

EpiTuub[®] Fecal *Giardia lamblia* Antigen Test Kit Rapid Monoclonal Immunochromatographic Test Device for the detection of *Giardia lamblia* Antigen in Feces



KT 927



30 Tests



2 – 8°C

US: For In Vitro Diagnostic Use

EU:



INTENDED USE

This *Giardia lamblia* antigen test kit is intended for the direct qualitative detection of the presence of *Giardia lamblia* antigen in a fecal sample. The test might be used as an aid for detecting patients or animals with acute and chronic gastroenteritis infected with *Giardia lamblia*. It is for professional use only.

SUMMARY OF PHYSIOLOGY

Giardia lamblia (also known as *Giardia intestinalis*) has a characteristic tear-drop shape and measures 10-15 µm in length. It has twin nuclei and an adhesive disk which is a rigid structure reinforced by supelicular microtubules. There are two median bodies of unknown function, but their shape is important for differentiating between species. There are 4 pairs of flagella, one anterior pair, two posterior pairs and a caudal pair. These organisms have no mitochondria, endoplasmic reticulum, golgi, or lysosomes. *Giardia* has a two-stage life cycle consisting of trophozoite and cyst. The life cycle begins with ingested cysts, which release trophozoites (10-20 µm x 5-15 µm) in the duodenum. These trophozoites attach to the surface of the intestinal epithelium using a ventral sucking disk and then reproduce by binary fission. The trigger for encystment is unclear, but the process results in the inactive, environmentally resistant form of *Giardia* -- a cyst (11-14 µm x 7-10 µm) that is excreted in feces.

Giardiasis is a diarrheal illness caused by *Giardia lamblia*, after ingestion of *Giardia* cysts. Once a person has been infected with *Giardia*, the parasite lives in the intestine and is passed in the stool. Millions of germs can be released in a bowel movement from an infected human or animal. *Giardia* is found in soil, food, water, or surfaces that have been contaminated with the feces from infected humans or animals. Because the parasite is protected by an outer shell, it can survive outside the body and in the environment for long periods of time. Because it is spread world-wide, *Giardia lamblia* has become one of the most important causes of chronic diarrheas. About 15-20% of children under age ten years and 19% of male homosexuals have been infected. *Giardia* infection can cause a variety of intestinal symptoms either acute or chronic, which include diarrhea, gas or flatulence, greasy stools that tend to float, stomach cramps, upset stomach or nausea. These symptoms may lead to weight loss and dehydration. Some people with giardiasis have no symptoms at all. Those asymptomatic cases still shed *Giardia* cysts. Generally, symptoms of giardiasis begin 1 to 2 weeks after becoming infected and they may last 2 to 6 weeks.

It is important to diagnose *Giardia lamblia* infection in humans. Diagnosis of giardiasis can be established based on the detection of the parasite specific antigen by a specific immunoassay methods. The fecal *Giardia lamblia* antigen test have significant clinical tracking value in diagnosis and monitoring the effectiveness of treatment and the recurrence of the infection in comparison to serum antibody test. In summary, accurate diagnosis of *Giardia* infection requires an antigen test or, if that is unavailable, an ova and parasite examination of stool. Multiple stool examinations are recommended,

since the cysts and trophozoites are not shed consistently.

ASSAY PRINCIPLE

The *Giardia lamblia* Antigen Rapid Test Strip employs dye-conjugated monoclonal antibody against *Giardia lamblia* antigen, and solid-phase/membrane coated specific anti-*Giardia lamblia* monoclonal antibody. In this test the specimen is first treated with an extraction solution to extract *Giardia lamblia* antigens from the feces. Following extraction, the only step required is to screw the *Giardia lamblia* test strip tube into the sample collection tube. As the sample extraction upward flows through chamber and reach the test strip, the colored particles migrate. In the case of a positive result the specific antibody present on the membrane will capture the colored particles. Different colored lines will be visible, depending upon the bacteria content of the sample. These lines, after 10 minutes of incubation at room temperature, are used to interpret the result.

REAGENTS: Preparation and Storage

This test kit must be stored at 2 – 8°C upon receipt. For the expiration date of the kit refer to the label on the kit box. All components are stable until this expiration date.

Prior to use allow all reagents to come to room temperature if the kit is stored at refrigerated condition.

1. <i>Giardia lamblia</i> Antigen Test Strip Tube	30
2. Fecal Sample Collection Tube	30
3. Patient label for sample collection tube	30
4. Paper for stool sample collection	30
5. Instruction for use	1

SAFTY PRECAUTIONS

The reagents are for professional use only. Source material from which reagents of bovine serum was derived in the contiguous 48 United States. It was obtained only from donor health animals maintained under veterinary supervision and found free of contagious diseases. Wear gloves while performing this test and handle these reagents and patient samples as if they are infectious. Do not get in eyes, on skin, or on clothing. Do not ingest. On contact, flush with copious amounts of water for at least 15 minutes. When the assay procedure is completed, dispose of specimens (biohazard materials) carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal. Use Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Disposable pipette for watery sample collection
2. Positive Control

Both are for internal quality control use only. They are available from Epitope Diagnostics. Please contact your distributor or sales representative.

SPECIMEN COLLECTION

Stool samples must be collected in clean container or directly into the Fecal Sample Collection Tube. The assay should be done right after collection. The collected specimen can be stored in the refrigerator (2-8°C) for 5 days prior to testing. For longer storage, the specimen can be kept frozen at -20°C for maximum 1 year. In this case, the sample should be totally thawed, and brought to room temperature and homogenized before testing.

For each solid specimen: Unscrew the sampling lid and keep the sampling tube in a vertical position to prevent the loss of any extraction solution. Insert and twist the tip of the sampling lid into the stool specimen at two or more different sites. Collect fecal sample that is stuck to the surface of the sampling lid. Do not intentionally collect any separate and large pieces of fecal sample into the tube. Replace the sampling lid into the tube and secure tightly.

ASSAY PROCEDURE

1. Bring foil pouch sealed test strips and collected specimens to room temperature (8 - 30°C).
2. Mix the sampling tube vigorously to ensure a good liquid suspension.
3. Position the sampling tube upper side down in vertical and let it sediment for about 1 minute.
4. Remove the test strip from the sealed foil pouch.
5. Screw the test strip **in a vertical position** into the sampling tube by **breaking into** the bottom seal of the sampling tube. Tighten securely!
6. Allow the solution flow into the bottom space of the test strip and keep the device **in a vertical position**.
7. Read test result at **10 minutes** and do not interpret test result after 20 minutes.

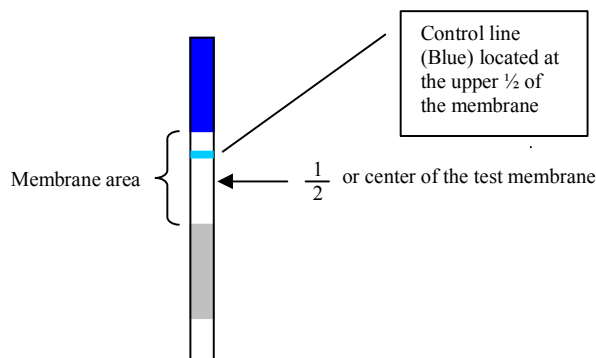
PROCEDURAL NOTES

1. After screw the test strip tube into the sampling tube, we should see that there is a minimum 5 mm height of liquid at the bottom of the test strip tube and the dye color liquid migrates on the test strip. If there is not migration of the liquid through the test membrane area, one should tap the whole device against the table to see if the liquid is migrating.
2. Keep light sensitive reagents in the original amber bottles.
3. Incubation times or temperatures other than those stated in this insert may affect the results.

INTERPRETATION OF RESULTS

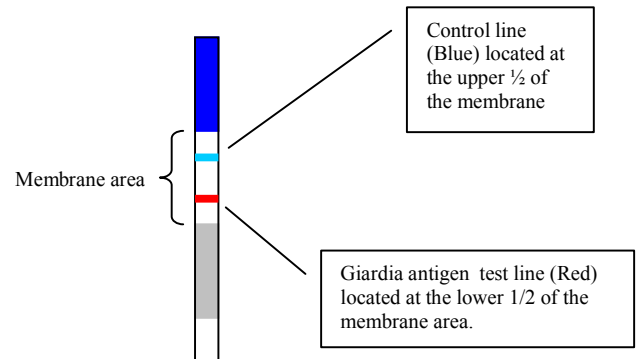
• Valid Test:

The appearance of a **blue** control line on the test reading membrane area indicates the test is valid. The control line located at the upper half of the test membrane area.



• Positive:

If two bands of one blue control line and one red test line are visible within 10 minutes, the test result is positive and valid.

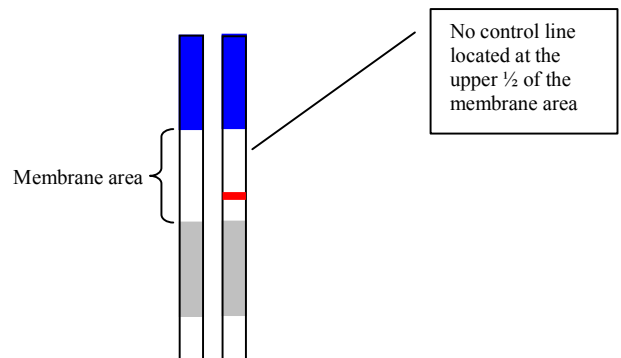


• Negative:

If there is a blue colored band displayed in the control area and there is no red colored band displayed in the test line area, the test result is negative (see figure as Valid Test).

• Invalid:

If a blue colored band does not form in the control area regardless there is any band in the test area, the test result is invalid.



QUALITY CONTROL

Good laboratory practices recommend the use of appropriate controls. There are two types of controls for the *EpiTuub*TM Giardia lamblia antigen test, the internal procedural control and external controls.

1. **Internal procedural control:** Each *EpiTuub*TM fecal Giardia lamblia antigen test consists a built in procedural control (blue colored band). It will appear if the test has been performed correctly and the reagents are reactive. It does not ensure that the test line antibody is accurately detecting the presence or absence of viral antigen in the test fecal sample.
2. **External controls:** It is recommended to use external positive controls. The external positive controls are not provided with this kit, but are commercially available from Epitope Diagnostics. External controls are used to assure that the test line antibody is reactive. However, external controls will not detect an error in performing the patient sample test procedure. It is recommended that the external control be tested once per kit.

You should always follow local, state, federal guidelines for running quality control.

LIMITATION OF THE PROCEDURE

1. The test should be used only for the detection of Giardia lamblia antigen in fecal samples.
2. The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line, when reporting the result
3. One hundred twenty samples were evaluated to assure the correct performance of the test. The correlation of the results with other techniques (ELISA) was satisfactory. However, interferences in the performance of the tests should not be excluded.
4. No cross-reactions with other viruses or substances were observed during the evaluation of the test. A negative result does not totally exclude a possible Giardia lamblia infection. Multiple stool examinations are recommended, since the cysts and trophozoites are not shed consistently. The significance of the results must be evaluated in relation to the patient's clinical symptoms.
5. As with all diagnostic tests, the definitive clinical diagnosis must not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated. *EpiTuub™* fecal Giardia lamblia antigen test is designed for the aid of clinical diagnosis and should not replace other diagnostic procedures. Alternatively, one can detect the Giardia lamblia cyst or trophozoites by using a fecal parasite concentration kit (Epitope Diagnostics catalog number: FPC200)

PERFORMANCE

Sensitivity

Detection limit: purified Giardia lamblia cysts were sonicated, centrifuged and its protein concentration was determined. This reference antigen preparation of Giardia lamblia was diluted in 0.01M PBS-BSA buffer and tested with this kit according to the above described test procedures. The detection limit of Giardia lamblia is about 2 – 10 ng/ml.

Specificity

The evaluation was performed by comparison this rapid test with an commercial Giardia lamblia antigen ELISA kit. The detection of Giardia lamblia showed over 98% of concordance with the ELISA.

The possibility for interference of human anti-mouse antibodies (HAMA) or high levels of RF in the stool sample have not been evaluated.

LITERATURES












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TECHNICAL ASSISTANCE AND CUSTOMER SERVICE
 For technical assistance or place an order, please contact Epitope Diagnostics, Inc. at (858) 693-7877 or fax to (858) 693-7678.
www.epitopediagnostics.com

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 Manufacturer	 No. of tests
 Catalog Number	 Keep away from heat and direct sun light
 Concentrate	 Store at
 In Vitro Diagnostic Device	 Use by
 Read instructions before use	 Lot No.
 Authorized Representative In Europe	