FLASHTEST

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Giardia/Cryptosporidium Antigen Rapid Test (GIA/CRY Ag)

Intended Use

Giardia/Cryptosporidium Antigen Rapid Test is a lateral flow immunoassay intended for the simultaneous qualitative detection of specific antigen from Giardia (GIA) and Cryptosporidium (CRY) in pet feces. The test is useful for simultaneous determination of GIA/CRY infection.

Reagent and Materials Provided

· Test devices · Swabs
· Buffer tubes · Workstation

Storage and Stability

The test device is sealed and should be stored away from light at a room temperature (4-30℃). Do not freeze.
The test device should be used before the expiration date marked on the package label.

Warnings, Precautions and Safety Information

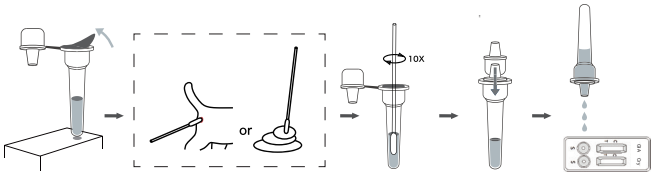
1. The test device is used for cat, dog, and calf only.
2. The results may be influenced by humidity and temperature.
3. Make sure that the foil pouch containing the test is not damaged before open. Perform the test immediately when the pouch package is opened.
4. Do not reuse the test components.
5. Do not use after the expiry date.
6. Do not mix product components in different lot numbers.
7. As all samples are potentially infectious. Operators should wear protective gloves while handling samples and wash hands thoroughly afterwards.
8. Decontaminate and dispose of all samples, used kits and potentially contaminated materials safely in accordance with national and local regulations.

Specimen Collection, Handling, and Transport

1.Feces sample should be used with this test.
2.The samples should be tested immediately after collection.
3.Samples should be stored at 2~8°C, if samples are not tested immediately. Please freeze the samples at －20°C or below for longer storage and avoid repeated freezing and thawing.
4.Samples containing precipitate may yield inconsistent test results. They must be clarified prior to assaying.
5.The amount of fecal swab may affect the results. Excessive fecal amount may induce a false positive result and slow migration. Cotton swabs are dipped directly into fresh feces or anal secretions, and the sample collection amount is 1/2 to 2/3 of the head of the swab.

Test Procedure

1.Check the product contents and make sure the test operation is under the room temperature (15–30 ℃) before testing.
2. Unseal the extraction tube containing the buffer.
3. Place the extraction tube in the workstation.
4. Use the swab to collect some fresh feces or fecal sample from patient's rectum. And then put the swab into the buffer.
5. Rotate the swab more than 10 times.
6. Close the cap of the buffer tube.
7. Take the test device out of the aluminum foil bag, and place it on a clean and flat table. Add three drops (about 90 μL) of specimen (mixed sample) vertically into the specimen well (S) of the test device.
8. Read the result at 5-10 minutes. The result is invalid after 15 minutes.



Result Interpretation

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 region, regardless of T line's appearance.

Limitations

Although the Giardia/Cryptosporidium Antigen Rapid Test is very accurate in simultaneously detecting Giardia and Cryptosporidium Antigen, a low incidence of false results may be occurred. Other clinically or laboratory tests might be required if questionable results are obtained. As other diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be diagnosed by the veterinarian after all clinical and laboratory findings have been evaluated.

Performance Characteristics

Method		PCR		Total
		Positive	Negative	
GIA Ag	Positive	69	2	71
	Negative	1	228	229
Total		70	230	300

Diagnostic Sensitivity of GIA Ag: 69/70=98.57%（95%CI*（92.30%-99.96%））
Diagnostic Specificity of GIA Ag: 228/230=99.13%（95%CI*（96.89%-99.97%））
Total Agreement of GIA Ag：297/300=99.00%（95%CI*（96.96%-99.80%））

Method		PCR		Total
		Positive	Negative	
Cry Ag	Positive	33	1	34
	Negative	2	57	59
Total		35	58	93

Diagnostic Sensitivity of Cry Ag: 33/34=97.06%（95%CI*（84.67%-99.93%））
Diagnostic Specificity of Cry Ag: 57/59=96.61%（95%CI*（88.29%-99.59%））
Total Agreement of Cry Ag: 90/93=96.77%（95%CI*（90.89%-99.33%））

LOT	batch code		use by
	manufacturer	Σ	contains sufficient for <n> tests
IVD	in vitro diagnotic medical device		temperature limitation
	do not reuse		consult instructions for use