



FCV Nucleic Acid Test Card

For veterinary use only

Product Name

Product Name: FCV Nucleic Acid Test Card

Trade name: Pluslife FCV Card

Intended Use

Feline upper respiratory tract disease (FURTD) is an important cause of morbidity and mortality in kittens and is usually caused by infection by one or more pathogens, thereby resulting in feline respiratory disease complex (FRDC), characterized by respiratory tract or ocular disease.

The FCV Nucleic Acid Test Card is used for in vitro qualitative detection of Feline Calicivirus (FCV).

Testing Principle

The assay is based on isothermal amplification method and enzyme digestion probe technology, and conserved regions 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 assay 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		
	RM2010500-1	RM2010500-10	RM2010500-50
FCV Reaction Card (piece)	1 Test	10 Tests	50 Tests
Nucleic Acid Releasing Agent 01 (1 tube)	1	10	50
Disposable Sampling Swab (branch)	1	10	50
Waste Bag (piece)	1	10	50

NOTE: 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 (Model:PM003), 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 PM008P, please refer to the corresponding user manual.

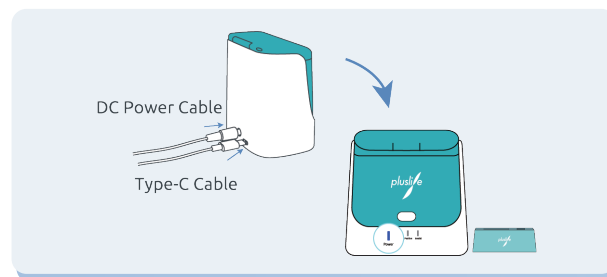
Preparation

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

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

3.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.


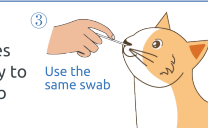


Sample Requirements

The following steps outline the standard procedure for collecting respiratory samples from cats using swabs. These samples include oropharyngeal, ocular, and nasal specimens:

Note: Use the same swab to gently wipe the Oropharyngeal, Ocular and Nasal area 3~5 times in sequence.

Type	Instruction
Oropharyngeal Swab	Insert the swab tip into the pet's oropharynx, targeting the posterior and lateral pharyngeal walls, as well as the gums. Gently swab these areas 3-5 times to collect the sample. 

Ocular Swab	Gently swipe the swab tip 3-5 times along the middle part of the pet's lower eyelid, to collect secretions from the ocular area. 
Nasal Swab	Use the swab tip to gently swipe 3-5 times inside the nasal cavity to collect the nasal swab sample. 

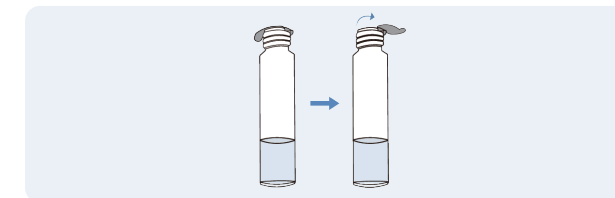
NOTE:

- 1) Avoid scratching the test subject.
- 2) Samples should be tested immediately after collection.
- 3) The sampling swab does not require moistening prior to use.
- 4) When collecting a nasal sample, if thick mucus is present, it should be wiped away before using the sampling swab.

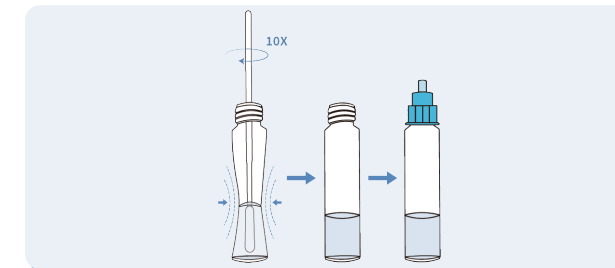
Sample Processing and Test Procedure

1.Sample Processing

① Open the aluminum foil sealing film of Nucleic Acid Releasing Agent 01 vial carefully to avoid spilling the liquid.



② Insert the sampled disposable sampling swab into the vial and make sure the absorbent tip is in the liquid. Then twist the disposable sampling swab tip against the bottom and sides of the nucleic acid releasing agent 01 vial 10 times and pinch the disposable Sampling Swab tip.



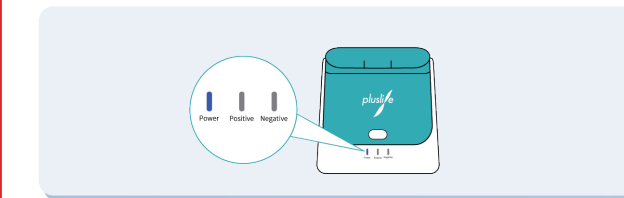
③ Discard the disposable sampling swab into waste bag.

④ Screw on the cap.

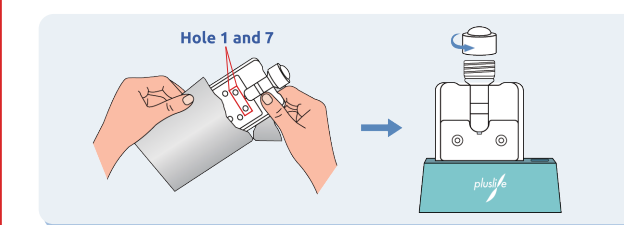
NOTE: Be careful to avoid contact with eyes or skin by the nucleic acid releasing agent 01. If it happens unfortunately, wipe off the liquid immediately and rinse with plenty of water.

2.Test Procedure

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



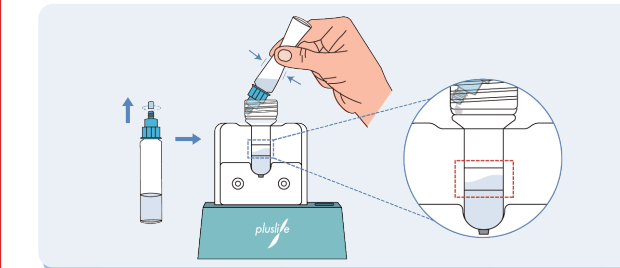
- ① Tear open the aluminum foil bag of one FCV Reaction Card and take it out.
- ② Check the freeze-dried microspheres in the chip. There are freeze-dried microspheres in holes 2, 3, 4, 5, 6; but no freeze-dried microspheres in holes 1 and 7.
- ③ Place the FCV Reaction Card on the card holder and unscrew the cap of the sample tube on the FCV Reaction Card.



NOTE: The FCV 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.

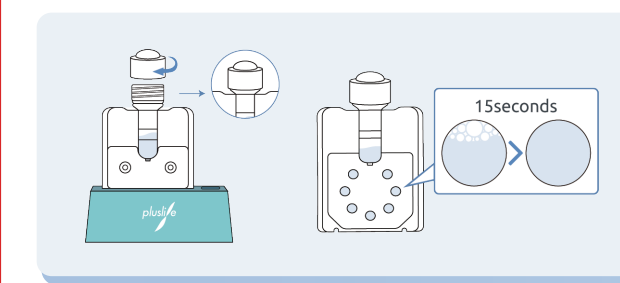
④ Open the top cap of the nucleic acid releasing agent 01 vial from 1.Sample Processing, use one hand to stabilize the card holder, use the other hand to slowly pour the nucleic acid releasing agent 01 solution on the tube inside wall of the FCV Reaction Card between the two liquid injection lines by squeezing the nucleic acid releasing agent 01 vial wall.

NOTE: There are two liquid injection lines marked on the FCV Reaction Card sample tube. Add nucleic acid releasing agent 01 solution into the FCV Reaction Card sample tube until the liquid level between the two lines.



⑤ Place the nucleic acid releasing agent 01 vial in waste bag for disposal.

⑥ Screw the cap of the FCV Reaction Card sample tube tightly. Allow the card stand still for 15 seconds.



⑦ Firmly press the protruding arc-shaped air bag on the sample tube cap of the FCV Reaction Card to deform it and recess it into the tube.

NOTE: Discard the card if the bubble volume occupies more than 1/3 of the chamber.

⑧ 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.



NOTE: The Reaction Card must be tested immediately.

⑨ 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 FCV Reaction Card, and push it to the fixed position of the bottom card slot, close the cabin door.



⑩ Press start button on the software to start the run. The light is flashing blue during the operation.



⑪ Wait 15-30 minutes.

⑫ When the run is completed, result is presented on the software. Record the result in time. The assay is finished.

⑬ Open the cabin door, take out the FCV Reaction Card, and put it into waste bag, seal the waste bag, and dispose of the waste following local regulations.

⑭ 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 1. Sample Processing). If not, press the button for over 3 seconds to turn it off.

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 more of FCV.	In case of a positive result: a) Export the data on the computer for analysis of the detection results of each target of FCV.
	Negative indicator light on	The sample was determined to be negative for FCV.	In case of a negative result: a) If symptoms of feline respiratory syndrome 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 a FCV test are viewed using the analysis software installed in the computer, as shown in the following table:

Test Results	Results Determination
POSITIVE	The sample was determined to be FCV POSITIVE.
NEGATIVE	The sample was determined to be FCV NEGATIVE.
INVALID	Invalid result. ① The reaction was prematurely terminated. ② Internal control failed to be detected*.

*NOTE:

Possible reasons:

- 1) The sample quantity is insufficient.
- 2)The reaction is inhibited.
- 3) The operation error.

Suggestions:

- 1) Repeat test using a new FCV Reaction Card.
- 2) If test still fails, collect a new sample for retesting, or please contact the local distributor for assistance.

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 virus.

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): FCV 1000 copies/mL.

2.Specificity: This kit does not cross-react with other common pathogens from cats with similar symptoms, e.g. Feline herpesvirus 1 (FHV-1), Chlamydomphila felis (C.felis), Mycoplasma felis(M.felis), Bordetella bronchiseptica (Bb), Feline panleukopenia virus (FPV) and feline coronavirus (FCoV).

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.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.

4.When opening the cover of the FCV Reaction Card, do not touch the reaction tube and the inside of the tube cover.

5.Make sure there are no damage of the FCV Reaction Card bag, and no liquid leakage of the nucleic acid releasing agent 01. Do not use them if any leakage occurs.

6.If there are clinical symptoms of contagious respiratory diseases, even if the test result is negative, the test result should be reassessed by the doctor.

7.Hold the disposable sampling swab handle, not the head.

8.All parts of this kit are for external use and should not be swallowed.

9.Avoid contact with eyes or skin by the Nucleic acid releasing agent 01 solution.

10.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.

11.Exposure of the contents of the FCV Reaction Card is likely to cause contamination, and the FCV Reaction Card seal and its components shall not be damaged any time.

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

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

14.If the collection and sample processing are not well controlled, resulting in cross-contamination, false positives may occur.

15.A variety of factors during the storage, transportation and use of reagents may cause performance changes, such as sample collection, sample processing, and non-standard operation in the testing process. Please strictly follow the instructions. Due to the characteristics of the swab and other sample collection process and the virus infection process itself, there may be false-negative results caused by insufficient sample size. It should be combined with other clinical diagnosis and treatment information to make a comprehensive judgment, and retest if necessary.

16.Do not disassemble the Reaction Card, whether it is used or not.

Manufacturer

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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		

Version: A/1

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