Giardia Ag Rapid Test Kit

Cat. No. S035-01

INTENDED USE

Sensit Giardia Ag Rapid Test Kit is a lateral flow immunochromatographic assay for the qualitative detection of Giardia lamblia antigen in human feces.

SUMMARY & TEST DESCRIPTION

Giardiasis is a diarrhoeal illness seen throughout the world. It is caused by a flagellate protozoan parasite, Giardia intestinalis, also known as G. lamblia and G. duodenalis.

Giardia is a common cause of gastrointestinal disturbance in both high- and low-income countries. The incidence of Giardia is generally higher in low-income countries (e.g. many countries of Africa, Asia, and South and Central America) where access to clean water and basic sanitation is lacking. Nearly all children in this setting will acquire Giardia at some point in their childhood, and the prevalence of the parasite in young children can be as high as 10%-30%. In areas such as Western Europe and the United States of America, Giardia infection is associated with ingestion of contaminated water, person-to-person spread, recent foreign travel, and recreational swimming. Giardia may be a cause of 2%-5% of cases of diarrhoea in high-income countries.

TEST PRINCIPLE

Sensit Giardia Ag Rapid Test Kit is a lateral flow immunochromatographic assay based on sandwich format. The test cassette has a testing window. During testing, sample is applied into the sample well on the cassette. Giardia antigens, if present in the specimen, react with anti-Giardia antibodies coated colloidal gold particles in the test strip.The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with anti-Giardia antibodies on the membrane in the test line region. If the specimen contains Giardia antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain Giardia antigens, a colored line will not appear in the test line region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS & MATERIALS PROVIDED

1. Each test pouch contains :
   a. One test card
   b. Desiccant
   c. Dropper
   d. Assay diluent
2. Instruction Leaflet

PRECAUTIONS & WARNINGS

- Use within 10 minutes after opening pouch.
- Do not touch result window.
- Do not reuse test kit.
- Do not use test kit beyond expiry date.
- Use only for in-vitro diagnostic purpose.

STORAGE & STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION.

Collect sufficient quantity of feces (1-2mL or 1-2g) in a clean, dry specimen collection container to obtain enough pathogens. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2- 8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.

To process fecal specimens:

- **For Solid Specimens**: Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen atleast 5 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
- **For Liquid Specimens**:Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops of the liquid specimen (approximately 80 µL) into the specimen collection tube containing the extraction buffer. Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the collection tube for reaction for 2 minutes.

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 3 drops of the specimen to the Sample well “S”
3. Wait for 10 minutes and interpret the result. The result is considered invalid after 15 minutes.

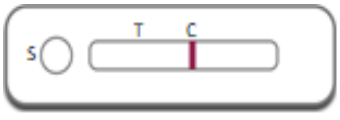
RESULT AND INTERPRETATIONS

Positive

A cleared colored band(C) and a detectable test band (T) appears,indicating a positive result.

Negative

A single-colored band appears only at the control region (C), indicating a negative result.



Invalid

No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Sensit Giardia Ag Rapid Test for the detection of Giardia in human feces are the most common signs appearing on medical devices and their packaging.

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

Manufactured by,

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