Li StarFish S.r.l.
Via Cavour, 35 - 20063 Cernusco S/N (MI), Italy
Tel. +39-02-92150794 - Fax. +39-02-92157285
info@listarfish.it -www.listarfish.it

Rapid-VIDITEST

Cryptosporidium Card

IVD

One Step Cryptosporidium Antigen Test device

Instruction manual

Producer: VIDIA spol. s r.o., Nad Safinou II 365, Vestec, 252 42 Jesenice, Czech Republic,
Tel.: +420 261 090 565, www.vidia.cz

INTENDED USE:

The Rapid-VIDITEST *Cryptosporidium* Card is a rapid chromatographic immunoassay for the qualitative detection of *Cryptosporidium parvum* antigens in human faeces specimens to aid in the diagnosis of *cryptosporidiosis*.

INTRODUCTION:

Cryptosporidiosis is a diarrhoeal disease caused by microscopic parasites of the genus *Cryptosporidium*. Once an animal or person is infected, the parasite lives in the intestine and passes in the stool. The parasite is protected by an outer shell that allows it to survive outside the body for long periods of time and makes it very resistant to chlorine-based disinfectants. Both the disease and the parasite are commonly known as "Crypto."

PRINCIPLE:

The Rapid-VIDITEST *Cryptosporidium* Card is a qualitative lateral flow immunoassay for the detection of *Cryptosporidium* antigen in human faeces samples. The membrane is pre-coated with antibodies against *Cryptosporidium* antigens in the test line region. During testing, the sample reacts with a particle coated with anti-*Cryptosporidium* antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane capture the coloured conjugate and generate a red coloured line. A green coloured band always appears in the control region (second line) and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

MATERALS PROVIDED:

- Rapid-VIDITEST *Cryptosporidium* test devices
- Instructions for use
- Specimen collection vial with buffer

MATERIALS REQUIRED BUT NOT PROVIDED:

- Specimen collection container
- Disposable gloves
- Timer

SPECIMEN COLLECTION AND PREPARATION:

Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in a refrigerator (2-4ºC/36-40ºF) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at –20ºC/4ºF. In this case, the sample will be totally thawed and brought to room temperature before testing.

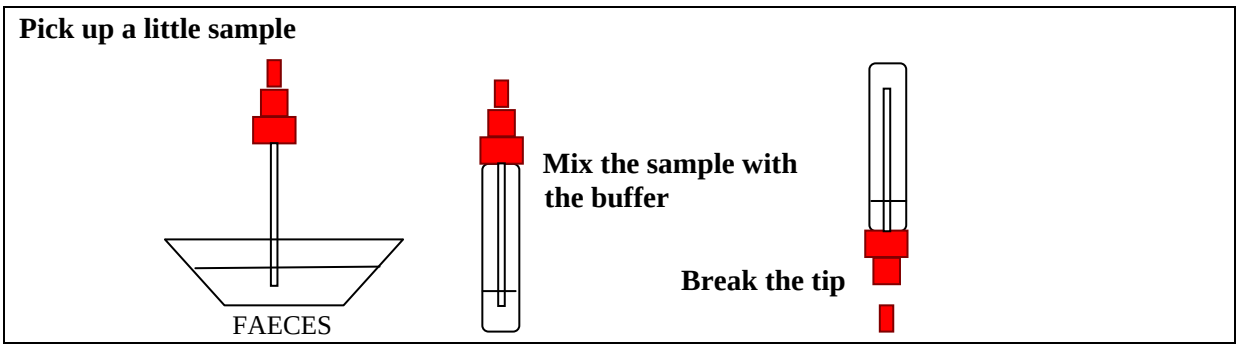
Make sure that specimens are not treated with solutions containing formaldehyde or its derivatives.

PROCEDURES:

To process the collected stool samples (see illustration 1):

Use a separate specimen collection vial with 1 mL of buffer for each sample. Unscrew the cap of the vial and introduce the stick two times into the faecal specimen to pick up a small sample (150 mg). Close the vial with the buffer and the stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add 150 µL into the specimen collection vial with buffer.

Illustration 1

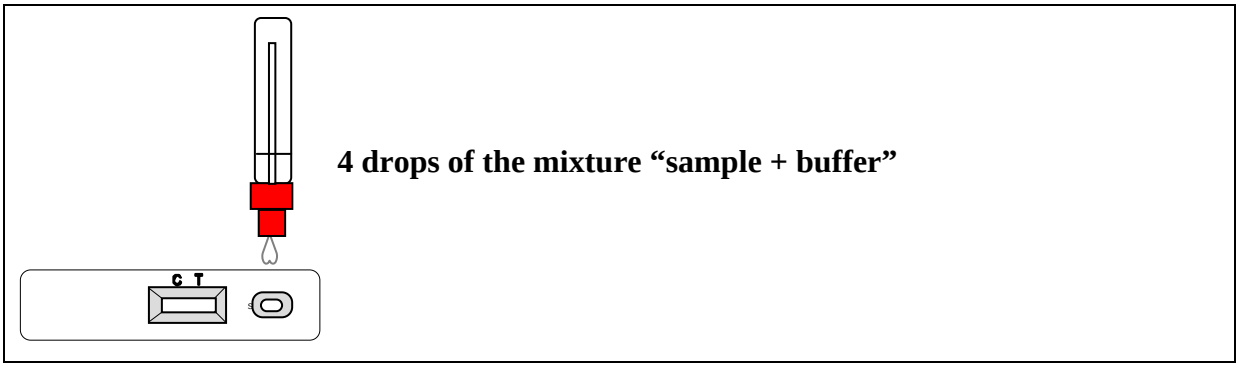


Test Procedure (see illustration 2)

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

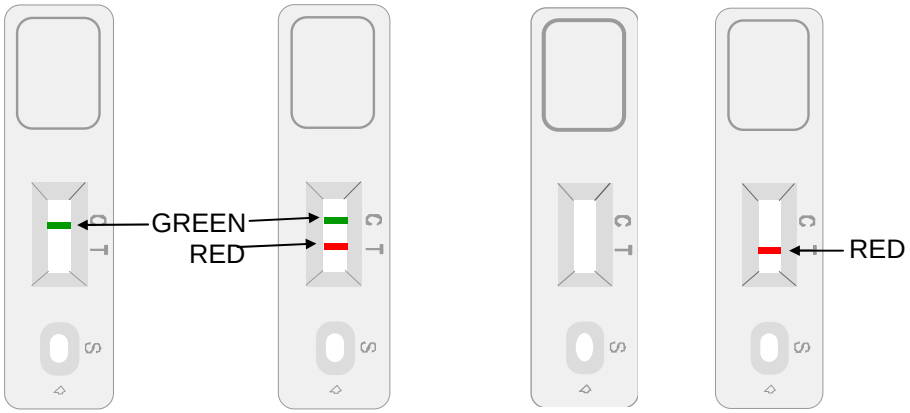
1. Remove the Crypto Device from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the tip of the vial.
3. Use a separate device for each sample. Dispense exactly 4 drops or 100 µL into the specimen well (S). Start the timer.
4. Read the result at 10 minutes after dispensing the sample.

Illustration 2



INTERPRETATION OF RESULTS:

Illustration 3



POSITIVE: Two lines appears across the central window in the result line region (**red** test line marked with the letter T) and in the control line region (**green** control line marked with the letter C). See illustration 3.

NEGATIVE: Only one **green** band appears across the control line region marked with the letter C (control line). See illustration 3.

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

NOTES TO THE INTERPRETATION OF RESULTS:

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

QUALITY CONTROL:

Internal procedural controls are included in the test:

- A line appearing in the control line region. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS:

1. *Crypto* device will only indicate the presence of parasites in the specimen (qualitative detection) and only should be used for the detection of *Cryptosporidium* antigens in faeces specimens. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Do not use specimens treated with solutions containing formaldehyde or its derivatives.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of cryptosporidiosis.
5. After one week of infection, the number of parasites in faeces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
6. This test provides a presumptive diagnosis of cryptosporidiosis. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES:

Cryptosporidium has caused several large waterborne disease outbreaks of gastrointestinal illness, with symptoms that include diarrhea, nausea, and/or stomach cramps. People with severely weakened immune systems (that is, severely immunocompromised) are likely to have more severe and more persistent symptoms than healthy individuals.

PERFORMANCE CHARACTERISTICS:

Sensitivity and specificity

It was studied some stool samples (determined by microscopy techniques) from patients in a local Hospital in Spain. The result showed using *Crypto* Card:

- >99% of sensitivity and
- >99% of specificity

The samples were confirmed with microscopy technique.

Cross-reactivity

The evaluation was performed to determine the cross reactivity of Rapid-VIDITEST *Cryptosporidium* Card. There is no cross reactivity with common gastrointestinal parasites occasionally present in faeces.

- *Entamoeba hystolitica*
- *Giardia lamblia*

STORAGE AND STABILITY:

Different Rapid-VIDITEST *Cryptosporidium* Card lots were exposed to 18 cycles of chnage of temperature and humidity (from +2ºC to +40º C/90% RH) into a climatic room for 4 days. After that, the devices are used to determine the influence of ageing on the sensibility against *Cryptosporidium* antigen reference standard preparation.
Rapid-VIDITEST *Cryptosporidium* Card maintains its properties even to stand extreme temperature conditions.
As most of materials and reagents are the same or very similar we can conclude that the device will be stable 24 months.
Freezing or storage in the refrigerator does not affect the performance of Rapid-VIDITEST *Cryptosporidium* Card. However the sample dilution buffer should not be frozen and should be kept at +2ºC-8ºC or at room temperature. The limits are between +2 to +30ºC.

PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

REFERENCES:

- Hill DR, Nash TE. Intestinal Flagellate and Ciliate Infections. In: Guerrant RL, Walker DH, Weller PF, eds. Tropical Infectious Diseases. Principles, Pathogens & Practice. 2nd ed. Elsevier, Philadelphia. 2006:984-8.
- Copue S, Delabre K, Pouillot R et al. Detection of Cryptosporidium, Giardia and Enterocytozoon bieneusi in surface water, including recreational areas: a one year prospective study: FEMS Immunol Med Microbiol. 2006; 47:351-9.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS:

	Manufacturer		For i*n vitro* diagnostic use only
	Lot Number		Use by

Last Revision: 08/2012