

Crypto/Giardia Canine & Feline

Cryptosporidium parvum and Giardia duodenalis Ag Detection Kit

For in vitro veterinarian diagnostic use only

Cat.no – 80GCP205/80GCP250

Instructions for Use

Intended use

ImmunoRun Crypto/Giardia test Kit is intended for the detection of specific antigens of *Cryptosporidium parvum* and *Giardia duodenalis* in feces of dogs and cats.

Specifications

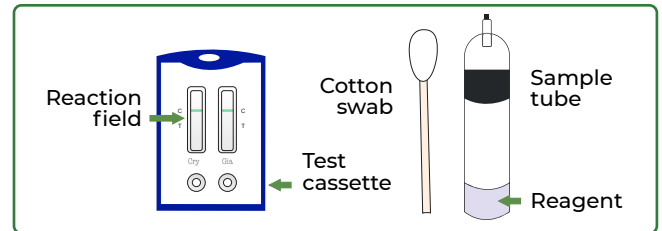
Samples	Fresh dog or cat feces		
Time to result	10 minutes		
Storage temp.	2-30°C		
Shelf life	24 months		
*	Sensitivity	Specificity	Accuracy
Crypto Ag	95.00%	97.50%	96.25%
Giardia Ag	91.89%	97.87%	95.24%

*According to internal comparison study 2016 / 2017.
ELISA (Enzyme - linked immunosorbent assay).

Components of the test kit

Components	5 Tests/kit 80GCP205	50 Tests/kit 80GCP205
Test Cassette	5	50
Cotton Swab	5	50
Sample tube	5	50

Components of the test kit



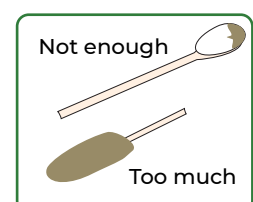
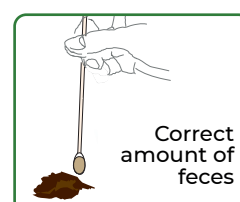
Note: In the reaction field, before starting the test, a green/blue line appears in the control line region. This is used for quality control and will be washed away by the sample liquid during the test.

Precautions

- Do not freeze the kit.
 - Do not open or remove the test cassette from its individually sealed pouch until it is to be used.
 - Do not use the test if the cassette pouch or the device is damaged.
 - Do not touch the exposed membrane in the device window.
 - Handle and dispose all contaminated materials in accordance with approved sanitary standards for biohazardous waste.
 - Components in this kit have been quality control approved as a standard batch unit. Do not mix components from different lot numbers.
 - Each component of the kit is intended for a single use only
- STORAGE:**
- Store at 2-30°C. Avoid exposure to direct sunlight.
 - The kit is stable for up to 24 months, do not use beyond expiration date.

Sample Preparation

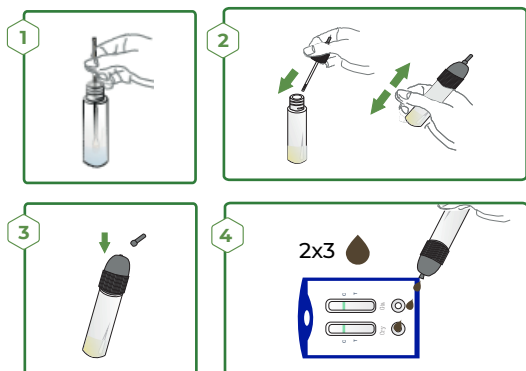
- Collect fresh fecal samples using the swab. Insert the tip of the swab into the sample and rotate to collect a thin film of feces. Repeat this sampling in at least **3 different locations** of the fecal sample. Alternatively, insert the swab through the rectal sphincter and gently rotate to recover visible fecal material.
- Make sure the cotton swab is evenly covered with feces.
- Do not collect an excessive amount of feces as this may lead to false results or test malfunction.



- Do not collect samples from cat litter or other coarse particles.
- For pooled fecal samples, stir well prior to testing.
- For postponed testing, samples can be stored up to **maximum 6 days at 2 to 8°C**.

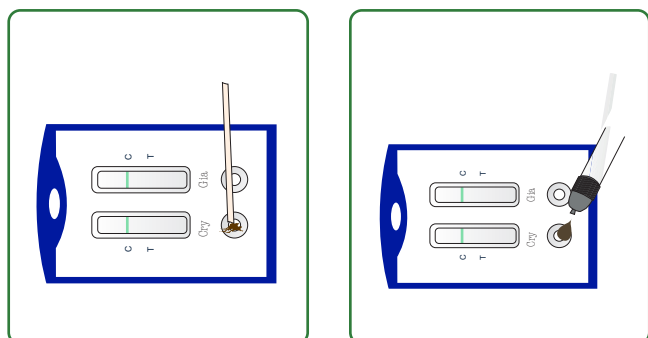
Test Instructions

- If stored in refrigeration, allow all kit components and specimen to reach room temperature prior to testing.
- Immediately insert the swab into the sample tube and stir vigorously (approximately 10 seconds) to assure good sample dissolution. Close the tube and shake briefly.
 - Remove the test cassette from its pouch and place it on a horizontal surface.
 - Use the test cassette **within 60 minutes** of opening the pouch.
- Break off the upper tip of the sample tube by pushing it firmly.
- Add 3 drops of the sample material to both sample wells.



Note: If the fluid does not begin to migrate through the test strip, use the cotton swab's upper tip to remove any solid material which may be interfering with the flow.

If still no migration occurs, apply another drop of liquid to the corresponding well.

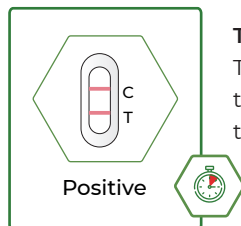


Note: Due to irregularity of the shedding of *Giardia*, at least **three** fecal examinations over a period of approximately **seven to ten days** should be carried out before *giardiasis* can be ruled out.

Test Results

The test results should be read after **10 minutes**.

Positive test result:



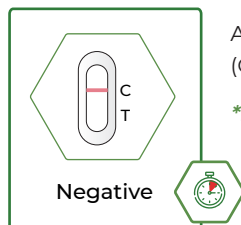
Two red bands will appear.

The upper control band (C) confirms that the test is working properly. The bottom test band (T) indicates a positive test result.

**A weak test line should also be considered a positive antigen test result.*

**A weak control line may occur when the applied sample is too concentrated, or as a result of certain components in the sample which interfere with the test run.*

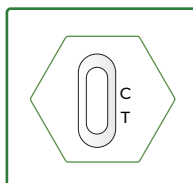
Negative test result:



A lack of a test band (T), while control band (C) is present.

***No antigen detected.**

Invalid test result:



If no control band (C) appears the test is considered invalid.

If the test line is colored brown by feces, this test is invalid and should be repeated.

Limitations & Troubleshooting

A low incidence of false results can occur.

All results must be considered together with additional clinical information available.

Symbols

Observe product information	For one-time use only Storage temperature	Protect against light
For professional use only	Number of Test/kit	Shelf life
Lot number	Protect from humidity	Manufacturer

Biogal Galed Labs.

YOUR
DIAGNOSTIC
COMPANION

www.biogal.com

For further information and assistance please contact your local distributor or Biogal Galed Labs. Acs. Ltd. directly by e-mail: info@biogal.com or by tel: 972-4-9898605