Canine Distemper Virus Antigen Test

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST



Introduction

Canine distemper is highly contagious and fetal disease of dogs with a worldwide distribution. Canine distemper virus (CDV, the species *Canine morbillivirus*), an enveloped, negative-sense, single-stranded RNA virus, is a member of the genus *Morbillivirus* in the family Paramyxoviridae[1, 2].

CDV infects different cell types, including epithelial, mesenchymal, neuroendocrine and hematopoietic cells of various organs and tissues[3]. A diphasic fever is a characteristic feature of the disease, occurring 7 or 8 days after infection, that drops rapidly and again climbs by day 11 or 12[4, 5]. Clinical signs of distemper are often unapparent or initially mild during this time, and the disease is characterized by mucopurulent oculonasal discharges, conjunctivitis, respiratory distress, anorexia, vomiting, diarrhea and dehydration, and cutaneous rash. Additional clinical signs that may occur are localized twitching, ascending paresis/paralysis, and/or convulsions. Hyperkeratosis of the foot pads and nose also may occur. Dogs that recover from acute disease with persistent infection may shed virus in urine and through the skin on the foot pads[4, 5].

Domestic dogs are the main host for CDV and could also be considered as a reservoir for other mammals. Due to its high morbidity and mortality rates and broad host range, CDV is not only a well-known pathogen of domestic dogs but also one of the most important pathogens of mammals with the ability to jump the species barrier and perhaps even infect humans[6].

Principle

The B!SAF CDV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of CDV antigens in canine eye discharges. This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the CDV antigen exists in the sample, it binds to the gold-conjugated anti-CDV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the anti-CDV antibody on the test line, resulting in a red line. The control line indicates that the test is performed correctly and should appear when the test is complete.

The highly selective and sensitive monoclonal antibody to CDV is used as a capture and detector in the kit. The B!SAF CDV Ag Test Kit can detect CDV in canine eye discharge (conjunctiva) with high accuracy.

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	−	Total
CDV Ag Test	+	85	3	88
	−	1	129	130
	Total	86	132	218

Sensitivity: 98.84% (85/86, 95% CI*: 93.70% ~ 99.79%)
Specificity: 97.73% (129/132, 95% CI: 93.53% ~ 99.22%)
Diagnostic Agreement: 98.17% (214/218, 95% CI: 95.38% ~ 99.28%)

* CI: Confidence Interval

2. Limit of Detection: 5 x 10^3 $TCID_{50}$/mL

3. Cross-Reactivity

Potentially cross-reactive substances listed below have no effect on the performance of the B!SAF CDV Ag Test Kit.

Pathogen	Titer	Result
Canine coronavirus	1.00 x 10^6 $TCID_{50}$/mL	Negative
Canine influenza virus	1.00 x 10^6 EID_{50}/mL	Negative
Canine parvovirus	1.00 x 10^6 $TCID_{50}$/mL	Negative
Escherichia coli	3.56 x 10^8 CFU/mL	Negative
Giardia spp.	1.42 x 10^5 Cysts/μL	Negative
Salmonella spp.	1.00 x 10^6 CFU/mL	Negative

Kit Components

Component	Quantity/kit by
1 CDV Ag test device	1
2 Dilution buffer	1
3 Disposable swab	1
4 Instructions for use	1
5 Collecrion bag	1

Storage & Stability

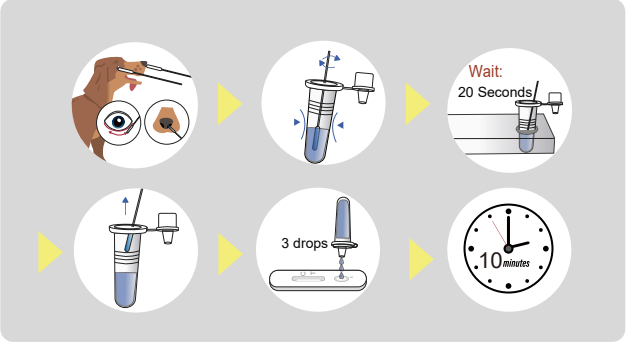
- Store in a dry place at 2-30°C
- Do not freeze
- Keep away from direct sunlight
- 24 months of shelf life (Production date to the expiration date).

Sample Preparation

1. The samples should be tested immediately after collection.
2. If samples cannot be tested immediately, they should be stored at 2~8°C (35.6~46.4°F) for up to 24 hours. For longer storage, freeze at −20°C (−4°F) or below. Frozen samples should be brought to room temperature (15~30°C/59~86°F) before use.

Test Procedure

1.All reagents and samples must be at room temperature (15~30°C/59~86 °F) before use.
2. Collect Ocular or nasal secretions using a swab.
3.Put the swab into the sample dilution buffer and stir the solution with the swab to disperse the sample into the buffer (approximately 10 seconds).
4. Wait for 20 seconds to settle down the large particles.
5. Remove the swab from the sample dilution buffer.
6. Remove the test device from the pouch and place it on a flat and drysurface.
7.Apply 3 drops of the mixed sample solution into the sample holes foreach , drop by drop vertically.
8.Read test results at 10 minutes.

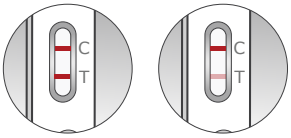


[Summary of Test Procedure]

Interpretation of Results

Positive(+)
Presence of two color bands "T"and "C"

Two lines, one nextto C and one next to T, even faint lines, shows the test is positive.



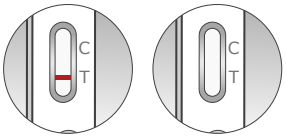
Negative (-)
No presence of color band ("T")

One red-coloredline only next to "C" indicates a negative result.



Invalid
No presence of color band ("C")

If the red-colored line in the control region "C" is not visible, the result is invalid. Run a new test.



Precautions

1. This test kit is for veterinary *in vitro* diagnostic use only for dogs. Do not use this test kit for other animals.
2. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
3. Do not touch the membrane of the test device.
4. Do not use the test device if the foil pouch is damaged or the seal is open.
5. Do not use an expired test kit. The expiration date is marked on the package label.
6. Do not reuse the components (device, buffer, dropper, and swab).
7. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
8. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials in the accordance with national and local regulations.
9. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward

References

1. International Committee on Taxonomy of Viruses (ICTV). *Virus Taxonomy*: 2019 Release. Ratification March 2020 (Master Species List #35). https://talk.ictvonline.org/taxonomy
2. Rendon-Marin S, Budaszewski RF, Canal CW, Ruiz-Saenz J. Tropism and molecular pathogenesis of canine distemper virus. *Virol J*. 2019; 16: 30.
3. Beineke A, Puff C, Seehusen F, Baumgärtner W. Pathogenesis and immunopathology of systemic and nervous canine distemper. *Vet Immunol Immunopathol*. 2009; 127(1-2): 1-18.
4. Deem SL, Spelman LH, Yates RA, Montali RJ. Canine distemper in terrestrial carnivores: a review. *J Zoo Wildl Med*. 2000; 31(4): 441-451.
5. Kapil S, Yeary TJ. Canine Distemper Spillover in Domestic Dogs from Urban Wildlife. *Vet Clin Small Anim*. 2011; 41: 1069-1086.
6. Duque-Valencia J, Sarute N, Olarte-Castillo XA, Ruíz-Sáenz J. Evolution and Interspecies Transmission of Canine Distemper Virus-An Outlook of the Diverse Evolutionary Landscapes of a Multi-Host Virus. *Viruses*. 2019; 11(7): 582.

Symbol Descriptions

LIC	License number
CAT	Catalogue number
LOT	Batch code, Lot number
	Consult instructions for use
Σn	Contains sufficient for ⟨n⟩ tests
	Do not reuse
IVD	*In vitro* diagnostic medical device
	Temperature limitation
	Do not use, if the package is damaged
	Upper side
	Manufacturer

Manufacturer: Feng Chun Yuan Medical Equipment(Shenzhen)Co.,Ltd
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