

E. histolytica Enteric (Stool Antigen) ELISA

INFECTIOUS DISEASES

Qualitative Measurement of E.histolytica

Parasitic Diseases: Determination of E. histolytica 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



BIOMERICA

CE and EN ISO 13485 compliant

INTENDED USE

The Biomerica *E. histolytica* ELISA is intended for the qualitative detection of *E. histolytica* specific antigen in fecal specimens. This assay is intended for *in vitro* diagnostic use only.

BACKGROUND

Entamoeba histolytica is an anaerobic parasitic protozoan, part of the genus *Entamoeba*. *E. histolytica* and *E. dispar* are virtually indistinguishable species which are thought to infect up to 500 million people worldwide.^{1,2,3} However, *E. dispar*, which is nonpathogenic, represents approximately 90% of those infected.⁴ Thus, *E. histolytica*, the pathogenic species, infects approximately 50 million people worldwide.

Clinical symptoms in people infected with *E. histolytica* range from non-specific symptoms of gastrointestinal disease to dysentery, colitis, and amebiasis. Symptoms of amebiasis include cramp-like abdominal pains, nausea, and severe diarrhea – often bloody. Approximately 10% of cases of acute amebic dysentery result in extra-intestinal complications, such as hepatic abscesses, pulmonary abscesses, or even cerebral abscesses.⁵ If these more serious complications are not treated, death is often the result, and deaths attributed to *E. histolytica* infection are estimated to be approximately 80,000 per year worldwide.³

E. histolytica exists either as a trophozoite (active) stage which exists only in the host and in fresh, loose feces, or as cysts, which are very stable outside of the host in water, soils, and on moist foods. Thus, transmission occurs through the ingestion of contaminated water or foods. *E. histolytica* can also be transmitted through anal-oral sex. Research has shown that HIV-infected gay men are at greater risk of infection than the heterosexual population.

Diagnosis of amebiasis has been done through a variety of non-invasive techniques, the most common of which has been microscopic examination of fecal specimens. However, this requires an experienced technician, and very often, multiple stool specimens. Various studies have shown that correct diagnosis by microscopy is only achieved 50-76% of the time.^{6,7} More sensitive and specific procedures, such as ELISA, have been developed which eliminate the subjective evaluation associated with microbiology.^{8,9,10}

PERFORMANCE

A total of 83 stools were tested against a Reference ELISA. The following results were obtained:

		Reference ELISA		
		Positive	Negative	Total
Biomerica <i>E. histolytica</i> ELISA	Positive	26	0	26
	Negative	0	57	57
	Total	26	57	83

Accuracy: 100%
Sensitivity: 100%
Specificity: 100%

ORDERING

Catalog No.	Description
7078	<i>E. histolytica</i> ELISA kit - Qualitative (96 tests)

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

Bibliography

1. Gathiram, V., and Jackson, T.F. 1987. A longitudinal study of asymptomatic carriers of pathogenic zymodemes of *Entamoeba histolytica*. So. Afr. Med. J. 72:669-672.
2. Bruckner, D.A. 1992. Amoebiasis. Clin. Microbiol. Rev. 5(4): 356-369.
3. Walsh, J.A. 1986. Problems in recognition and diagnosis of amoebiasis: estimation of the global magnitude of morbidity and mortality. Rev. Inf. Dis. 8(2): 228-238.
4. Strachan, W.D., et. al. 1988. Immunological differentiation of pathogenic and non-pathogenic isolates of *Entamoeba histolytica*. Lancet 12: 561-563.
5. Ohnishi, K. et. al. 1994. Brain abscess due to infection with *Entamoeba histolytica*. Am. J. Trop. Med. Hyg. 51(2): 180-182.
6. Marsden, A. P. H., and Smith, H. F. 1946. The detection of the cysts of *E. histolytica* in the faeces by microbiology examinations. Med. J. Ant. 11: 915-919.
7. Stamm, W.P. 1957. The laboratory diagnosis of clinical amoebiasis. Trans. Roy. Soc. Trop. Med. Hyg. 51: 306-312.
8. Haque, Rashidul, et. al.: Rapid Diagnosis of *Entamoeba* Infection by Using *Entamoeba* and *Entamoeba histolytica* Stool Antigen Detection Kits, J Clin Micro, Oct. 1995, pp.2558-2561.
9. Pillai, Dylan, et. al.: *Entamoeba histolytica* and *Entamoeba dispar*: Epidemiology and Comparison of Diagnostic Methods in a Setting of Nonendemicity, Clin Infect Dis, #29, 1999, pp.1315-1318.
10. Petri, William Jr. and Singh, Upinder: Diagnosis and Management of Amebiasis: State-of-the-Art Clinical Article, Clin Infect Dis, #29. 1999. pp.1117-1125.



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