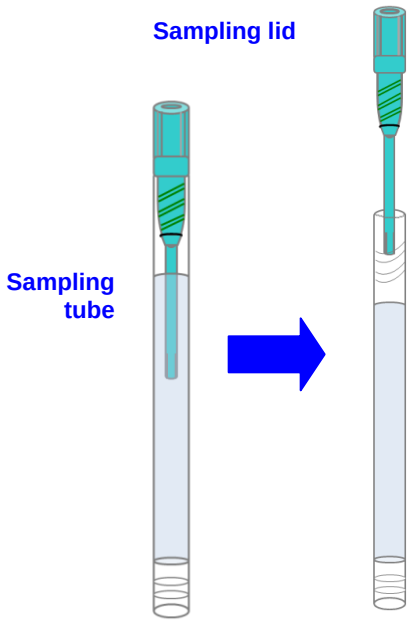
EpiTuub® Fecal Giardia lamblia Antigen Rapid Test - Instructions for Fecal Sample Collection

Qualitative detection of Giardia lamblia antigen in human feces.

Version 8

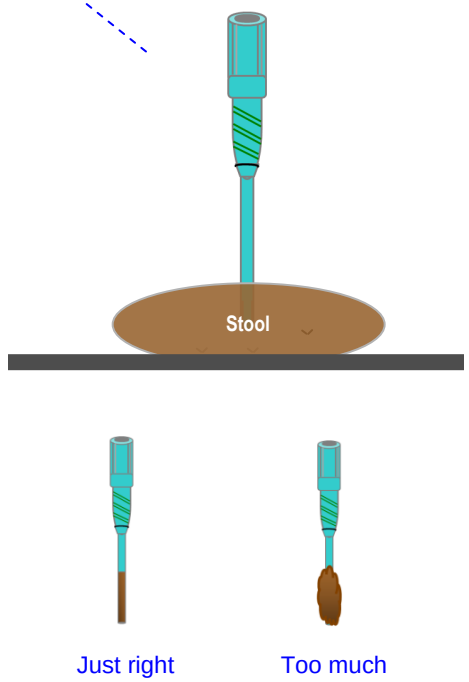
1

1. Collect a stool sample using the enclosed stool sampling paper:
   a. Clean the bowl and flush the toilet two times. Unfold and lay the Sample Collection Paper directly on the top of the water in the toilet bowl (the paper should float above the water).
   b. After bowel movement, take the sampling tube and unscrew the sampling lid, keeping the sampling tube in a **vertical position** to prevent loss of solution.



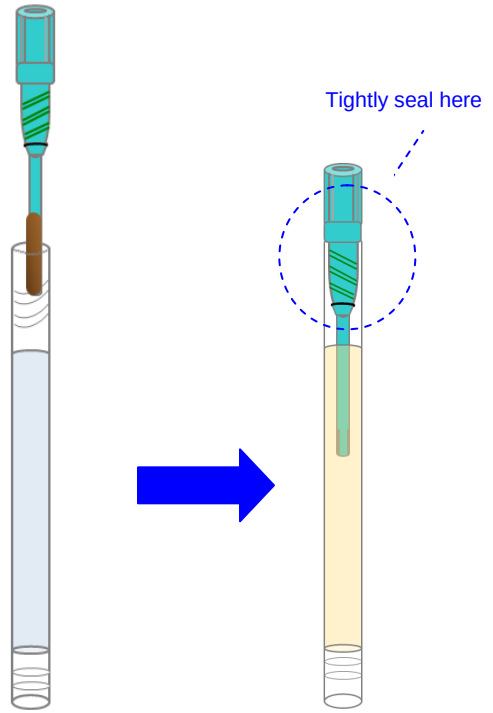
2

1. Hold the sampling lid by the **Thumb Grip**.
2. Use the tip of the sampling lid to collect a small amount of fecal sample at two or more sites. Only take the fecal sample that sticks to the sampling lid tip (never intentionally place any separate piece of fecal sample into the tube). The total amount of stool collected should be less than one grain of cooked rice. For liquid stool, collect 0.1mL into the sampling tube.



3

1. Insert and screw the sampling lid back into the sampling tube **in a vertical position**. Do not spill any solution from the tube.
2. Tightly seal the lid with the tube.
3. Flush toilet.



READ ALL THE INFORMATION IN THIS LEAFLET BEFORE SAMPLING

Store at 2-8°C. Do not freeze. Keep out of reach of children. For in-vitro diagnostic use. Not to be taken internally. Not to be sampled directly from anus.
If you have any questions, please contact your physician or laboratory staff or call Epitope Diagnostics at 858-693-7877 from 8:00 a.m. to 5:00 p.m. PST

EU: IVD CE +2 +8 °C

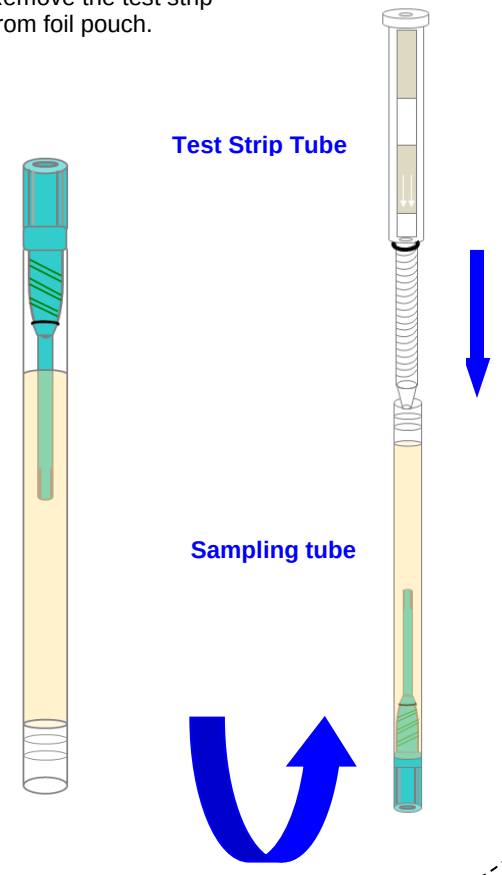
EC REP MDSS GmbH Schiffgraben 41 30175 Hannover Germany

EpiTuub® Fecal Giardia lamblia Antigen Rapid Test Kit - Instructions for Test Procedures

Qualitative detection of Giardia lamblia antigen in human feces.

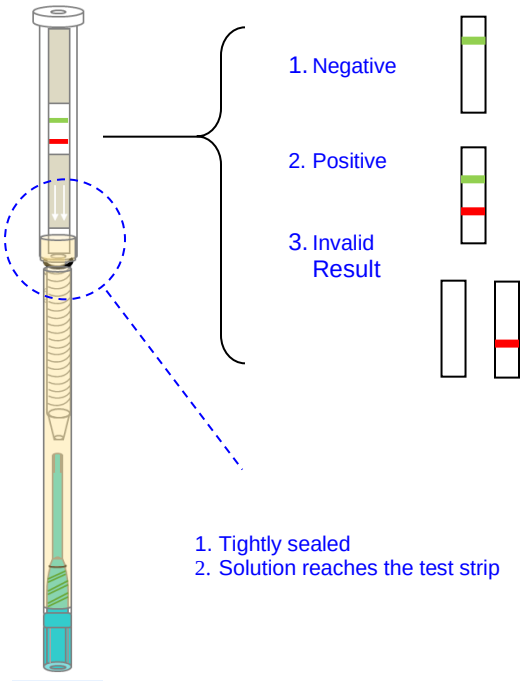
A

1. Shake to dissolve the stool into solution.
2. **Turn the sampling tube upside down vertically.**
3. Remove the test strip from foil pouch.



B

1. Insert and screw the test strip **in a vertical position** into the sampling tube by breaking the bottom seal of the sampling tube.
2. Allow the solution to flow into the bottom space of test strip, keeping the device **in a vertical position**.
3. You may soon see a red fluid moving across the white area of the test strip. Read test result after 5 minutes.



For In-Vitro Diagnostic Use

Catalog Number: KT927 (30T/Kit)
KT927.10 (10T/Kit)

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. These organisms have no mitochondria, endoplasmic reticulum, golgi, or lysosomes. 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. *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. Diagnosis of giardiasis can be established based on the detection of the parasite specific antigen by specific immunoassay methods. Accurate diagnosis of Giardia infection requires an antigen test or, if that is unavailable, an ova and parasite examination of stool.

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

1. Fecal specimen collection device (30389): containing sampling tube, sampling lid and pre-added extraction solution in the sampling tube. This device should be stored at 2 to 8°C. Do not freeze.

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EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

EpiTuub® Fecal Giardia *lamblia* Antigen Rapid Test - Instructions for Test Procedures

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2. Test strip tube (30388): one dipstick for the Giardia *lamblia* test is assembled in a transparent housing and sealed in a foil pouch with desiccant. It should remain in its original sealed pouch until ready for use. The test strip should be stored at 2 to 8ºC. Do not freeze.
3. Single use green pipette.
4. Patient label for sample collection device.
5. Instruction for use.

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Timer or clock

PRECAUTIONS

1. For in-vitro diagnostic use only. Not to be taken internally.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Do not reuse the test.

PATIENT PREPARATION

1. Dietary restrictions are not necessary.

SPECIMEN COLLECTION

Stool samples must be taken as soon as the symptoms appear. Viral particles decrease in number after one week, making the diagnosis more difficult. The samples can be stored at 2-8 ºC for 1 to 2 days. For longer storage they must be kept frozen at -20ºC. 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.

For each liquid specimen: Unscrew the sampling lid and keep the sampling tube in a vertical position to prevent the loss of any extraction solution. Using the green pipette to collect **three drops** of the liquid stool sample and add to the sampling tube. Replace the sampling lid into the tube and secure tightly.

TEST PROCEDURE

1. Bring the sealed foil pouch test strips and collected specimens to room temperature.
2. Shake the sampling tube vigorously to ensure a good liquid suspension.
3. Position the sampling tube upside down vertically and let it settle for about 1 minute.
4. Remove the test strip from the sealed foil pouch.
5. Screw the test strip tube into the sampling tube by **breaking** the bottom seal of the sampling tube. Secure tightly! (Figure A)
6. Allow the solution to flow into the bottom space of the test strip and keeping the device **in a vertical position**.
7. Read test result at 5 minutes. Do not interpret test result after 10 minutes.

PROCEDURAL NOTES

1. After the test strip tube is screwed completely into the sampling tube, you should see a minimum 5 mm extraction buffer liquid in the bottom of the strip tube.
2. You should see liquid migrating across the membrane area right after the screw in process. If not, take the tube and tap against the table several times, and the migration of the liquid should be observed.

INTERPRETATION OF RESULTS

- **Positive:**
  If two green/red colored bands are visible within 5 minutes, the test result is positive and valid (Figure B).
- **Negative:**
  If test area has no red colored band and the control area displays a green colored band, the test result is negative (Figure B).
- **Invalid:**
  If a colored band does not form in the control area regardless of there being any band in the test area, the test result is invalid (Figure B) and needs to be retested.

QUALITY CONTROL

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

1. **Internal procedural control:** Each EpiTuub® Giardia *lamblia* test has a built-in procedural control. It will appear if the test has been performed correctly, sample wicking has occurred and the reagents are reactive. It does not ensure that the test line antibody is accurately detecting the presence or absence of Giardia *lamblia* 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.

Follow local, state, and 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. Two hundred 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. 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.

PERFORMANCE CHARACTERISTICS

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.

REFERENCES

1. Regnath T, Klemm T, Ignatius R. Rapid and accurate detection of Giardia lamblia and Cryptosporidium spp. antigens in human fecal specimens by new commercially available qualitative immunochromatographic assays. Eur J Clin Microbiol Infect Dis. 2006 Dec;25(12):807-9.
2. Weitzel T, Dittrich S, Möhl I, Adusu E, Jelinek T. Evaluation of seven commercial antigen detection tests for Giardia and Cryptosporidium in stool samples. Clin Microbiol Infect. 2006 Jul;12(7):656-9.
3. el-Sahn AA, Megahed AM, Eissa SM, Barakat RM. Diagnosis of giardiasis using an enzyme-linked immunosorbent assay (ELISA) on formalin preserved stools. J Egypt Public Health Assoc. 2000;75(3-4):277-90.

	Manufacturer	IVD	For *in vitro* diagnostic use only
EC REP	Authorized representative		Consult instructions for use
Σ n	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by
DIL	Sample diluent		