Cryptosporidium Antigen Rapid Test Cassette (Feces)

Package Insert

REF ICR-602	English

A rapid test for the qualitative detection of Cryptosporidium Antigens in human feces.

For professional in vitro diagnostic use only.

【INTENDED USE】

The *Cryptosporidium* Antigen Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of *Cryptosporidium* Antigens in human feces.

【SUMMARY】

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 disease can spread through ingestion of contaminated water or through coughed fomites of an infected individual.[1,2] It can spread by fecal-oral route like other gastrointestinal pathogens.

【PRINCIPLE】

The *Cryptosporidium* Antigen Rapid Test Cassette is a qualitative lateral flow immunoassay for the detection of *Cryptosporidium* antigens in human feces. The membrane is pre-coated with monoclonal antibodies against *Cryptosporidium* antigens on the test line region. During testing, Cryptosporidium antigens, if present in the specimen, bind with anti-*Cryptosporidium* antibodies conjugated particles, which were 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 conjugate-antigen complex and generate a colored line in Test Line region(T). A red line always appears in the control line and serves as verification that sufficient volume was added and that proper flow was obtained and as an internal control for the reagents.

【REAGENTS】

The test contains anti-*Cryptosporidium* antibody conjugated particles and anti-*Cryptosporidium* antibodies coated on the membrane.

【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 used test should be discarded according to local regulations.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【MATERIALS】

Materials Provided

- Test cassettes
- Specimen collection tubes with extraction buffer
- Package insert
- Droppers

Materials Required But Not Provided

- A Specimen collection container
- Timer

【SPECIMEN COLLECTION AND PREPARATION】

Collect sufficient quantity of feces (1-2 g or 1-2mL). Fecal samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8ºC) for 7days 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.

【DIRECTIONS FOR USE】

1.To process fecal specimens:

- For **Solid Specimens**:
  Unscrew the cap of the specimen collection tube, then randomly **stab the specimen collection applicator into the fecal specimen at least 3 different sites** to collect approximately **50 mg of feces** (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
- For **Liquid Specimens**:
  Hold the dropper vertically, aspirate fecal specimens, and then transfer **2 drops of the liquid specimen (approximately 80 µL)** into the specimen collection tube containing the extraction buffer.

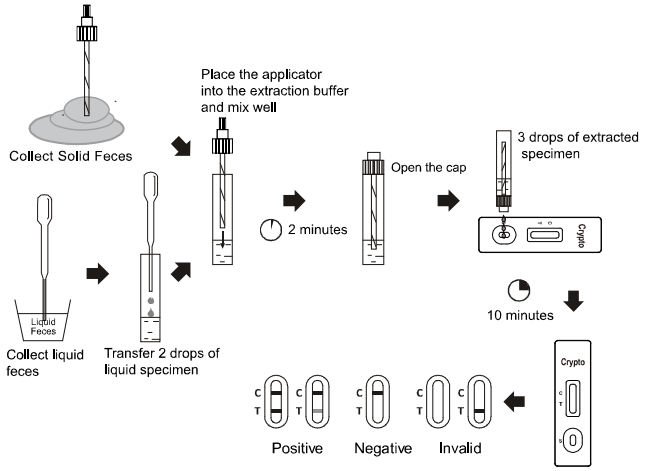
Tighten the cap onto the specimen collection tube, then **shake the specimen collection tube vigorously** to mix the specimen and the extraction buffer. Leave the collection tube for reaction for **2 minutes.**

2. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.

3. Hold the specimen collection tube upright and **unscrew the tip** of the specimen collection tube. Invert the specimen collection tube and **transfer 3 full drops of the extracted specimen (approximately 120 µL)** to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.

4. Read the results at **10 minutes**. Do not interpret the results after 20 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the diluted sample contained in the extraction buffer vial. Collect 120 µL of supernatant, dispense into the specimen well (S) of a new cassette. Start the timer and continue from step 4 onwards in the above instructions for use.



【INTERPRETATION OF RESULTS】

POSITIVE: Two lines appear. A red colored line appears in the Test line region (T) and another line appears in the C line region (C).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of antigens present in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

NEGATIVE: Only one line appears in control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques 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 immediately and contact your local distributor.

【QUALITY CONTROL】

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

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The *Cryptosporidium* Antigen Rapid Test Cassette will only indicate the presence of *Cryptosporidium* in the specimen (qualitative detection) and only should be used for the detection of *Cryptosporidium* antigens in feces 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. Dilute the sample with the buffer and repeat the test.

3. 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*.

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 of *cryptosporidiosis*. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

【EXPECTED VALUES】

The *Cryptosporidium* Antigen Rapid Test Cassette (Feces) has been compared with traditional thick or thin microscopic analysis. The correlation between the two systems is 97.5%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity - Specificity

Cryptosporidium Antigen Rapid Test Cassette (Feces) was evaluated on 285 clinical samples (determined by microscopy techniques) from patients in a Hospital.

Method		Microscopic techniques		Total Results
Cryptosporidium Antigen Rapid Test Cassette (Feces)	Results	Positive	Negative	
	Positive	21	6	27
	Negative	1	257	258
Total Results		22	263	285

Relative sensitivity: 95.5% (95%CI*:77.2%~99.9%); *Confidence Intervals
Relative specificity: 97.7% (95%CI*:95.1%~99.2%);
Accuracy: 97.5% (95%CI*: 95.0%~99.0%).

Repeatability and reproducibility

To check intra-batch accuracy (repeatability), the positive sample and negative sample were processed 3 times on kits of the same production batch in the same experimental conditions. All observed results were confirmed as expected.

To check inter-batch accuracy (reproducibility), same samples (positive and negative) were processed on kits from three different production batches. All results were confirmed as expected.

Cross-reactivity

Cross reactivity with following organisms has been studied at 1.0E+07 organisms/ml. The following organisms were found negative when tested with the *Cryptosporidium* Antigen Rapid Test Cassette (Feces):

H.pylori,	*Clostridium difficile*	*Salmonella Ifantis*
Shigella flexneri	*Shigella Sonnei*	*Shigella dysenteriae*
E.coli		

【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.

Index of Symbols

	Attention, see instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P. R. China
www.alltests.com.cn

EC REP
MedNet GmbH
Borkstrasse 10
48163 Muenster
Germany

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