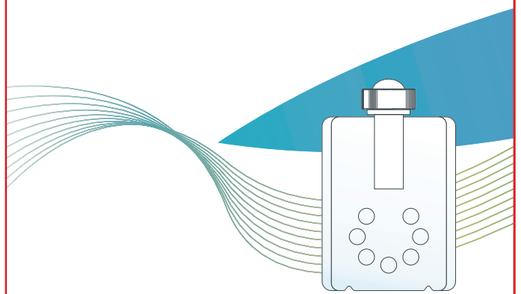
HandyVet

Feline and Canine SARS-CoV-2

Nucleic Acid Test Card

For veterinary use only



Product Name

Product Name: Feline and Canine SARS-CoV-2 Nucleic Acid Test Card

Trade name: Feline and Canine SARS-CoV-2 Card

Intended Use

This kit is used for in vitro qualitative detection of the N gene and ORF1ab gene of novel coronavirus SARS-CoV-2 in swab samples from suspected feline and canine pneumonia cases of SARS-CoV-2 infection.

Testing Principle

This kit is based on isothermal amplification and enzymatic cleavage 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.

Components and Catalog Number

Article No. and specifications / Component name	RM2011700-1 1 Test	RM2011700-5 5 Tests	RM2011700-10 10 Tests	RM2011700-50 50 Tests
Feline and Canine SARS-CoV-2 Reaction Card (piece)	1	5	10	50
Nucleic Acid Releasing Agent 01 (1 tube)	1	5	10	50
Disposable Sampling Swab (piece)	1	5	10	50
Waste Bag (piece)	1	5	10	50

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 (PM001)

Sample Requirements

Nasal Swabs

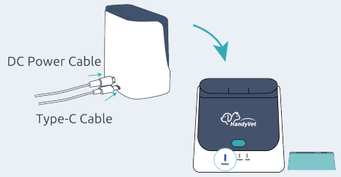
Testing Method

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).



STEP 2: Sample Collection

Take out a swab, and hold its handle end. Sampling instructions for each type of sample are as follows

Type	Instruction
Nasal Swab	Wipe pet's nasal secretions with a swab 5-6 times. 

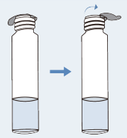
NOTE:

1) Avoid scratching the test subject.

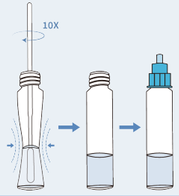
2) Samples should be tested immediately after collection.

STEP 3: Sample Treatment

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 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 into waste bag.

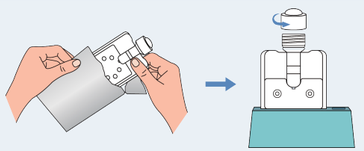
4. Screw on the cap.

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.

STEP 4: Sample Testing

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

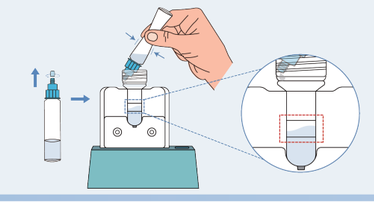
2.Tear open the aluminum foil bag of one Feline and Canine SARS-CoV-2 Reaction Card and take it out, place the Feline and Canine SARS-CoV-2 Reaction Card on the card holder and unscrew the cap of the sample tube on the Feline and Canine SARS-CoV-2 Reaction Card.



NOTE: The Feline and Canine SARS-CoV-2 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.

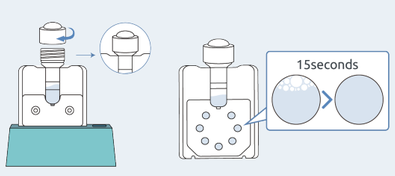
3. Open the top cap of the nucleic acid releasing agent 01 vial from STEP 3, use one hand to stabilize the card holder, use the other hand to slowly pour the nucleic acid releasing agent 01 solution on the tube inside wall of the Feline and Canine SARS-CoV-2 Reaction Card between the two liquid injection lines by squeezing the nucleic acid releasing agent 01 vial wall.

NOTE: There are two liquid injection lines marked on the Feline and Canine SARS-CoV-2 Reaction Card sample tube. Add nucleic acid releasing agent 01 solution into the Feline and Canine SARS-CoV-2 Reaction Card sample tube until the liquid level between the two lines.



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

5.Screw the cap of the Feline and Canine SARS-CoV-2 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 Feline and Canine SARS-CoV-2 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 Feline and Canine SARS-CoV-2 Reaction Card, and push it to the fixed position of the bottom card slot, close the cabin door.

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

10. Wait 15-35 minutes.

11. When the run is completed, the result displays with indicator lights on. Record the result in time. The assay is finished.

12. Open the cabin door, take out the Feline and Canine SARS-CoV-2 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 and Suggestions

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 SARS-CoV-2.	In case of a positive result: a) Export the data on the computer for analysis of the detection results of each target of SARS-CoV-2.
	Negative indicator light on	The sample was determined to be negative.	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. Test should be repeated. Possible reasons are: ① Inhibited reaction due to insufficient sample quantity. ② Operation error. ③ Contaminated sample.	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.

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 and dog 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.

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. Sensitivity (Limit of Detection): 400 copies/mL.

2. Specificity: This kit does not cross-react with other common pathogens from dogs and cats with similar symptoms, e.g. canine herpesvirus (CHV), canine pneumovirus (CnPnV), mycoplasma cynos, canine adenovirus 2 (CAV-2), canine distemper virus (CDV), canine parainfluenza virus (CPIV) feline calicivirus (FCV), feline herpesvirus 1 (FHV-1), Chlamydophila felis (c. felis), mycoplasma felis (M. felis) or Bordetella bronchiseptica (Bb).

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 Feline and Canine SARS-CoV-2 Reaction Card bag, and no liquid leakage of the nucleic acid releasing agent 01. Do not use them if any leakage occurs.

6. Avoid contact with eyes or skin by the Nucleic acid releasing agent 01 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 Feline and Canine SARS-CoV-2 Reaction Card should not be opened too early. If it is not used for testing as soon as possible after opening the package, the Feline and Canine SARS-CoV-2 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

Distributor

Altruan GmbH
Morolding 6, 84323 Massing , Germany
Phone: +49 8724 28596 800

Explanation of Symbols

	Consult instructions 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
	Contains sufficient for<n> tests		Fragile,handle with care
	This way up		Do not roll
	Stacking limit by number		Distributor

Version: A/1

Date: june., 2024