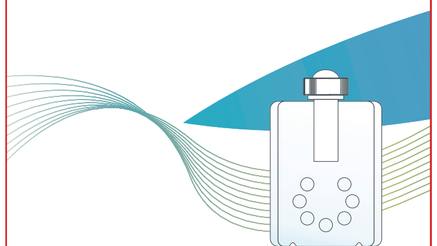
CDV/CPIV/CAV-2/Bb

Nucleic Acid Test Card

For veterinary use only



Product Name

Product Name: CDV/CPIV/CAV-2/Bb Nucleic Acid Test Card

Trade Name: Pluslife CRQ Card

Intended Use

Canine infectious respiratory disease complex (CIRDC), commonly referred to as "kennel cough," refers to a syndrome characterized by acute onset of contagious respiratory disease in dogs that can be caused by a wide range of etiologic agents.

This kit is used for rapid in vitro qualitative detection of pathogens cause CIRDC, including Canine adenovirus 2 (CAV-2), Canine distemper virus (CDV), Canine parainfluenza virus (CPIV) and Bordetella bronchiseptica (Bb).

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 signals 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	RM2010 200-1	RM2010 200-2	RM2010 200-5	RM2010 200-10	RM2010 200-20	RM2010 200-50
	1 Test	2 Tests	5 Tests	10 Tests	20 Tests	50 Tests
CDV/CPIV/CAV-2/Bb Reaction Card (piece)	1	2	5	10	20	50
Nucleic Acid Releasing Agent 01 (1 tube)	1	2	5	10	20	50
Disposable Sampling Swab (branch)	1	2	5	10	20	50
Waste Bag (piece)	1	2	5	10	20	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

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

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

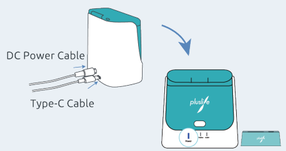
NOTE: This instruction for use only provides instructions of the operations on PM003.

Preparation

1.The room temperature should be between 15°C~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

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

Type	Instruction	
Eye Swab	Wipe the pet's eye secretions with a swab 5-6 times.	
Nasal Swab	Wipe pet's nasal secretions with a swab 5-6 times.	
Oropharyngeal Swab	Wipe the pet's throat with a swab 5-6 times.	

NOTE:

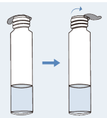
1) Samples should **be tested immediately** after collection;

2)It is recommended taking oropharyngeal samples after **1 hour** of fasting to prevent food residues from affecting the results.

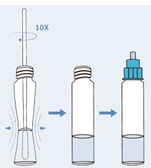
Sample Processing and Test Procedure

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.

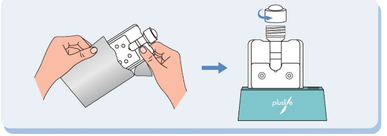
④ Screw on the cap.

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).**

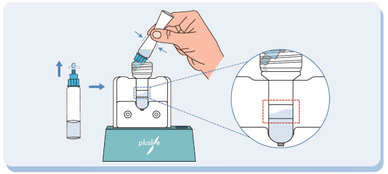
1.Tear open the aluminum foil bag of one CDV/CPIV/CAV-2/Bb Reaction Card and take it out, place the CDV/CPIV/CAV-2/Bb Reaction Card on the card holder and unscrew the cap of the sample tube on the CDV/CPIV/CAV-2/Bb Reaction Card.



NOTE: The CDV/CPIV/CAV-2/Bb 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.

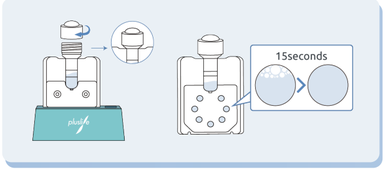
2.Open the top cap of the nucleic acid releasing agent 01 vial from STEP 3, use one hand to stabilize the card holder, use the other hand to slowly pour the nucleic acid releasing agent 01 solution on the tube inside wall of the CDV/CPIV/CAV-2/Bb Reaction Card between the two liquid injection lines by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

NOTE: There are two liquid injection lines marked on the CDV/CPIV/-CAV-2/Bb Reaction Card sample tube. Add nucleic acid releasing agent 01 solution into the CDV/CPIV/CAV-2/Bb Reaction Card sample tube until the liquid level **between the two lines.**



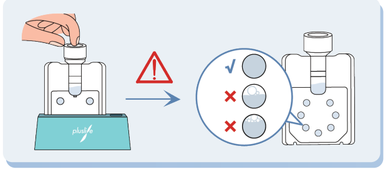
3.Place the nucleic acid releasing agent 01 vial in waste bag for disposal.

4.Screw the cap of the CDV/CPIV/CAV-2/Bb 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 CDV/CPIV/CAV-2/Bb 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.**

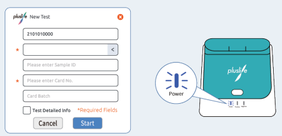


6.Hold the card, shake it up and down for **10 times in about 5 seconds**. Then proceed to next step immediately.

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 CDV/CPIV/CAV-2/Bb 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 **15-35 minutes**.

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

11.Open the cabin door, take out the CDV/CPIV/CAV-2/Bb 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 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 CDV/CPIV/CAV-2/Bb.	In case of a positive result: a) Export the data on the computer for analysis of the detection results of each target of CDV/CPIV/CAV-2/Bb.
	Negative indicator light on	The sample was determined to be negative for CDV/CPIV/CAV-2/Bb.	In case of a negative result: a) If symptoms of canine 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 canine respiratory tract triple test are viewed using the analysis software installed in the computer, as shown in the following table:

Test Results				Results Determination
CDV	CPIV	CAV-2	Bb	
Positive	Negative	Negative	Negative	The sample is positive for CDV but negative for CPIV, CAV-2 and Bb.
Negative	Positive	Negative	Negative	The sample is positive for CPIV but negative for CDV, CAV-2 and Bb.
Negative	Negative	Positive	Negative	The sample is positive for CAV-2 but negative for CDV, CPIV and Bb.
Negative	Negative	Negative	Positive	The sample is positive for Bb but negative for CDV, CPIV and CAV-2.
Positive	Positive	Negative	Negative	The sample is positive for CDV and CPIV but negative for CAV-2 and Bb.
Positive	Negative	Positive	Negative	The sample is positive for CDV and CAV-2 but negative for CPIV and Bb.
Positive	Negative	Negative	Positive	The sample is positive for CDV and Bb but negative for CPIV and CAV-2.
Negative	Positive	Positive	Negative	The sample is positive for CPIV and CAV-2 but negative for CDV and Bb.
Negative	Positive	Negative	Positive	The sample is positive for CPIV and Bb but negative for CDV and CAV-2.
Negative	Negative	Positive	Positive	The sample is positive for CAV-2 and Bb but negative for CDV and CPIV.
Positive	Positive	Positive	Negative	The sample is positive for CDV, CPIV and CAV-2 but negative for Bb.
Positive	Positive	Negative	Positive	The sample is positive for CDV, CPIV and Bb but negative for CAV-2.
Positive	Negative	Positive	Positive	The sample is positive for CDV, CAV-2 and Bb but negative for CPIV .
Negative	Positive	Positive	Positive	The sample is positive for CPIV, CAV-2 and Bb but negative for CDV.
Positive	Positive	Positive	Positive	The sample is positive for CDV, CPIV, CAV-2 and Bb.
Negative	Negative	Negative	Negative	The sample is positive for CDV, CPIV, CAV-2 and Bb.
Invalid				Invalid result, test should be repeated with a new specimen. Possible reasons might be: ①The sample quantity is insufficient. ②The reaction is inhibited. ③The operation error.

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 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.

Product Performance Index

1.Sensitivity (Limit of Detection): CDV 1500 copies/mL; CPIV 1000 copies/mL; CAV-2 1500 copies/mL; Bb 1500 copies/mL.

2.Specificity: This kit does not cross-react with other common pathogens from dogs with similar symptoms, e.g. canine herpesvirus (CHV), canine respiratory coronavirus (CRCoV), canine pneumovirus (CnPnV) and Mycoplasma cynos.

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 CDV/CPIV/CAV-2/Bb Reaction Card, do not touch the reaction tube and the inside of the tube cover.

5.Make sure there are no damage of the CDV/CPIV/CAV-2/Bb 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 CDV/CPIV/CAV-2/Bb Reaction Card is likely to cause contamination, and the CDV/CPIV/CAV-2/Bb 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 CDV/CPIV/CAV-2/Bb Reaction Card should not be opened too early. If it is not used for testing as soon as possible after opening the package, the CDV/CPIV/CAV-2/Bb 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	LOT	Batch code
	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		

Version: A/4
Date: Nov., 2023