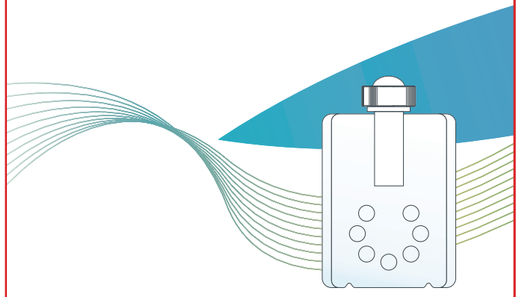
FPV/CPV

Nucleic Acid Test Card

For veterinary use only



Product Name

Product Name: FPV/CPV Nucleic Acid Test Card

Trade name: Pluslife FPV/CPV Card

Intended Use

Cats and Dogs affected by acute infections with Feline Parvovirus(FPV) or Canine Parvovirus (CPV), display similar enteric diseases symptoms. Both FPV and CPV, linear singe-stranded DNA virus, belong to the genus Parvovirus, family Parvoviridae. The clinical severity of FPV/CPV varies with age, immune status, and coinfection. FPV/CPV can cause a highly contagious and fatal disease in dogs and also in cats. Animals infected with FPV/CPV develop acute gastroenteritis characterized by loss of appetite, vomiting, fever, diarrhea and leucopenia with high morbidity and mortality, within 3-7 days.

The FPV/CPV Nucleic Acid Test Card is used for in vitro qualitative detection of Feline Parvovirus(FPV) and Canine Parvovirus (CPV).

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.

Materials Provided

Article No. and specifications / Component name	RM2010400-1 1 Test	RM2010400-10 10 Tests	RM2010400-50 50 Tests
FPV/CPV Reaction Card (piece)	1	10	50
Nucleic Acid Releasing Agent 02 (tube)	1	10	50
Disposable Sample swab (piece)	1	10	50
Waste Bag (piece)	1	10	50

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

Materials Required but Not Provided

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.

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.

Sample Requirements

Rectal swab

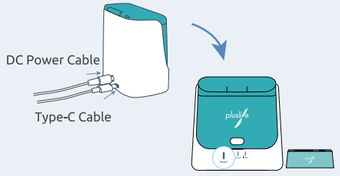
Testing Method

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

STEP 1: Instruments Preparing

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

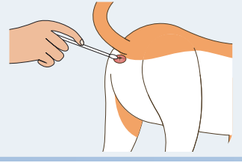
2.Put the Integrated Nucleic Acid Testing Device on a flat surface, connect the power supply, press the button in front of the Instrument to enter the warm-up process (the power light is flashing red). After 2 minutes, the warm-up is completed and in standby (the power light is blue). Connect the Integrated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



STEP 2: Sample Collection

Rectal swab:

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.



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).

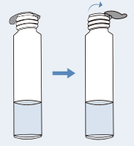
NOTE: The utilization of non-standard sampling methods may result in false negative findings or invalid outcomes.

Sample preservation and transportation:

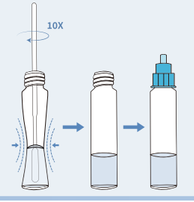
It can be immediately used for detection, room temperature storage not more than 24 hours, 2~8 °C storage not more than 5 days, -20 °C storage not more than 6 months, -80 °C storage for long-term, and repeated freezing and thawing not more than 5 times. The specimen should be transported with ice in a foam box.

STEP 3: Sample Processing

1.Open the seal of the Nucleic Acid Releasing Agent 02 vial carefully to avoid spilling the liquid. Discard the seal into waste bag.



2.Insert the sampled disposable sampling swab into the vial and make sure the absorbent tip is in the liquid. Then twist the swab head against the bottom and sides of the tube for 10 times and pinch the swab head in the meantime. Discard the used swab into the biohazard bag.



3.Discard the disposable sampling swab following local regulations.

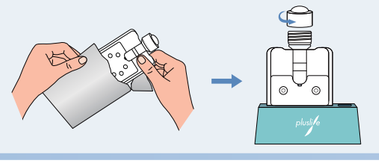
4.Screw the cap.

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

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

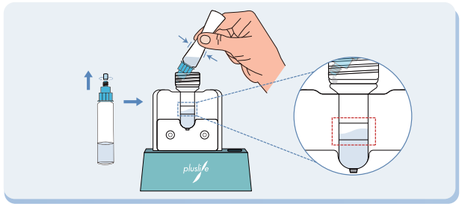
1.Tear open the aluminum foil bag of one Reaction Card and take it out, place the Reaction Card on the card holder and unscrew the cap of the sample tube on the Reaction Card.



NOTE:
① Proceed to the next step immediately when the tube cap is unscrewed and the aluminum foil pouch is torn.
② The reaction card contains several intentionally designed empty holes, which have no impact on the product's functionality.

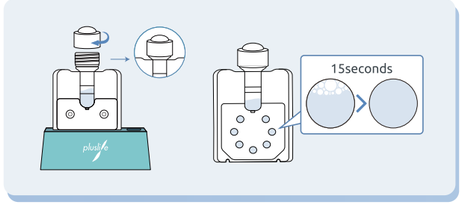
2.Open the top cap of the Nucleic Acid Releasing Agent 02 vial from STEP 3, use one hand to stabilize the card holder, use the other hand to pour the Nucleic Acid Releasing Agent 02 solution on the tube inside wall of the Reaction Card between the two liquid injection lines by squeezing the Nucleic Acid Releasing Agent 02 vial wall.

NOTE: There are two liquid injection lines marked on the Reaction Card sample tube. Add Nucleic Acid Releasing Agent 02 solution into the Reaction Card sample tube until the liquid level between the two lines.



3.Place the Nucleic Acid Releasing Agent 02 vial in waste bag for disposal.

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



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

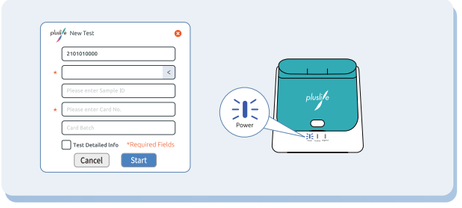
NOTE: Discard the card if the bubble volume occupies more than 1/3 of the chamber.

6.Hold the card and shake it up and down 10 times in about 5 seconds. The Reaction Card is ready to be tested.

NOTE: The Reaction Card must be tested immediately.

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

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



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

10.When the run is completed, the result displays by indicator lights on the software. Record the result in time. The assay is finished.

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

12.If move on to next test, press the power button to eliminate the last test result, the power indicator will turn solid blue. Then start from STEP 1. If no further testing to be performed, press the button for over 3 seconds to turn it off.

STEP 5: Interpretation of Test Results and Suggestions

1.The results of a FPV/CPV test are viewed using the analysis software installed in the computer,as follows:

Phenomenon	Test Results	Result determination
Power Positive Negative	Positive	The sample was determined to be Feline Parvovirus or Canine Parvovirus positive.

Phenomenon	Description	Result determination
Power Positive Negative	Negative	The sample was determined to be Feline Parvovirus or Canine Parvovirus negative.
Power Positive Negative	Invalid	Invalid result. Test should be repeated. Possible reasons are: ① Inhibited reaction due to insufficient sample quantity. ② Operation error. ③ Contaminated sample

NOTE:
Recommended Actions after Obtaining Invalid:
① For symptomatic cats or dogs, it's recommended to dilute the eluate with the release agent by at least 10 times or resampling before proceeding with the test.
② For asymptomatic cats or dogs, it's recommended to heat the eluate from the release agent at 65 for 5 minutes or resampling before proceeding with the test.

Limitations of Detection Methods

1.The test results of this kit are for clinical reference only. Comprehensive analysis and interpretation should be carried out based on the cat or dog's symptoms/signs, medical history, and other laboratory diagnosis results. It should not be used as the sole basis for clinical diagnosis, treatment or management of cat or dog.

2.If the amount of virus in the sample is insufficient, false negative results may occur.

3.False positive results may occur if cross-contamination between samples occurs during sample processing.

4.Mutation of the target sequence during the virus epidemic or the sequence changes caused by other reasons may lead to false negative results.

Product Performance Index

1.Positive coincidence rate: the positive coincidence rate is 100% when testing the company's positive reference substances.

2.Negative coincidence rate: the negative coincidence rate is 100% when testing the company's negative reference substance.

3.Sensitivity (Limit of Detection): 1000 copies/mL.

4.Repeatability: the intra-assay repeatability detection rate reaches 100%; the inter-assay repeatability detection rate reaches 100%.

5.Specificity: Other pathogens that are similar or cause similar symptoms have no cross-reactivity.

Precautions

1.This kit is for in vitro veterinary 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 testing 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 Reaction Card, do not touch the reaction tube and the inside of the tube cover.

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

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

8.Avoid contact with eyes or skin by the Nucleic Acid Releasing Agent 02 solution.

9.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.

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

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

12.The freeze-dried reaction microspheres are very easy to deliquesce. The sealed package of 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.

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

14.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.

15.Do not re-use the test kit components.

References

1.Nicola Decaro, Domenico Buonavoglia, Costantina Desario et al., Characterisation of canine parvovirus strains isolated from cats with feline panleukopenia.Res Vet Sci. 2010..

2.Yu-Ling SUN, Chon-Ho YEN and Ching-Fu TU. Visual Detection of Canine Parvovirus Based on Loop-Mediated Isothermal Amplification Combined with Enzyme-Linked Immunosorbent Assay and with Lateral Flow Dipstick. Virology. 2013.

3.Nicola Decaro, Vito Martella, Gabriella Elia et al., Tissue distribution of the antigenic variants of canine parvovirus type 2 in dogs. Veterinary Microbiology. 2007.

Manufacturer

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Explanation of Symbols

	Consult instruction for use		Keep dry
	Use-by date	LOT	Batch number
	Temperature Limit	REF	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
n	Contains sufficient for <n> tests		Fragile,handle with care
	This way up		Do not roll
n	Stacking limit by number		

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