

# Canine Parvovirus Antigen Test Device Package Insert

Language English



For Veterinary Use Only

## INTENDED USE

The Canine Parvovirus Antigen Test Device is intended for the qualitative detection of canine parvovirus (CPV) antigens (Ag) from the dog's fecal secretions.

## PRINCIPLE

This product mainly uses immunochromatographic technology to detect canine parvovirus antigen. During testing, target antigens, if present in the corresponding secretions, will be released into the extraction buffer. As the specimen migrates along the strip by capillary action and then interacts with reagents on the Sample Pad, the target antigens will bind to antibodies on the Conjugate Pad. Consequently, the antigen-antibody complex will be captured by the antibodies immobilized at the Test Region. Excess colored particles will be captured at the Control Region of the NC membrane. The presence of a colored band in the test region indicates a positive result, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

## MATERIALS PROVIDED

- Individually Packed Test Devices
- Dilute Buffer
- Individually Wrapped Swab
- Package Insert

## PRECAUTIONS

- Do not use kit or components beyond the expiration date.
- Do not reuse.
- Do not touch the membrane of the strip.
- Do not use the different samples to avoid cross contamination.
- Use only the supplied test components. Do not replace the buffer with any other liquid.
- The test contains material of animal origin and should be handled as a potential biohazard.

## STORAGE AND STABILITY

- Store the Canine Parvovirus Antigen Test Device at 2-30°C (36-86°F) in a cool, dry place and keep out of direct sunlight when not in use.
- DO NOT FREEZE.
- The kit components are stable till the expiration dates marked on the corresponding outer packaging and containers.

## TEST PROCEDURE

### 1. Sample collection

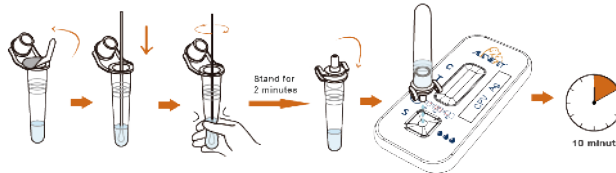
Specimen: Dog's fecal secretions.

- Collect canine feces with the provided swab. Peel off the aluminum foil cover of the extraction buffer and place the swab into buffer tube and rotate 6 to 8 times along the sides of the buffer bottle. For best results, the sample should be performed within one hour.
- Mix thoroughly and stand for 2 minutes.

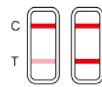
### 2. Testing

Please read the instructions carefully before testing. Bring devices, reagents and specimens and/or controls to room temperature (15~30°C) before use.

- Remove the test from its packing. Label the device with the pet's identification. For best results, the assay should be performed within one hour.
- Put the nozzle back to the buffer tube, transfer 3 drops of the specimen into the specimen well of the test device.
- Read the results at 10 minutes. Do not read the results after 15 minutes.



## INTERPRETATION OF RESULTS



**Positive:** Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



**Negative:** Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



**Invalid:** Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

## LIMITATIONS

The test is for veterinary use only, and should only be used for the qualitative detection of viral antigens specific for canine parvovirus. If there is a positive result, please confirm it with a confirmatory method. For other further clinical diagnosis, please consult the veterinarian.

## PERFORMANCE

### 1) Clinical study

Table: Canine Parvovirus Virus Antigen Test Device vs PCR

		PCR		Total
		+	-	
Relative Sensitivity: 93.9% (80.4%-98.3%)*	Parvovirus Rapid Test	+	31	33
Relative Specificity: 98.8% (95.6%-99.7%)*		-	2	163
Overall Agreement: 98.0% (94.9%-99.2%)*				196
*95% Confidence Interval				
			33	163

Specificity: This product has no cross reactivity with feline calicivirus, feline herpes virus, canine adenovirus and canine coronavirus.

## INDEX OF SYMBOLS

	Manufacturer		Consult instructions for use
	Temperature limitation		Catalog number
	Do not reuse		Contains sufficient for <n> tests
	Batch code		Used by
	Authorized representative in the European Community		



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