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Rapid-VIDITEST

Giardia Card Cat VID-ODZ-016

One Step Giardia Card test.

Instruction manual CE IVD

INTENDED USE:

The Rapid-VIDITEST *Giardia* Card is a one step coloured chromatographic immunoassay for the qualitative detection of *Giardia* in stool samples.

INTRODUCTION:

Giardiasis is a diarrheal illness caused by a very small parasite, *Giardia intestinalis* (also known as *Giardia lamblia or Giardia duodenalis*). Once an animal or person is infected with *Giardia*, the parasite lives in the intestine and is passed in the stool. The parasite is protected by an outer shell (cyst) and can survive outside the body and in the environment for a long time.
Giardia infection has become one of the most common causes of waterborne disease in humans. The most common symptoms of giardiasis include: diarrhea, loose or watery stool, stomach cramps and upset stomach. These symptoms generally begin 1-2 weeks after infection, and may last 2-6 weeks in healthy individuals. Sometimes symptoms last longer, and may lead to weight loss and dehydration. Some people will have no symptoms. However, people with weakened immune systems (e.g., persons with HIV/AIDS, cancer patients, and transplant patients) or the elderly may have a more serious infection that can lead to severe illness or death.

PRINCIPLE:

The Rapid-VIDITEST *Giardia* Card is a qualitative immunochromatographic assay for the determinativ of *Giardia* in stool samples. The membrane is pre-coated with antibodies, on the test band region, against *Giardia* antigens.
During testing, the sample is allowed to react with the coloured conjugate (anti-*Giardia* antibodies-red microspheres) which was pre-dried on the test. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. The mixture continues to move across the membrane to the immobilized antibody placed in the control band region, a GREEN coloured band always appears. The presence of this GREEN band serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.

MATERALS PROVIDED:

- Rapid-VIDITEST *Giardia* Card tests
- Instructions for use
- Stool collection tubes with sample diluent

MATERIALS REQUIRED BUT NO PROVIDED:

- Specimen collection container
- Disposable gloves
- Timer

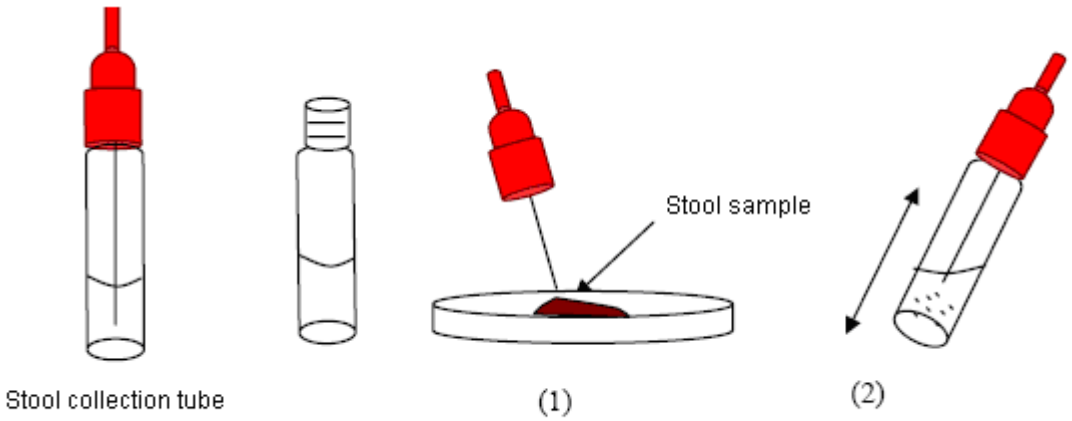
SPECIMEN COLLECTION AND PREPARATION:

Stool samples should be collected in clean containers and the assay should be done right after collection. The samples can be stored in the refrigerator (2-4 ºC) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at –20ºC. In this case, the sample will be totally thawed, and brought to room temperature before testing.

PROCEDURES:

To process the collected stool samples:

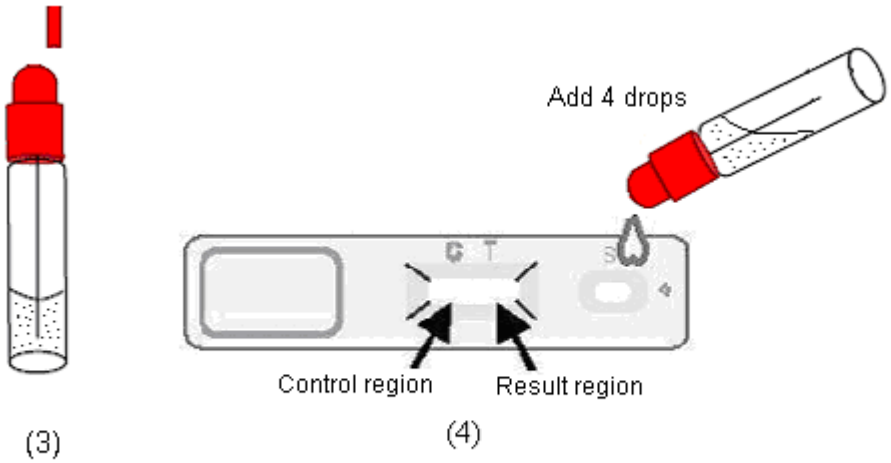
Use a separate vial for each sample.
(1) Unscrew the tap and use the stick to pick up a little sample (approx. 150mg), if the stool sample was liquid take approx. 150 µL using a pipette, and add the sample into the stool collection tube.
(2) Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion.



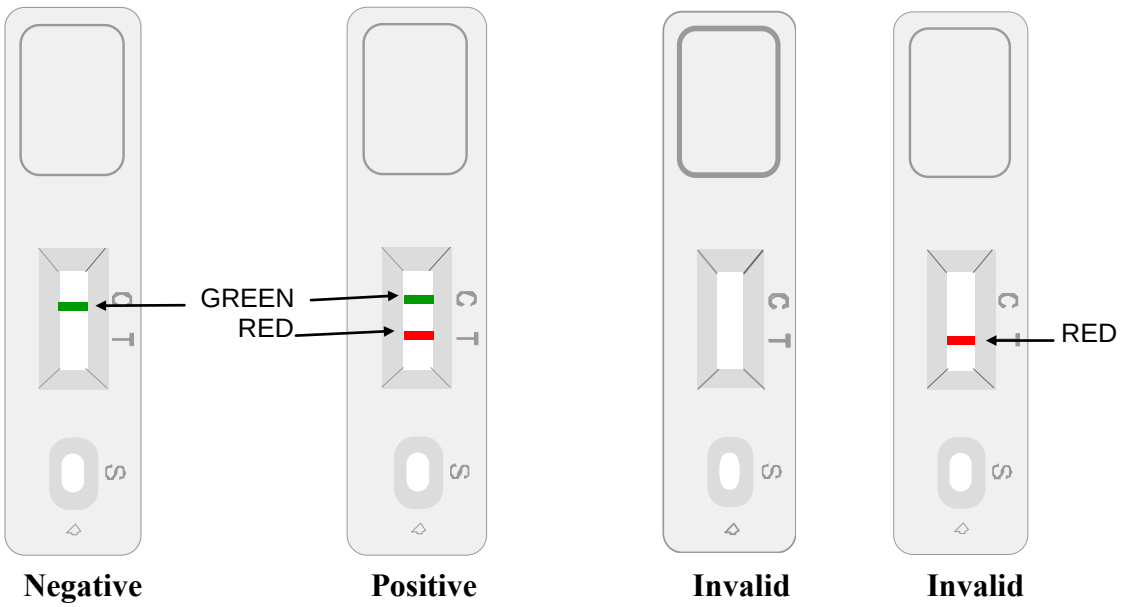
Test Procedure:

Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the pouch until ready to perform the assay.

1. Proceed to shake the stool collection tube in order to assure good sample dispersion. Cut the end of the top (3).
2. Remove the Rapid-VIDITEST *Giardia* Card device from its sealed bag just before using.
3. Use a separate stool collection tube and device for each sample or control. Dispense exactly 4 drops into the circular window marked with an arrow, avoiding to add solid particles with the liquid (4).
4. Read the result at **10 minutes** (the coloured bands appear).



INTERPRETATION OF RESULTS:



NEGATIVE: Only one GREEN band appears across the central window in the site marked with the letter C (control line).

POSITIVE: In addition to the GREEN control band, a distinguishable RED band also appeal in the site marked with the letter T (result line).

INVALID: A total absence of the control coloured band (GREEN) regardless of the appearance or not of the result line (RED). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the tests with a new test. If the problem persists, discontinue using the test kit and contact you local distributor.

NOTES ON THE INTERPRETATION OF RESULTS:

The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigen present in the specimen. However, neither the quantitative value, nor the rate of increase in antigen can be determined by this qualitative test.

QUALITY CONTROL:

Internal procedural controls are included in the test. A green line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS:

1. The test must be carried out within 2 hours of opening the sealed bag.
2. Only fresh or fresh-frozen unpreserved and unfixed stool samples can be tested.
3. An excess of stool sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
4. After one week of infection, the number of parasites in feces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
5. This test provides a presumptive diagnosis for Giardiasis. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS:

Sensitivity and specificity

It was studied 77 stool samples, *Giardia* positive and negative evaluated by microscopy, from patients in a local Hospital in Spain. The result showed >99% of sensitivity and >99% specificity for Rapid-VIDITEST *Giardia* Card.

Cross-reactivity

It was performed an evaluation to determine the cross reactivity of Rapid-VIDITEST *Giardia* Card test. There is not cross reactivity with other intestinal parasites:

- *Cryptosporidium parvum*
- *Entamoeba hystolitica*

STORAGE AND STABILITY:

Store as packaged in the sealed pouch at 2-30ºC. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The tests should be discarded in a proper biohazard container after testing.

REFERENCES:

1. MARSHALL, M.M., et al., "Waterborne Protozoan Pathogens", *Clinical Microbiology Review*, Jan. 1997, pp 67-85
2. DYLAN R. PILLAI and KEVIN C, KAIN, "Immunochromatographic Strip-Based Detection of *Entamoeba histolytica-E. dispar* and *Giardia lamblia* Coproantigen". *Journal of Clinical Microbiology*, Sept. 1999, Vol. 37, No 9, p. 3017-3019.
3. LYNNE S. GARCIA et al., "Commercial Assay for Detection of *Giardia lamblia* and *Cryptosporidium parvum* Antigens in Human Fecal Specimens by Rapid Solid-Phase Qualitative Immunochromatography", *Journal of Clinical Microbiology*, Jan. 2003, Vol. 41, No. 1, p. 209-212.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS:

IVD	*In vitro* diagnostic device	LOT	Batch code
	Use by		Manufacturer