Atlas Medical

CE

***Crypto* Device**

One Step Cryptosporidium Antigen Test Device

A rapid, One step test for the qualitative detection of *Cryptosporidium* antigens in human faeces.

IVD *For In-Vitro diagnostic and professional use only*

2 – 30°C Store at (2-30º C)

INTENDED USE

The Crypto Device test is a rapid chromatographic immunoassay for the qualitative detection of Cryptosporidium parvum antigens in human faeces specimens to aid in the diagnosis of cryptosporidiosis

SYNTHESIS

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 Crypto Device 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 on the test line region. During testing, the sample reacts with the 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 will react with the mixture conjugates and generate one or two coloured lines. A green coloured band always appears in the control line (third line) and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

PRECAUTION

- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pack until use.
- Do not use the test if pack 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.

STORAGE AND STABILITY

Store as packaged in the sealed pack either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pack. The test must remain in the sealed pack until use. Do not freeze.

MATERIALS PROVIDED

- Devices
- Instructions for use
- Stool Collection vial with buffer

MATERIAL 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 the 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.

PROCEDURE

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

Use a separate specimen collection vial for each sample with 1 ml of the buffer. Unscrew the cap of the vial and introduce the stick two times into the faecal specimen to pick up a little of sample (150 mg) . Close the vial with the buffer and 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.

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 pouches 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 1

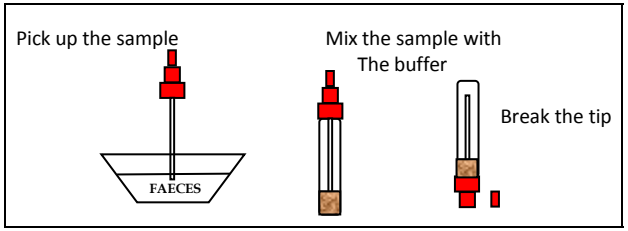
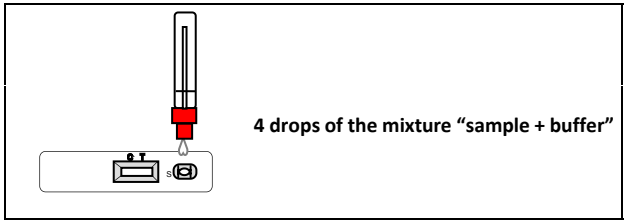
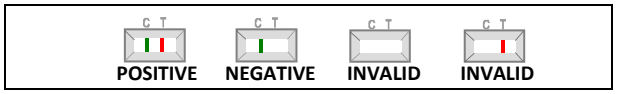


Illustration 2



INTERPRETATION OF RESULT

Illustration 3



POSITIVE: Two lines appear across the central window. In the result line region, a **red** test line marked in the illustration 3 with the letter T, and in the control line region, a **green** control line marked in the illustration 3 with the letter C.

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

INVALID: A total absence of the green control coloured band regardless the appearance or not of the red test line. See illustration 3. 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 your 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 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 green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATION

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 GHARACTERISTICS

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* Device:

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

The samples were confirmed with microscopy technique.

CROSS-REACTIVITY

It was performed an evaluation to determine the cross reactivity of *Crypto* Device. There is not cross reactivity with common gastrointestinal parasites occasionally present in feces.

- *Entamoeba hystolitica*
- *Giardia lamblia*

REFERENCE

1. 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.

2. 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.

ATLASMEDICAL
William James House,
Cowley Road,Cambridge,CB40WX,UK
Tel:+44(0)1223858910
Fax:+44(0)1223858524

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REF	**Product Reference No.**	IVD	**For in-vitro diagnostic use.**
	Caution.		**Store at 2 - 30°C.**
	Read product insert before use.	Σ	**Number of tests in the pack.**
LOT	**Lot (batch) number.**		**Manufacturer.**
	Expiry date.		**Manufacturer telephone number.**
	Manufacturer fax number.		