CoproStrip™ *Crypto*sporidium

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

Instruction Manual

Test kit for 20 determinations
(Catalog No.41218)

For professional in vitro diagnostic use only
Store at 2-30°C. **Do Not Freeze**

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Intended Use: The CoproStrip™ *Cryptosporidium* is a rapid chromatographic immunoassay for the qualitative detection of *Cryptosporidium parvum* antigens in human faeces specimens to aid in the diagnosis of *cryptosporidiosis*.

SUMMARY AND EXPLANATION:

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 OF THE PROCEDURE

The CoproStrip™ *Cryptosporidium* 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.

MATERIALS PROVIDED

- Devices
- Instructions for use
- Stool collection vial with buffer
- Positive control

MATERIALS NOT PROVIDED

- Specimen collection container
- Disposable gloves
- Timer

WARNING AND 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 HANDLING

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: about the size of a small pea). 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 uL 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 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 uL into the specimen well (S). Start the timer.
4. Read the results at **10 minutes** after dispensing the sample.

Illustration 1

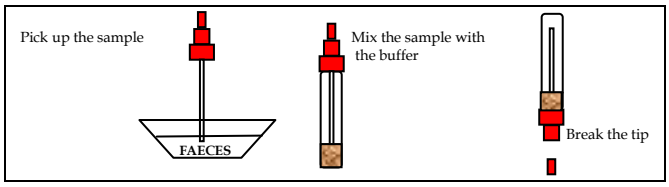
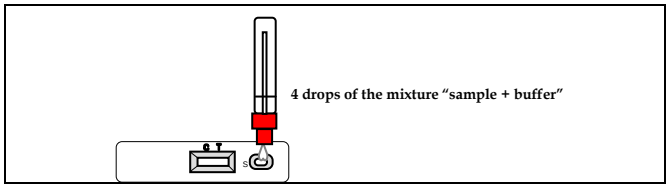
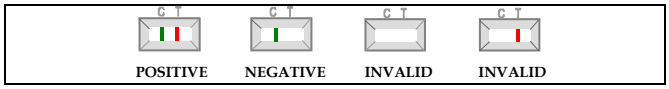


Illustration 2



INTERPRETATION OF RESULTS

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 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 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.
- External Quality Control-A Positive Control is included in the kit for the convenience of the user.

Procedure for External Quality Control Testing

1. Remove the positive control swab from its sealed bag just before use.
2. Unscrew the cap of the specimen collection vial and insert the positive control swab into the buffer.
3. Rotate the swab in the liquid for 10 seconds.
4. Pull out the swab carefully while squeezing it against the inner wall of the collection tube.
5. **Discard the swab**.

LIMITATIONS OF THE PROCEDURE

1. CoproStrip™ *Cryptosporidium* 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.

PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

An evaluation performed on stool samples (determined by microscopy techniques) from patients in a local Hospital in Spain using CoproStrip™ *Cryptosporidium* showed:

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

The samples were confirmed with microscopy technique.

CROSS-REACTIVITY

An evaluation was performed to determine the cross reactivity of CoproStrip™ *Cryptosporidium*. There is not cross reactivity with common gastrointestinal parasites occasionally present in feces.

- *Entamoeba hystolitica*
- *Giardia lamblia*

REFERENCES

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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.

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Symbols for IVD components and Reagents			
	Manufacturer	IVD	For i*n vitro* diagnostic use only
EC REP	Authorized representative		Consult instructions for use
	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by
DIL	Sample diluent		