the results are valid.

METHODS

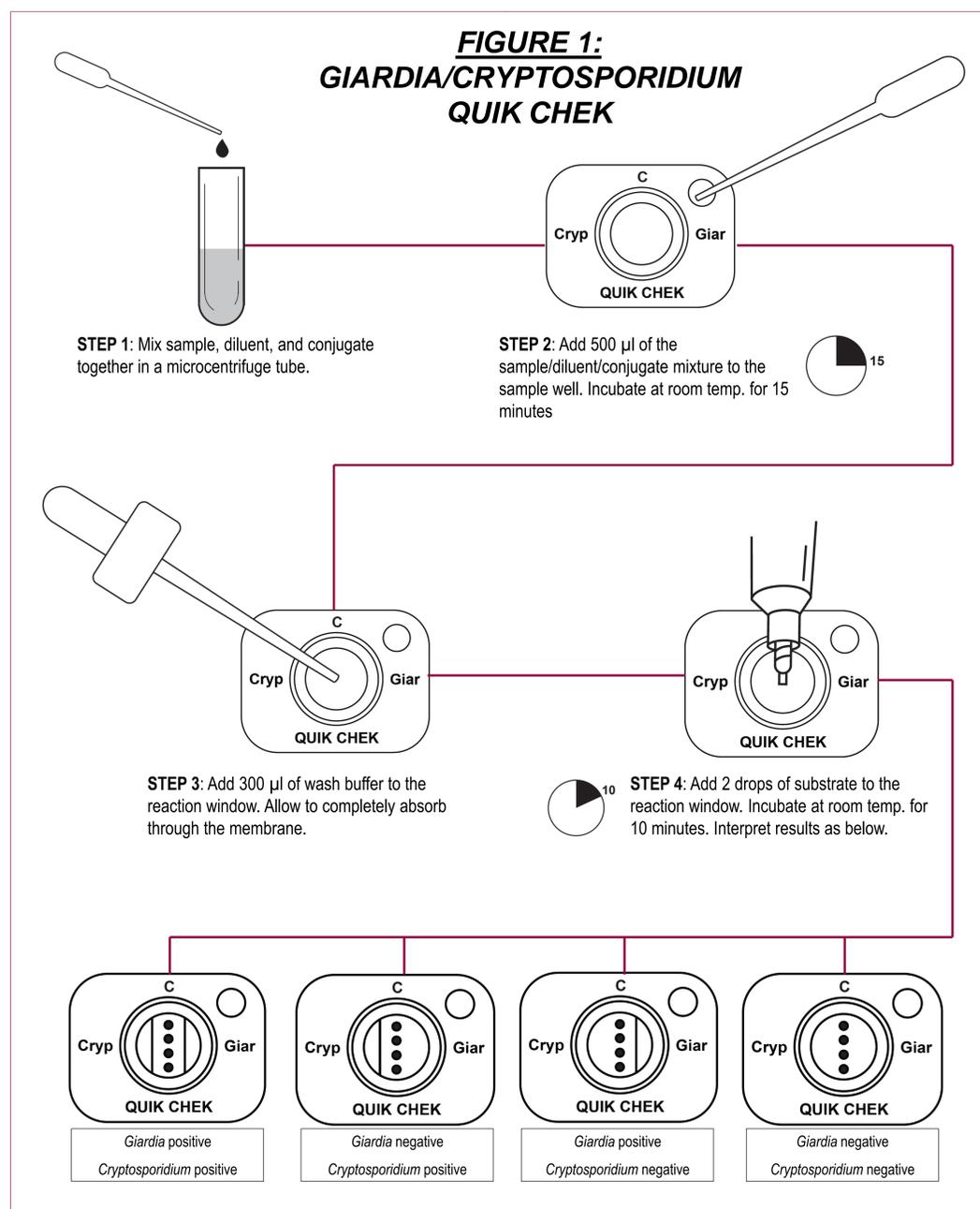
❖ The *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK* was evaluated at two independent sites. Specimens tested at LSG & Associates were part of a panel of preserved fecal specimens obtained following routine patient testing. Specimens tested at TechLab®, Inc. were initially submitted to a local clinical diagnostic laboratory for routine microbiology testing.

❖ Preserved specimens were stored in either SAF or 10% buffered formalin using a 1:4 dilution (1 part sample and 3 parts preservative). Unpreserved samples were refrigerated at 2-8°C or frozen at < -10°C.

❖ Specimens were diluted in buffer to a final fecal sample dilution of 1:20. This was accomplished by adding 25 µl of an unpreserved sample into 500 µl of diluent, or 100 µl of a preserved sample into 400 µl of diluent. Specimens were then processed according to the protocol outlined in **Figure 1**.

❖ Results were compared to a commercially available immunofluorescence antibody (IFA) detection assay specific for *Cryptosporidium* and *Giardia*, which is considered the “gold standard”.

❖ A *Giardia* positive was indicated by the presence of a blue line to the right of the control dots; a *Cryptosporidium* positive was indicated by the presence of a blue line to the left of the control dots. A negative was indicated by the presence of the control dots but an absence of lines.



GIARDIA RESULTS

TABLE 1A: Results for the *Giardia* portion of the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*

<i>Giardia</i> line of <i>GIARDIA/CRYPTOSPORIDIUM QUIK CHEK</i>		MICROSCOPY (IFA)		
		Positive	Negative	Total
<i>Giardia</i> line of <i>GIARDIA/CRYPTOSPORIDIUM QUIK CHEK</i>	Positive	181	0	181
	Negative	2	608	610
	Total	183	608	n = 791

Sensitivity: 98.9% Specificity: 100% Correlation: 99.7%

CRYPTOSPORIDIUM RESULTS

TABLE 1B: Results for the *Cryptosporidium* portion of the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK*

<i>Cryptosporidium</i> line of <i>GIARDIA/CRYPTOSPORIDIUM QUIK CHEK</i>		MICROSCOPY (IFA)		
		Positive	Negative	Total
<i>Cryptosporidium</i> line of <i>GIARDIA/CRYPTOSPORIDIUM QUIK CHEK</i>	Positive	140	1	141
	Negative	0	650	650
	Total	140	651	n = 791

Sensitivity: 100% Specificity: 99.8% Correlation: 99.9%

CONCLUSIONS

The *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK* displays strong correlation with IFA-confirmed microscopic identification of *Giardia* spp. and *Cryptosporidium* spp. in both preserved and unpreserved human fecal samples.

The *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK* is a fast, reliable assay for the detection of *Giardia* and *Cryptosporidium* antigen in human fecal specimens. The simple format and rapid detection ability of the test make it a useful tool for small-scale or large-scale screenings, field diagnostics, and use in developing countries.

