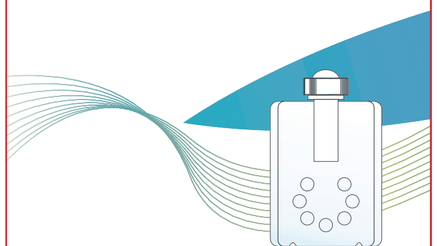
pluslife

Giardia lamblia/ Tritrichomonas foetus

Nucleic Acid Test Card

For veterinary use only



Product Name

Product Name: Giardia lamblia/Tritrichomonas foetus Nucleic Acid Test Card

Trade name: Pluslife G. lamblia/T. foetus Card

Intended Use

Giardia is a protozoan parasite that is distributed worldwide and infects a variety of mammals. Giardiasis in dogs and cats is an important zoonotic parasitic disease. Most dogs and cats infected with *Giardia* may not show clinical symptoms, and the clinical symptoms that do occur are mostly chronic diarrhea and weight loss. Currently, *Giardia* is classified into seven assemblages A-G based on molecular biological characteristics. Assemblages A and B are zoonotic, assemblages C and D mainly infect dogs, and assemblage F mainly infects cats. Survey results of *Giardia* assemblages in dogs and cats show that dogs are infected with assemblages C and D, while cats are mainly infected with assemblage F.

Tritrichomonas foetus is a single-celled organism, belonging to the order *Trichomonadida,* family *Trichomonadidae,* and genus *Tritrichomonas.* It is more common in cats and mainly parasitizes the terminal ileum and colon of cats. It is named for its three anterior flagella, which are its locomotive organs, helping it move within the host. It can invade the cat's ileum, cecum, and colon, causing enteritis. The typical clinical symptom of infection is chronic or intermittent diarrhea, with an average duration of diarrhea of 135 days, and the longest lasting up to 7.9 years. Other clinical symptoms include anorexia, depression, weight loss or no increase, and vomiting. The main mode of transmission is fecal-oral, and contaminated food and water sources can also spread Tritrichomonas foetus.

This test kit is used for the qualitative and rapid detection of *Giardia* and *Tritrichomonas foetus* DNA in anal swab samples from cats and dogs. The test results should be combined with the symptoms or signs, medical history, and other diagnostic information of dogs and cats for comprehensive analysis and interpretation, and should not be used as the sole basis for treatment or other pet management decisions.

Testing Principle

This kit is based on isothermal amplification and enzymatic cleavage probe technology,and conserved regions of *Giardia lamblia* and *Tritrichomonas foetus* are selected for specific primers and specific probes design. A large number of target sequence's copies were generated in the reaction system during the isothermal amplification. When the probe hybridizes to the complementary sequence, it is cleaved and fluorescence is emitted. Integrated Nucleic Acid Testing Device detects and analyzes fluorescence signal automatically, reporting negative, positive or invalid result. The kit includes internal control for monitoring of sample collection, processing, and amplification to reduce false negative results.

Components and Catalog Number

Article No. and specifications / Component name	RM2011800 -1 1 Test	RM2011800 -5 5 Tests	RM2011800 -10 10 Tests
G. lamblia/T. foetus Reaction Card (piece)	1	5	10
Nucleic Acid Releasing Agent 02 (tube)	2	10	20
Disposable Sampling Swab (piece)	1	5	10
Waste Bag (piece)	1	5	10

NOTE: 1. The above components of different batches of kits shall not be used interchangeably.

Storage Conditions and Expiry Date

1. 2 °C~28 °C storage, valid for 13 months.

2. The production date and expiration date are shown on the package label.

Applicable Devices

Integrated Nucleic Acid Testing Device (PM003,Guangzhou Pluslife Biotech Co., Ltd.)

Integrated Nucleic Acid Testing Device (Model:PM003 Ultra), Guangzhou Pluslife Biotech Co., Ltd.

Eight-Channel POC Molecular Analyzer (Model:PM008P), Guangzhou Pluslife Biotech Co., Ltd.

NOTE: This instructions for use only provides instructions of the operations on PM003. For instructions on PM003Ultra and PM008P, please refer to the corresponding user manual.

Sample Requirements

Anal Swabs

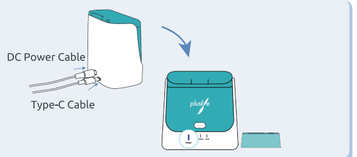
Testing Method

The room temperature should be between 15~28 °C. Please read all the instructions carefully before you begin.

STEP 1: Test Preparation

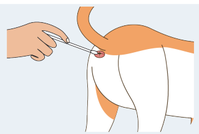
1. Take out the device, power adapter, and card holder from the Integrated Nucleic Acid Testing Device package.

2. Put the Integrated Nucleic Acid Testing Device on a flat surface, connect the power supply, press the button in front of the device to enter the warm-up process (the power light is flashing red). After 2 minutes, the warm-up is completed and in a standby mode (the power light is blue). Connect the Integrated Nucleic Acid Testing Device to a computer with a data line and open the installed Pluslife software.



STEP 2: Sample Collection

1. Carefully insert the swab approximately 1-2 cm into the anal canal. Gently rotate against the walls of the rectum 3 times. Withdraw the swab carefully.



NOTE:

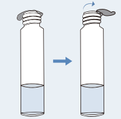
1) Avoid scratching the test subject.

2) Samples should be tested immediately after collection.

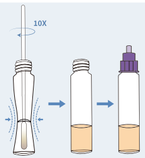
2. Confirm swab is not overloaded. If the swab is grossly contaminated with feces, discard and repeat the collection, See figures below for reference: Acceptable Specimens (1,2); Unacceptable Specimens (3, 4).

STEP 3: Sample Treatment

1. Open the aluminum foil sealing film of Nucleic Acid Releasing Agent 02 vial carefully to avoid spilling the liquid.



2. Insert the sampled disposable sampling swab into the releasing agent vial and make sure the absorbent tip is in the liquid. Then rotate the swab along the bottom and sides of the releasing agent vial 10 times while gently squeezing the swab through the vial to increase sample release.

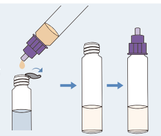


NOTE: Please be careful to avoid spilling the liquid.

3. Discard the disposable sampling swab following local regulations.

4. Open the seal of a new releasing agent vial, and add approximately 5 drops of the eluted sample from the original release agent vial into the new release agent vial.

5. Screw the cap.

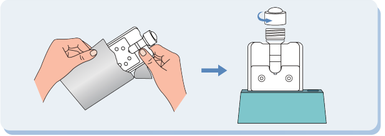


NOTE: Be careful to avoid contact with eyes or skin by the nucleic acid releasing agent 02. If it happens unfortunately, wipe off the liquid immediately and rinse with plenty of water.

STEP 4: Sample Testing

1. Make sure the Integrated Nucleic Acid Testing Device is in standby (the power light is blue).

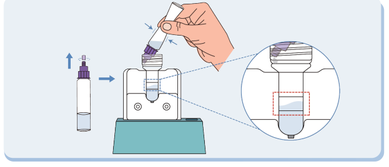
2. Tear open the aluminum foil bag of one *G. lamblia/T. foetus* Reaction Card and take it out, place the *G. lamblia/T. foetus* Reaction Card on the card holder and unscrew the cap of the sample tube on the *G. lamblia/T. foetus* Reaction Card.



NOTE: The *G. lamblia/T. foetus* Reaction Card must be proceeded to subsequent operations as soon as possible after the aluminum foil bag has been torn and proceed to the next step immediately when the cap of the tube is unscrewed.

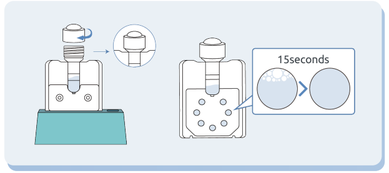
3. Open the top cap of the nucleic acid releasing agent 02 vial from STEP 3, use one hand to stabilize the card holder, use the other hand to slowly pour the nucleic acid releasing agent 02 solution on the tube inside wall of the *G. lamblia/T. foetus* Reaction Card between the two liquid injection lines by squeezing the nucleic acid releasing agent 02 vial wall.

NOTE: There are two liquid injection lines marked on the *G. lamblia/T. foetus* Reaction Card sample tube. Add nucleic acid releasing agent 02 solution into the *G. lamblia/T. foetus* Reaction Card sample tube until the liquid level between the two lines.



4. Place the nucleic acid releasing agent 02 vial in waste bag for disposal.

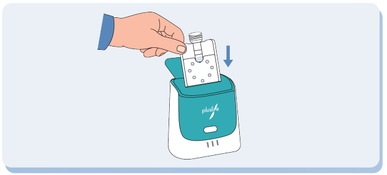
5. Screw the cap of the *G. lamblia/T. foetus* Reaction Card sample tube tightly. Allow the card stand still for 15 seconds.



6. Firmly press the protruding arc-shaped air bag on the sample tube cap of the *G. lamblia/T. foetus* Reaction Card to deform it and recess it into the tube.

7. Hold the card, shake it up and down for 10 times in about 5 seconds. Then proceed to next step immediately. Discard the card if the bubble volume occupies more than 1/3 of the chamber.

8. Open the cabin door of Integrated Nucleic Acid Testing Device, and insert the Reaction Card into the device according to the direction indicated on the *G. lamblia/T. foetus* Reaction Card, and push it to the fixed position of the bottom card slot, close the cabin door.



9. Press start button on the software to start the run. The light is flashing blue during the operation.

10. Wait about 30 minutes. High positive results may appear sooner.

11. When the run is completed, result is presented on the software. Record the result in time. The assay is finished.

12. Open the cabin door, take out the *G. lamblia/T. foetus* Reaction Card, and put it into waste bag, seal the waste bag, and dispose of the waste following local regulations.

13. If move on to next test, press the power button to eliminate the last test result (the power indicator is steady on), insert the reaction card to be tested, and then press the power button for the next normal test (back to STEP 1). If not, press the button for over 3 seconds to turn it off.

STEP 5: Interpretation of Test Results

1. The results of the device are determined as follows:

Phenomenon	Description	Result determination	Suggestions
	Positive indicator light on	The sample was determined to be positive for any one or two of *Giardia lamblia/Tritrichomonas foetus.*	In case of a positive result: a) Export the data on the computer for analysis of the detection results of each target of *Giardia lamblia/Tritrichomonas foetus.*
	Negative indicator light on	The sample was determined to be negative.	In case of a negative result: a) If symptoms appear, do a new test.
	All lights on at the same time	Invalid result. Internal control failed to be detected	In case of invalid result: a) No conclusion can be made with this result. b) Perform a new test. c) If the problem persists, please contact the local distributor for assistance.

2. The results of *Giardia lamblia/Tritrichomonas foetus* test are viewed using the analysis software installed in the computer, as shown in the following table:

Test Results		Results Determination
Giardia lamblia	*Tritrichomonas foetus*	
Positive	Negative	The sample is positive for *Giardia lamblia* and negative for *Tritrichomonas foetus*
Negative	Positive	The sample is negative for *Giardia lamblia* and positive for *Tritrichomonas foetus*
Negative	Negative	The sample is both negative for *Giardia lamblia* and *Tritrichomonas foetus*
Positive	Positive	The sample is both positive for *Giardia lamblia* and *Tritrichomonas foetus*
INVALID		Invalid result, test should be repeated with a new specimen. Possible reasons might be: ① The sample quantity is insufficient. ② The reaction is inhibited. ③ The operation error. ④ Sample is contaminated.

Limitations of Detection Methods

1. The test results from this kit are only for clinical reference and should be used in conjunction with signs/symptoms, medical history, other laboratory test results for the cat for a comprehensive analysis and interpretation. They should not be used as the sole basis for clinical diagnosis and treatment.

2. False negative results may occur if the sample contains an insufficient amount of pathogens.

3. False positive results may occur if cross-contamination of the sample or contamination from the laboratory environment occurs during sample handling.

Product Performance Index

1. Sensitivity (Limit of Detection): *Giardia lamblia* 1000 copies/mL; *Tritrichomonas foetus* 1000 copies/mL

2. Specificity: This kit does not cross-react with other common pathogens from cats with similar symptoms.

3. Repeatability: The intra-assay repeatability detection rate is 100% and the inter-assay repeatability detection rate is 100%.

Precautions

1. This kit is for in vitro diagnostic use only, please read this instruction carefully before use, and operate strictly in accordance with the instruction.

2. The correct collection of swab samples and accurate operation according to the inspection method are critical to the accuracy of the test results.

3. The validity period must be checked before the test. The test kit shall not be used after the expiry date indicated on the outer packaging.

4. Avoid excessively high test environment temperature. If the kit is stored at a lower temperature, it must be returned to room temperature before opening to avoid moisture condensation.

5. Make sure there are no damage of the Reaction Card bag, and no liquid leakage of the nucleic acid releasing agent 02. Do not use them if any leakage occurs.

6. Avoid contact with eyes or skin by the Nucleic acid releasing agent 02 solution.

7. Disposal: all parts used have a potential risk of infection. Please use the provided waste bag for disposal.

8. The freeze-dried reaction microspheres are very easy to deliquesce. The sealed package of the Reaction Card should not be opened too early. If it is not used for testing as soon as possible after opening the package, the Reaction Card cannot be used.

9. It is recommended that the next step of the experiment be carried out as soon as samples are collected.

10. False positive results may occur if cross-contamination is not controlled during collection and sample handling.

Manufacturer

Guangzhou Pluslife Biotech Co., Ltd.
Room 402, 6 Lianhuayan Road, Huangpu District, Guangzhou, Guangdong, China
+86-20-31703986
www.pluslife.com
Service@pluslife.com

Explanation of Symbols

	Consult instructions for use		Keep dry
	Use-by date		Batch number
	Temperature limit		Catalogue number
	Manufacturer		Date of manufacture
	Do not re-use		Do not use if package is damaged and consult instructions for use
	Biological risks		Keep away from sunlight
	Contains sufficient for<n> tests		Fragile,handle with care
	This way up		Do not roll
	Stacking limit by number		

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