



Cryptosporidium Antigen Rapid Test Cassette (Feces)

Package Insert

REF VICR-602

English

INTENDED USE

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

PRINCIPLE

The Cryptosporidium Antigen Rapid Test Cassette is a qualitative lateral flow immunoassay for the detection of cryptosporidium antigens in animal 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. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test 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.**

PRECAUTIONS

- Do not use after expiration date.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Humidity and temperature can adversely affect results.
- Do not remove test cassette from its pouch until immediately before use.
- Do not reuse the test kit.
- Do not mix components from different lot and different products.

MATERIALS

Materials Provided

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

Materials Required but Not Provided

- Timer
- Specimen collection containers

DIRECTIONS FOR USE

Allow the test cassette, specimen and buffer to equilibrate to room temperature (15-30 °C) prior to testing.

- Collect sufficient quantity of feces (1-2 g or 1-2mL) samples in clean and dry containers. The samples can be stored in the refrigerator (2-8°C) for 7 days prior to testing. For longer storage, the specimen must be kept frozen at -20°C.
- 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**

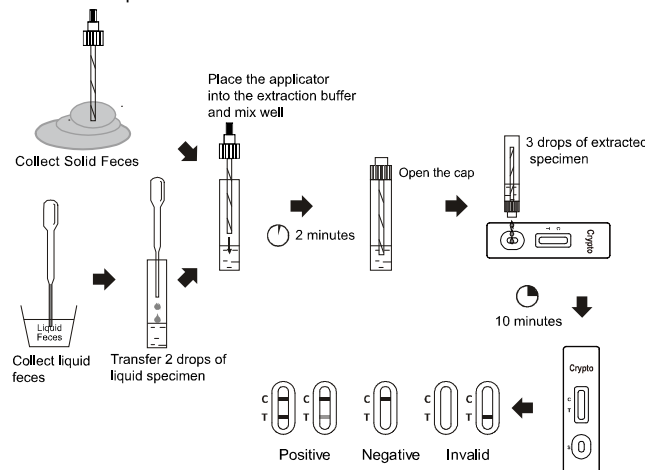
3 different sites to collect approximately **50 mg of feces** (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

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.
- 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.
- 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.
- 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). Start the timer and continue from step 6 onwards in the above instructions for use.



INTERPRETATION OF RESULTS

Positive: The presence of both C line and T line, regardless of T line being strong or faint.

Negative: Only clear C line appears.

Invalid: No colored line appears in C zone, regardless of T line's appearance.

ACCURACY

The Cryptosporidium Ag Test Cassette has been evaluated with specimens obtained from Veterinary hospital. Commercial Control Test is used as the reference method for the Cryptosporidium Ag Test. Specimens were considered positive if Commercial Control Test indicated a positive result.

Cryptosporidium Ag tests	Commercial Control Test		Total
	Positive	Negative	
Test Positive	37	1	38
Test Negative	2	37	39
Total	39	38	77

Relative Sensitivity: 94.87% (95%CI*: 82.68%-99.37%)

Relative Specificity: 97.37% (95%CI*: 86.19%-99.93%)

Accuracy: 96.10% (95%CI*: 89.03%-99.19%)

*Confidence Interval

CROSS REACTIVITY

The Cryptosporidium Antigen Rapid Test has been tested by Panleukopenia virus, Giardia, FIV and FeLV positive samples. The results showed no cross-reactivity.

LIMITATION

- An excess of sample could cause wrong results. Dilute the sample with the buffer and repeat the test.
- After one week of infection, the number of parasites in feces is decreasing, making the sample less reactive. Feces samples should be collected within one week of the onset of symptoms.
- This test is for diagnostic use only for animals. All results should be considered with other clinical information available from veterinarian. For confirming the results, confirmatory methods such as PCR are recommended.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	Manufacturer		Batch code		Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use



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