

# CRYPTOSPORIDIUM Enteric (Stool Antigen) ELISA

## INFECTIOUS DISEASES



*Qualitative Measurement of Cryptosporidium*

### Parasitic Diseases: Determination of Cryptosporidium antigen

#### Simple

Microwell Enzyme-based assay (ELISA)  
Rapid turnaround  
Room temperature incubation

#### Convenient

Ready to use reagents  
Controls provided

#### ORDERING

Catalog No.	Description
7060	Campylobacter
7063	Cryptosporidium
7066	E. coli O157
7069	Giardia
7072	Verotoxin
7075	C. difficile Toxins A&B
7078	E. histolytica



CE and EN ISO 13485 compliant

**BIOMERICA**

## INTENDED USE

The Biomerica Cryptosporidium ELISA is intended for the qualitative detection of Cryptosporidium-specific antigen (CSA) in fecal specimens. This assay is intended for *in vitro* diagnostic use only.

## BACKGROUND

Cryptosporidium is a protozoan parasite commonly found in animals. It is considered an important pathogenic organism in domestic farm animals – particularly in calves. Historically, cryptosporidium was thought to cause diarrhea in animals only, until the first case of human infection was reported in 1976.<sup>1</sup> Since that time, this parasite has been associated with diarrheal disease throughout the world. It is particularly prevalent in tropical developing countries and has been known to cause epidemics of diarrhea among children.<sup>4</sup> Cryptosporidium is often the cause of travelers' diarrhea.

Symptoms of cryptosporidiosis include mild to severe diarrhea, which may last from three to ten days, and possible abdominal pain, fever, nausea, vomiting and weight loss.<sup>2,9,10,11,12,14</sup> In immunocompetent (normal) patients, the disease is usually manifested as a self-healing gastroenteritis.<sup>14</sup> However, the infection in immunocompromised patients can be much more severe and may often be life threatening due to dehydration. Loss of water, from three to twelve liters per day, has been reported.<sup>2,3,13,16</sup>

The infection can be transmitted from animals to humans through contaminated water. The oocysts involved in transmission have been shown to be remarkably resistant to common disinfectants and routine chlorination of drinking water. The infection can also be passed human to human, between household members, schoolchildren, and members of high-risk groups such as homosexual men and those with HIV.<sup>2,3,4,13,16</sup>

In the past, diagnosis of Cryptosporidium infections was done by microscopic detection of oocysts in the stool, or the microscopic examination of intestinal biopsy samples. However, these methods can be time-consuming and rely on experienced technicians. Because of the historically low proficiency of correct microscopic examinations, alternative diagnostic methods have been investigated.<sup>5,6,16,17</sup>

One important alternative has been the development of an enzyme-linked immunosorbent assay (ELISA) for the detection of CSA in stool specimens. These tests have been shown to have comparable sensitivity to experienced microscopic examinations, do not require personnel specially trained in parasitology, are fairly simple to perform and do not require the observation of intact organisms in the stool sample.<sup>7,8</sup>

## PERFORMANCE

A total of 80 stool specimens were tested on the Biomerica Cryptosporidium ELISA and a Reference ELISA for comparison. The results are shown in the following table.

		Reference Crypto ELISA	
		+	-
Biomerica Cryptosporidium ELISA	+	25	2
	-	0	53

Accuracy: 98%

Sensitivity: 100%

Specificity: 96%

## ORDERING

Catalog No.	Description
7063	Cryptosporidium ELISA kit - Qualitative (96 tests)

 and EN ISO 13485:2003 Compliant, Multi-language inserts available

### Bibliography

1. Meisel, J.L., Perera, D.R., Meligro, C., and Rubin, C.E. "Overwhelming watery diarrhea associated with Cryptosporidium in an immunosuppressed patient." 1976. *Gastroenterology* 70: 1156-60.
2. Chapman, P.A. "Cryptosporidiosis: Recent Trends in Epidemiology, Diagnosis, and Treatment." *Serodiag & Immunother Infect Dis* #2, 1988, pp. 311-317.
3. Meyer, E.A. "Waterborne Giardia and Cryptosporidium." *Parasit Today*. Vol. 4, #7, 1988, pp. 200-201.4
4. Alpert, G., Bell, L.M., Kirkpatrick, C.E., et al. "Cryptosporidiosis in a day-care centre." *New Eng. J. Med.* 311:860-1.
5. Stibbs, H., Ongerth, J. "Immunofluorescence Detection of Cryptosporidium Oocysts in Fecal Smears." *J Clin Micro*, Vol 24 #4, Oct. 1986, pp.517-521.
6. McLaughlin, J. et al. "Identification of Cryptosporidium Oocysts by Monoclonal Antibody." *Lancet*, January 3, 1987, pp.51.
7. Ungar, B. "Enzyme-Linked Immunoassay for Detection of Cryptosporidium Antigens in Fecal Specimens." *J Clin Micro*, Vol. 28 #11, Nov 1990, pp. 2491-2495.
8. Anusz, K., et al. "Detection of Cryptosporidium parvum Oocysts in Bovine Feces by Monoclonal Antibody Capture Enzyme-Linked Immunosorbent Assay." *J. Clin Micro*, Vol. 28 #12, dec. 1990, pp. 2770-2774.
9. Jokipii, L., et al. "Cryptosporidium: A Frequent Finding In Patients With Gastrointestinal Symptoms." *Lancet*, August 13, 1983, pp. 358-360.
10. Shephard, R., et al. "Shedding of Oocysts of Cryptosporidium in Immunocompetent Patients." *J Clin Pathol*, Vol. 41, 1988, pp. 1104-1106.
11. Holten-Anderson, W., et al. "Prevalence of Cryptosporidium Among Patients with Acute Enteric Infection." *J. Infect*, Vol. 9, 1984, pp. 277-282.
12. Jokipii, L. and Jokipii, M. "Timing of Symptoms and Oocyst Excretion in Human Cryptosporidiosis." *N Engl J Med*, Vol. 315 #26, 1986, pp.1643-1647.
13. Egger, M., et al. "Symptoms and Transmission of Intestinal Cryptosporidiosis." *Arch Dis Child*, Vol 65, pp 445-447.
14. Hart, M., et al. "Acute Self-Limited Colitis Associated with Cryptosporidium in an Immunocompetent Patient." *J Ped Gastro Nutr*, Vol. 8, 1989, pp. 401-403.
15. Sloan, L.M., and Rosenblatt, J.E. "Evaluation of Enzyme-Linked Immunosorbent Assay for Detection of Cryptosporidium spp. in Stool Specimens." *J Clin Micro*, Vol. 31 #6, June 1993, pp. 1468-1471.
16. Current, W. and Garica, L. "Cryptosporidiosis." *Clin Micro Rev*, Vol. 4 #3, July 1991, pp. 325-358.
17. Weber, R. et al. "Threshold of Detection of Cryptosporidium Oocysts in Human Stool Specimens; Evidence for Low Sensitivity of Current Diagnostic Methods." *J Clin Micro*, Vol. 29 #7, July 1991, pp. 1323-1327.



17571 Von Karman Avenue • Irvine, CA 92614 USA • Tel (949) 645-2111  
Fax (949) 553-1231 • email: [bmra@biomerica.com](mailto:bmra@biomerica.com) • [www.biomerica.com](http://www.biomerica.com)