AG- GIARDIA Ag RAPID TEST KIT

INTENDED USE

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

PRINCIPLE

AstraGene's 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.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassette with Desiccant	10 Cassette	1 Cassette
Specimen collection tube with extraction buffer	10 No's	1 No's
Instruction for Use	1 No's	1 No's

Catalogue Number	10 tests	1 test
Cassette Model	AG/RTK/GDAAg/23/01	AG/RTK/GDAAg/23/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Specimen collection container.
- Personal protective equipment in accordance with local recommendations (i.e. lab coat, face mask, face shield/goggles and gloves)
- biohazard waste bin
- Pipette
- Clock or timer.

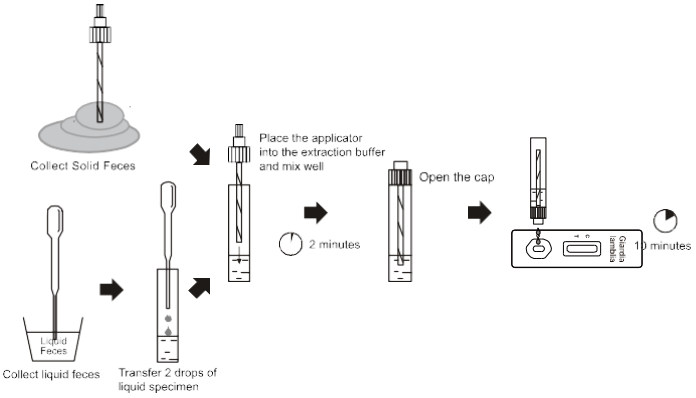
STORAGE &STABILITY

- 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.

SAMPLE COLLECTION & PROCEDURE

This kit in intended to use with human fecal specimens only. Antigen detection is improved by collecting the specimen at the onset of symptoms. It has been reported that the maxiumum collection of Giardia Lamblia in the feces of patients with gastroenteritis occurs 3-5 days after onset of symptoms. Allow the test cassette, specimen, buffer, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

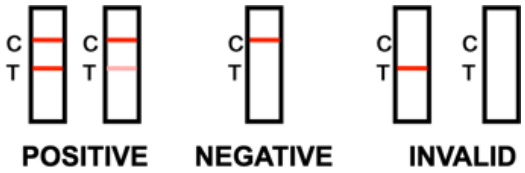
1. Collect sufficient quantity of feces (1-2mL or 1-2g) in a clean, dry specimen collection container to obtain enough pathogens. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. 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.
2. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
3. Hold the specimen collection tube upright and unscrew the tip of the specimen collection tube. Invert the specimen collection tube and transfer 3 full drops of the extracted specimen (approximately 80 uL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
4. Read the results at 10 minutes after dispensing the specimen. Do not read results after 20 minutes.
   Note: If the specimen does not migrate (presence of particles), centrifuge the diluted sample contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.



RESULT INTERPRETATIONS

Positive

A clear colored control band (C) and a detectable test band (T) appear, indicating a positive result.
Band T: Positive for Canine Parvovirus antigen



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.

LIMITATION OF THE PROCEDURE:

- This test is an acute-phase screening test. In the life history of giardia, there are two different stages of development: trophozoite and cysts. Generally speaking, cysts exists in formed faeces and trophozoite exists in watery feces with diarrhea.
- This kit is used for detecting of giardia at the trophozoite stage.
- All results should be combined with clinical information obtained.

WARNING & PRECAUTIONS:

- For in vitro diagnostic use only. Do not reuse. Do not use the pouch seal or its packaging is compromised.
- Do not use it after the expiration date shown on the pouch. Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay. Wash your hands thoroughly after finishing the tests.
- Do not eat, drink, or smoke in the area where the specimens or kits are being handled. Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of hazardous materials should follow local, national, or regional regulations. Keep out of children's reach

SYMBOLS

Do not use if package is damaged

LOT Batch Code

CE mark of Conformity

ISO 13485:2016 ISO

GMP

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