Entamoeba MonlabTest®

CE

IVD

MO-804021 20 TESTS

One Step Entamoeba Antigen Test Device

A rapid, one step test for the qualitative detection of *Entamoeba* antigens in human feces.
For professional *in vitro* diagnostic use only.

INTENDED USE

The Entamoeba MonlabTest® test is a rapid chromatographic immunoassay for the qualitative detection of *Entamoeba* antigens in human feces specimens to aid in the diagnosis of amoebiasis.

SYNTHESIS

Amoebiasis is the infection of the human gastrointestinal tract by *Entamoeba histolytica*, a protozoan parasite that is capable of invading the intestinal mucosa and may spread to other organs, mainly the liver. *Entamoeba dispar*, an ameba morphologically similar to *E. histolytica* that also colonizes the human gut, has been recognized recently as a separate species with no invasive potential. The acceptance of *E. dispar* as a distinct but closely related protozoan species has had profound implications for the epidemiology of amoebiasis, since most asymptomatic infections found worldwide are now attributed to this noninvasive ameba.
Invasive amoebiasis due to *E. histolytica* is more common in developing countries. In areas of endemic infection, a variety of conditions including ignorance, poverty, overcrowding, inadequate and contaminated water supplies, and poor sanitation favor direct fecal-oral transmission of amebas from one person to another. Being responsible for approximately 70 thousand deaths annually, amoebiasis is the fourth leading cause of death due to a protozoan infection after malaria, Chagas' disease, and leishmaniasis and the third cause of morbidity in this organism group after malaria and trichomoniasis, according to recent World Health Organization estimates.
Patients with dysentery have an average of three to five mucosanguineous evacuations per day, with moderate colic pain preceding discharge, and they have rectal tenesmus. In patients with bloody diarrhea, evacuations are also few but the stools are composed of liquid fecal material stained with blood. While there is moderate colic pain, there is no rectal tenesmus. Fever and systemic manifestations are generally absent.

PRINCIPLE

The Entamoeba MonlabTest® is a qualitative lateral flow immunoassay for the detection of *Entamoeba* antigen in human feces samples. The membrane is pre-coated with monoclonal antibodies against *Entamoeba* antigens on the test line region. During testing, the sample reacts with the particle coated with anti-*Entamoeba* antibodies which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result, the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. A green coloured line always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pack until use.
- Do not use the test if pack is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

STORAGE AND STABILITY

Store as packaged in the sealed pack either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pack. The test must remain in the sealed pack until use. Do not freeze.

MATERIALS PROVIDED	MATERIALS REQUIRED BUT NO PROVIDED
- 20 Tests - Instructions for use - 20 specimen collection vial with buffer	- Specimen collection container - Disposable gloves - Timer

SPECIMEN COLLECTION AND PREPARATION

Collect sufficient quantity of feces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8ºC/36-46.4ºF) for 1-2 days prior to testing. For longer storage, maximum 1 year the specimen must be kept frozen at -20ºC/-4ºF. In this case, the sample will be totally thawed, and brought to room temperature before testing.

PROCEDURES

To process the collected stool samples (see illustration 1):
Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick four times into the fecal specimen to pick up the sample (aprox.125 mg).
Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the fecal specimen with a dropper and add 125 µL into the specimen collection vial with buffer.
Test Procedure (see illustration 2)
Allow the tests, stool samples and buffer to reach to room temperature (15-30°C/59-86°F) prior to testing. Do not open pouches until ready to perform the assay.
1. Remove the Entamoeba MonlabTest® from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the cap of the vial.
3. Use a separate device for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.

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Illustration 1

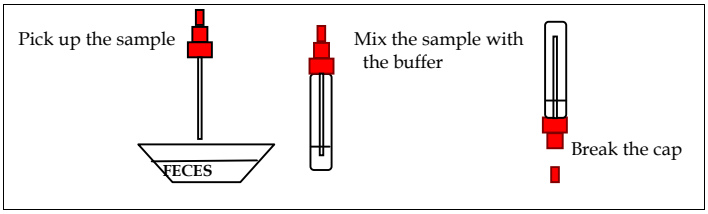
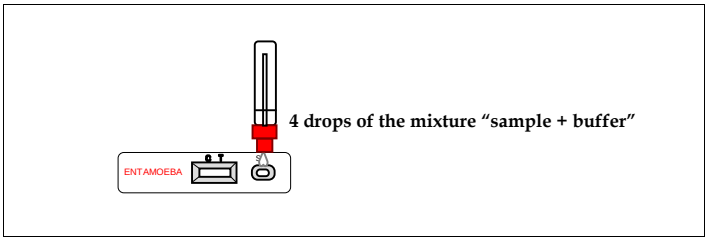
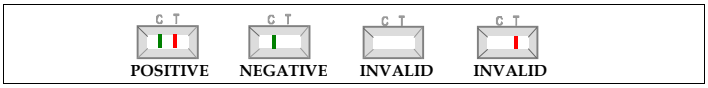


Illustration 2



INTERPRETATION OF RESULTS

Illustration 3



POSITIVE**:** Two lines appears across the central window. In the result line region, a **red** test line marked in the illustration 3 with the letter T, and in the control line region, a **green** control line marked in the illustration 3 with the letter C.

NEGATIVE**:** Only one **green** band appears across the control line region marked with the letter C at the illustration 3 (control line).

INVALID: A total absence of the **green** control coloured band regardless the appearance or not of the **red** test line. See illustration 3. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

NOTES ON THE INTERPRETATION OF RESULTS

The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL

Internal procedural controls are included in the test:

- A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. Entamoeba MonlabTest® will only indicate the presence of parasites in the specimen (qualitative detection) and should be used for the detection of *Entamoeba* antigens in feces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown lines appear). Dilute the sample with the buffer and repeat the test.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of amoebiasis.
4. After one week of infection, the number of parasites in feces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
5. This test provides a presumptive diagnosis of *Entamoeba* infection. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

Entamoeba histolytica infects more than 500 million people worldwide. Almost from the time of its discovery, it was observed that although *E. histolytica* most often causes mild or asymptomatic infections, 10% of patients develop severe dysentery and life-threatening invasive and extraintestinal disease.

100,000 people are estimated to die each year from amebic colitis and amebic liver abscess.

Dysenteric and diarrheic syndromes account for 90% of cases of invasive intestinal amoebiasis.

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity

It was studied some stool samples from patients of different Hospital in Spain The results showed using Entamoeba MonlabTest® in comparison with other commercial immunoassays test (RIDA®QUICK Entamoeba, R-Biopharm AG) were:

- >99% of sensitivity and
- >99% of specificity

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of Entamoeba MonlabTest®. There is not cross reactivity with common gastrointestinal parasites occasionally present in feces.

- *Campylobacter*
- *Clostridium difficile*
- *Cryptosporidium parvum*
- *E. Coli*
- *Shigella*
- *Giardia lamblia*
- *H. Pylori*
- *Listeria monocytogenes*
- *Salmonella*
- *Staphylococcus aureus*

REFERENCES

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2. HAQUE R., et al. "Diagnosis of Amebic Liver Abscess and Intestinal Infection with
3. The TechLab *Entamoeba histolytica* II Antigen Detection and Antibody Tests". *Journal of clinical microbiology*, Sept. 2000, p. 3235–3239.
4. ESPINOSA-CANTELLANO M., et al. "Pathogenesis of Intestinal Amebiasis: From Molecules to Disease". *Clinical Microbiology Reviews*, Apr. 2000, p. 318–331.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

	Manufacturer	IVD	For *in vitro* diagnostic use only
	Don't re-use		Consult instructions for use
Σ n	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by

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