

Antigen Detection Kit GIARDIA

Cat. No. 80CFG105/80CFG150
INSTRUCTION MANUAL

I. Intended Use

ImmunoRun Giardia Antigen Detection Kit is intended for detection of *Giardia duodenalis* (syn. *lamblia*) antigen (Ag) in dog/cat feces. The kit contains all components required for performing an easy and accurate test in less than 10 minutes.

II. General Information

ImmunoRun Giardia Antigen Detection Kit contains individual devices intended for performing immuno-chromatographic assays to qualitatively detect Giardia-Ag in dog/cat feces. Each device contains 2 main windows: a round window, which is the specimen application well, and a rectangular result window, marked by 2 letters: "C" for Control line and "T" for Test line. Both lines are invisible before reaction takes place. The control purple line should appear with each ongoing reaction, as it is used for validation of the test. A specific antibody to Giardia is conjugated with gold particles and another specific antibody is immobilized as a band on a nitrocellulose membrane. Parasite in fecal specimen binds to the gold conjugated and forms a parasite-conjugate complex that migrates to the result area, where it is captured and its accumulation creates a band. A purple test line will be visible in the result window in case of enough Giardia-Ag in the specimen. The specially selected anti-Giardia antibodies are used in test band as both capture and detection materials. These enable Giardia-Ag device to identify Giardia in dog/cat feces with a high degree of accuracy.

III. Description Of The Disease

Giardia duodenalis is a protozoa that infects the small intestine of dogs and cats causing diarrhea. These protozoans are found in the intestines of many other animals, including humans. In the intestine, Giardia prevents proper absorption of nutrients, damages the delicate intestinal lining and interferes with digestion. Young dogs, especially housed in group, are more susceptible to clinical disease. Without treatment, giardiasis may continue, either chronically or intermittently, for weeks or months.

Giardia infections are transmitted via ingestion of trophozoites or cysts of the parasite in contaminated water or food. Transmissions also occurs by direct contact, especially with asymptomatic carriers. More recently, giardiasis has also been recognized as being able to be sexually transmitted.

IV. Diagnosis Of The Disease

Giardiasis is very difficult to diagnose because the protozoans are so small and are not passed with every stool. Finding cysts or trophozoites by microscopy is not sensitive enough. Apart of the smelly watery and foamy diarrhea, there are no specific signs, and there are asymptomatic carriers.

The ImmunoRun Giardia Antigen Detection Kit is the simplest screening diagnostic method available to detect the presence of Giardia. It has been validated to give 100% sensitivity and specificity.

V. Kit Contents

Component	5 Tests Kit (80CFG105)	50 Tests Kit (80CFG150)
Giardia Ag test device	5	50
Disposable droppers	5	50
Sample collection tubes with assay diluent	5	50
Collection swabs	5	50
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VI. Storage And Handling

- Shipment may be performed at room temperature.
- Store at 2-30°C (room temperature or refrigerated). Avoid exposure to direct sunlight.
- Kit is stable for up to two years, do not use beyond expiration date stated on the package label.
- **Do not freeze!**
- Do not open or remove test kit from their individually sealed pouches until immediately before their use (do not use kit if the pouch or the device are damaged).
- Avoid touching exposed membrane in device windows.
- Components in this kit have been quality control approved as standard batch unit. Each component in the kit is for a single use only. Do not mix components from different lot numbers, and do not try to reuse a device.
- Handle and dispose of used samples, swabs, extraction buffer and used device in accordance with accepted sanitary requirements designated for biohazardous waste.

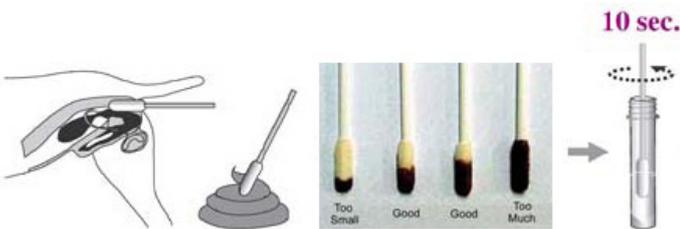
VII. Step By Step Protocol

For best results, strict adherence to these instructions is required (see Figures 1 and 2):

Sample Preparation:

1. Collect sample from canine/feline feces using a swab or insert swab into rectum to cover it with a thin layer of feces.
2. The specimen should be extracted immediately after collection.
3. Insert the swab into the assay diluent and agitate vigorously (~10") to assure good sample extraction.
4. This kit is designated for dog/cat feces exam.
5. For best results sample should be tested immediately after its extraction.

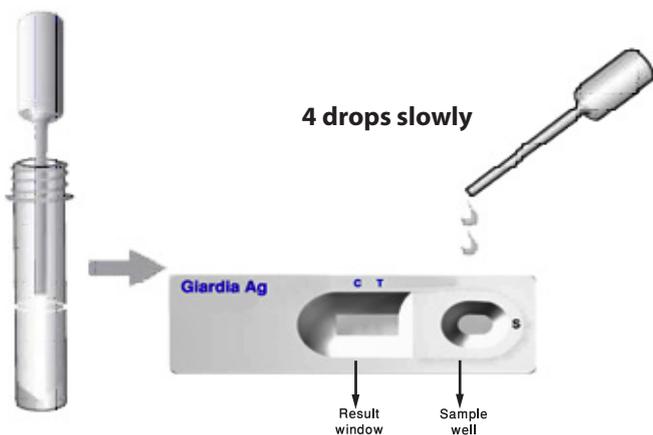
Figure 1: Use of swab with feces



Test Protocol:

1. If stored in refrigeration, allow all kit components and specimen to reach room temperature prior to testing.
2. Remove the test cassette from its pouch and place it horizontally.
3. Using the disposable dropper, slowly apply four drops of the diluted/extracted specimen from the tube into the sample well, (drop by drop). Avoid touching membrane with the dropper.

Figure 2: Application of extracted specimen with dropper.

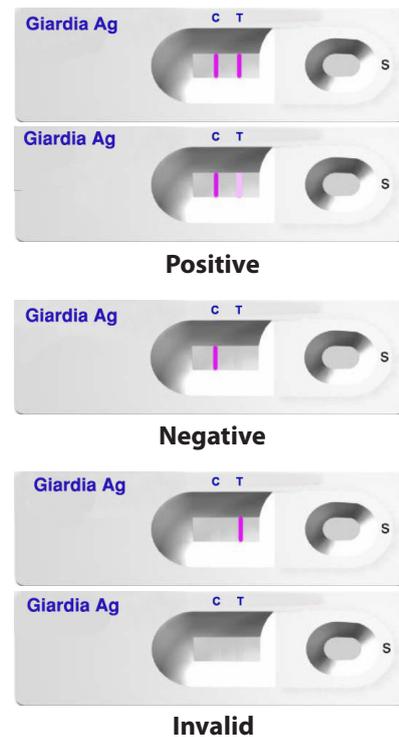


4. If migration through result window (purple color) does not start within a minute, apply another drop of diluent.
5. Follow the control line ("C") as it appears in the result window. In case of a positive result, a test line ("T") should appear as well. Results should be read within **5-10 minutes** from sample application. Clear positive result may be accepted earlier. Interpretation should not be based on reading accepted beyond 20 minutes.

VIII. Reading And Interpreting The Results

- See Figure 3.
- The presence of any two visible bands: the test band (T) and the control band (C) within the result window (no matter which band appears first) indicates a **positive** result, regardless of test band intensity.
- A lack of a test band, while control band is present within the result window, indicates a **negative** result.
- If the control band is not visible within the result window, the result is considered **invalid** (even if the test band appears).

Figure 3: Giardia Ag bands interpretation



IX. Limitations And Troubleshooting

- For veterinary *in vitro* use only. Do not use internally or externally in humans or animals.
- As with all diagnostic tests, a low incidence of false results can occur. All results must be considered with other laboratory findings and clinical information available to the veterinarian.
- In case of a negative result, it is recommended to perform subsequent tests for every stool obtained within 48-72 hours.

X. References

- Barr Sc (2006) Giardiasis. In: Infectious Diseases of the dog and cat. Greene CE, Saunders 3rd Ed.:736-742.

For further information and assistance please contact your local distributor or Biogal Galed Labs. Directly by e-mail: info@biogal.co.il or by tel: 972-4-9898605 / fax: 972-4-9898690.



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