

Canine Parvovirus Antigen Rapid Test (CPV Ag)

REF: ABH-IC03-CPV

❖ INTENDED USE

The Canine Parvovirus Antigen Rapid Test is a lateral flow immunochromatographic assay for the qualitative detection of Canine Parvo virus antigen (CPV Ag) in dog's feces or vomit specimen.
Assay Time: 5-10 minutes

❖ PRINCIPLE

The Canine Parvovirus Antigen Rapid Test is based on sandwich lateral flow immunochromatographic assay. The test device has a testing window for the observation of assay running and result reading. The testing window has an invisible T (test) zone and a C (control) zone before running the assay. When the treated sample was applied into the sample hole on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated monoclonal antibodies. If there is CPV antigen in the specimen, a visible T line will appear. The C line should always appear after a sample is applied, which indicates a valid result. By this means, the device can accurately indicate the presence of parvovirus antigen in the specimen.

❖ REAGENTS AND MATERIALS

- Test devices, with disposable droppers
- Assay buffer
- Cotton swabs
- Products Manual

❖ STORAGE AND STABILITY

The kit can be stored at room temperature (4-30°C). The test kit is stable through the expiration date (18 months) marked on the package label. DO NOT FREEZE. Do not store the test kit in direct sunlight.

❖ TEST PROCEDURE

- Collect dog's fresh feces or vomit with the cotton swab from dog's anus or from the ground.
- Insert the swab into the provided assay buffer tube. Agitates it to get efficient sample extraction.
- Take out the test device from the foil pouch and place it horizontally.
- Suck the treated sample extraction from the assay buffer tube and place 3 drops into the sample hole "S" of the test device.
- Interpret the result in 5-10 minutes. Result after 10 minutes is considered as invalid.

❖ INTERPRETATION OF RESULTS

- Positive (+): The presence of both "C" line and zone "T" line, no matter T line is clear or vague.

- Negative (-): Only clear C line appear. No T line.
- Invalid: No colored line appears in C zone. No matter if T line appears.

❖ PERFORMANCE CHARACTERISTICS:

■ Clinical Sensitivity and Specificity

The CPV Ag Rapid Test has been valuated with specimens obtained from patients. A commercialized molecular assay was used as the reference method. The results show that the CPV Ag Rapid Test has a high overall accuracy.

Relative Sensitivity: 97.6%

Relative Specificity: 100%

Accuracy: 99%

Table 1: The CPV Ag Rapid Test vs RT-PCR

Result		RT-PCR Test Kit	
		Positive	Negative
Canine ParvoVirus Antigen Rapid Test	Positive	81	0
	Negative	2	114

■ Cross-reactivity and

There were no cross-reactivities of Coronavirus, Rotavirus, Giardia, Cryptosporidium, Coccidia, Toxoplasma and Distemper virus.

■ Interference

Not interfered for Feces, Bloody feces, and vomit.

❖ PRECAUTIONS

- All reagents must be at room temperature before running the assay.
- Do not remove test cassette from its pouch until immediately before use.
- Do not use the test beyond its expiration date.
- The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.
- All specimens are of potential infection. It must be strictly treated according to the rules and regulations by local states.

❖ LIMITATION

Canine Parvovirus Antigen Rapid Test is for in vitro veterinary diagnosis use only. All result should be considered with other clinical information available with veterinarian. It is suggested to apply a further confirmative method such as RT-PCR when positive result was observed.

















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❖ **Index of Symbols**

	Use by date		Consult instructions for use
	Contains sufficient for tests		Caution
	Date of Manufacture		Manufacturer
	In vitro diagnostic medical device		Temperature limit
	Batch Code		Do not reuse
	Catalog Number		Do not use if package is damaged
	Keep dry		Keep away from sunlight

