Atlas Medical

***Cryptosporidium* Antigen Rapid Test Cassette**

IVD **For *in vitro* diagnostic and professional use**

2 30°C Store at 2-30 °C

INTENDED USE

Atlas Crypto test cassette is a manual rapid chromatographic immunoassay forthe qualitative detection of *Cryptosporidium* antigens in human stool specimens to aid in the diagnosis of *cryptosporidiosis*.

INTRODUCTION

Cryptosporidiosis is a diarrheal disease caused by microscopic parasites of the genus *Cryptosporidium*; this parasite is recognized as a highly infectious enteric pathogen, the infective stage is transmitted by the fecal-oral rout. Once an animal or personis infected, the parasite lives in the intestine and passes in the stool.

Symptoms of cryptosporidiosis include watery diarrhea, stomach cramps, weight loss, nausea and sometimes fever.

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

Atlas Crypto test cassette is a qualitative lateral flow immune-chromatographic assay for the detection of *Cryptosporidium* antigen in human stool specimens. The membrane is pre-coated with mouse monoclonal antibodies against *Cryptosporidium* antigens on the test line region (T) and with rabbit polyclonal antibody on the control line (C). During testing, *Cryptosporidium* Antigen in the sample react with the polystyrene latex particles coated to anti-*Cryptosporidium* antibodies and pre-dried on the label pad. The mixture moves upward on the membrane by capillary action and is captured by antibodies on the test line generating one **red** line. If the sample is negative, there are no *Cryptosporidium* antigens present or antigens may be present in a concentration lower than the detection limit value, and red line will not appear.

A **green** colored line 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.

KIT COMPONENTS

Materials Provided

- Atlas Crypto Antigen Rapid Test Cassette.
- Extraction tube containing buffer.
- Package Insert.

Material required but not provided

- Specimen collection container.
- Disposable gloves.
- Timer.

Packaging contents

REF **8.16.01.0.0020: 20 sealed pouch containing test cassette and desiccant, 20 extraction tube containing 1 ml of buffer.**

REAGENT STORAGE AND STABILITY

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

PRECAUTIONS

- For *in vitro* diagnostic and professional use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if the foil pouch is damaged or open.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, never smoke, drink, or eat in the area where assay is performed.
- Reagents contain preservatives. Avoid any contact with skin or mucous membrane. Consult safety data sheet, available on request.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- A new test must be used for each sample to avoid contamination errors.
- The tests should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed pouch.

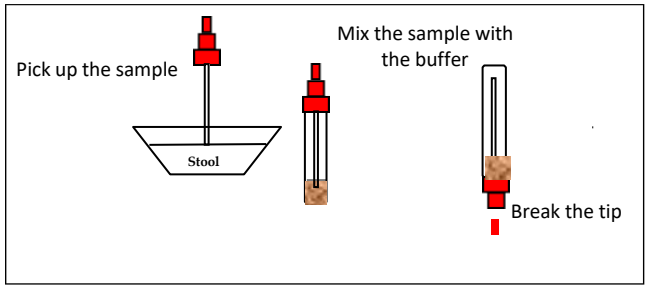
COLLECTION, PREPARATION AND HANDLING OF SPECIMEN

Specimen collection and storage

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

Specimen Preparation and handling (see the illustration below)

- Use a separate specimen collection tube for each specimen with 1 mL of the buffer.
- Unscrew the cap of the tube and introduce the stick four times into different parts of the fecal specimen to pick up the sample (approximately 125 mg or 125 µL for liquid sample).
- Close the tube with the buffer and stool sample. Shake the tube in order to assure good sample dispersion.

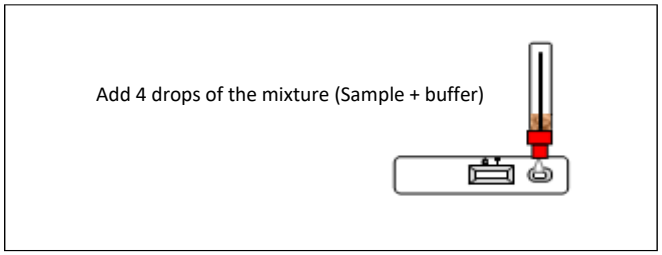


PROCEDURE (see illustration below)

Allow the tests, stool samples and buffer to equilibrate to room temperature (15-30˚C/59-86˚F) prior to testing. Do not open pouches until ready to perform the assay.

- Remove the Crypto test cassette from its sealed pouch and use it as soon as possible.
- Shake the specimen collection vial to assure good sample dispersion. Break off the tip of the tube.
- Dispense exactly 4 drops into the specimen well (S). Avoid adding solid particles with the liquid. Start the timer.
- Read the result at **10 minutes** after dispensing the sample. Do not read the result after **10 minutes.**

NOTE: If the test does not run due to solid particles, stir the sample added in the specimen well (S) with a stick. If it does not work, dispense a drop the diluent until seeing the liquid running through the reaction zone.



INTERPRETATION OF RESULT (see illustration below)

POSITIVE: Two lines appear across the central window. A **red** line marked with the letter (T) and a **green** control line marked with letter (C).

NEGATIVE: only one **green** line appears across the central window marked with letter (C).

INVALID: A total absence of the green control colored line regardless the appearance or not of the red test line.

NOTES:

- 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.
- The intensity of the red colored 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 ON THE TEST

- Crypto test cassette will only indicate the presence of parasites in the specimen (qualitative detection) and should only be used for the detection of *Cryptosporidium* antigens in stool specimens. 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.
- After one week of infection, the number of parasites in stool 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. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

Negative results are expected in healthy patients. This test is intended to be used for the diagnosis of cryptosporidiosis only.

PERFORMANCE GHARACTERISTICS

Sensitivity and specificity

An evaluation, with stool specimens, was performed using an ATLAS crypto test cassette, and these results were confirmed using a microscopy technique and PCR (positive results). The results were as follows:

	PCR Technique		
ATLAS Crypto test cassette	Positive	Negative	Total
Positive	25	0	25
Negative	0	229	229
Total	25	229	254

Sensitivity: >99%.
Specificity: >99%.
PPV: >99%.
NPV: >99%.

Cross reactivity

An evaluation was performed to determine the cross reactivity of ATLAS Crypto test cassette; no cross reactivity against gastrointestinal organism occasionally present in stool:

Campylobacter jejuni	*Helicobacter pylori*
Campylobacter coli	*Listeria monocytogenes*
Clostridium difficile	*Salmonella enteritidis*
Escherichia coli O157:H7	*Salmonella paratyphi*
Entamoeba hystolitica	*Salmonella typhi*
Giardia lamblia	*Salmonella typhimurium*
Shigella boydii	*Shigella flexneri*
Shigella dysenteriae	*Shigella sonnei*
Staphylococcus aureus	

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ATLAS Medical GmbH
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com
Website: www.atlas-medical.com

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry