CRYPTO- DIPSTICK

For *In Vitro* Diagnostic use only

In vitro immunochromatographic test for qualitative detection of Cryptosporidium 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." **The test is specific for the protozoo Cryptosporidium parvum.**

PRINCIPLE

The Crypto Dipstick is a qualitative 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 were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of any positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate one coloured lines. A green coloured band always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents

REAGENTS AND MATERIALS

1. Crypto-Dipstick (25 item) These strips come in a bottle with a desiccant.
2. Dilution Buffer (1 bottles from 25 mL**)** is a mix biological buffers, salts, detergents and proteins. Also contains NaN_3 as preservative at a concentration less than 0.1%
3. Instruction for use (1 item)

MATERIALS REQUIRED BUT NO PROVIDED

Specimen collection container; Disposable gloves; Timer; Testing tube/vial; Dropper

PRECAUTIONS

- 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.

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.
Use a separate swab or stick, dropper and testing tube or vial for each sample. Dispense exactly 0.5-0.75 mL(10-15 drops) of the buffer into a testing tube/specimen collection tube. Introduce the swab or stick two times into the faecal specimen to pick up a little sample (150 mg) and put into testing tube or vial with buffer. Shake the testing tube or 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 testing tube or vial with buffer.

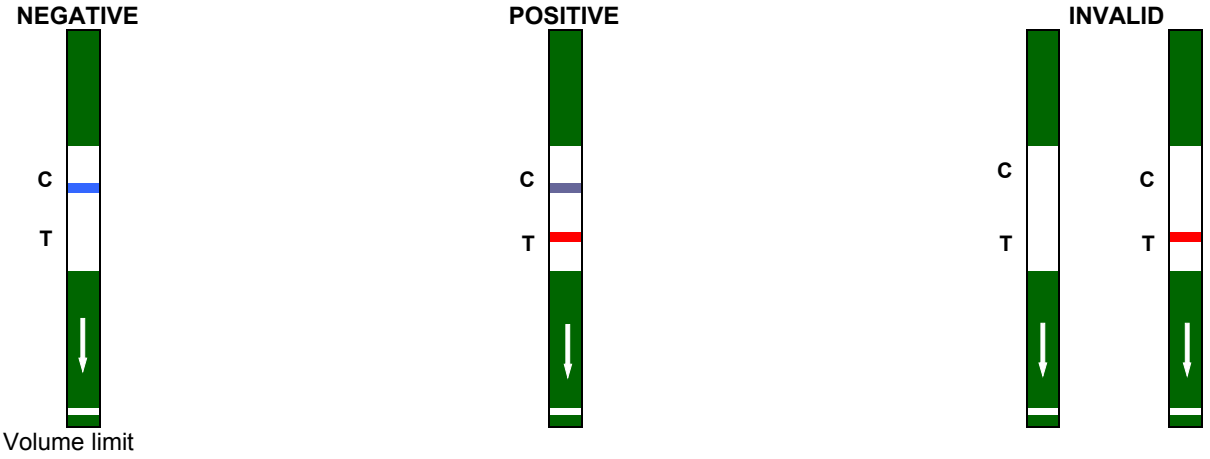
TEST PROCEDURE

Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the pack with strips until ready to perform the assay.
1. Use Crypto Strip as soon as possible when opening the pack.
2. Extract some liquid from the topside with a dropper and dispense 150 µL into a testing tube.
3. Use a separate test strip for each sample. Leave the test strip to stand vertically taking care of not surpassing the limit of immersion indicated with the arrows. Start the timer.
4. Read the result at 10 minutes after dispensing the sample

INTERPRETATION OF RESULTS

The results must be interpreted in the following way:
Positive: two colored bands appear. One in the control region violet /blue (C) and one in the test region pink red (T).
Negative: only one violet /blue colored band appears in the control region (C). No apparent faint pink to red colored band in the test region (T).
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.

ILLUSTRATION



Volume limit

NOTES ON THE INTERPRETATION OF RESULTS

The intensity of the red and blue coloured bands 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 the qualitative test

CHARACTERISTICS

Sensitivity e Specificity

Some faecal champions have been studied by means of microscopic examination and with Crypto Dipstick showing:
Results Cryptosporidium: Sensitivity >99% Specificity >99%

		Microscopy Technique		
		+	-	Total
Crypto Dipstick	+	4	0	4
	-	0	41	41
	Total	4	41	45

Sensitivity	Specificity
> 99%	> 99%

PPV	NPV
> 99%	> 98%

Cross-reactivity

It was performed an evaluation to determine the cross reactivity of Crypto Dipstick. There is not cross reactivity with common gastrointestinal parasites occasionally present in feces like :
Rotavirus, Adenovirus (A-F gruppi), Acinetobacter lwoffi, Campylobacter jejuni, Giardia lamblia, Aeromonas hydrophila, E. coli O157:H7, Salmonella thyphimurium, Salmonella enteritidis, Enterobacter cloacae, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus mirabilis, Serratia marescens, Shigella flexneri, Stenotrophomonas maltophilia, yersinia enterocolitica.

LIMITATIONS

- Crypto Dipstick will only indicate the presence of parasites in the specimen (qualitative detection) and should be used for the detection of Cryptosporidium and Giardia antigens in faeces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
- An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
- Do not use specimens treated with solutions containing formaldehyde or its derivatives.
- 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 or giardiasis.
- 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.
- This test provides a presumptive diagnosis of cryptosporidiosis and/or giardiasis. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

BIBLIOGRAPHY

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.
3. Stuart JM, Orr HJ, Warburton FG, et al. Risk Factors for Sporadic Giardiasis: A Case-Control Study in Southwestern England. Emerg. Infect Dis. 2003; 9, 2

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (25 tests) **COD. VC1005**

Dipstick	25 devices
Buffer	1 x 25 mL
Instruction for use	1 item

EDMA Code 15 70 01 90

CE IVD

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