



Prodox Vital GmbH – Eichweberstr. 4 – 25821 Bredstedt

Technical Data

Canine parvovirus Antigen Rapid Test

Relative Sensitivity and Specificity Studies



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Specification

Product Name	Canine parvovirus Antigen Rapid Test
Intended Use	Immunochromatographic assay for the qualitative detection of Canine parvovirus antigen (CPV Ag)
Specimens	dog's feces or vomit specimen
Reagents and Materials	<ul style="list-style-type: none">■ 1 test pouch, with cards and disposable droppers■ 1 vial of assay buffer■ 1 bags of cotton swab stick■ 1 package insert
Storage and Stability	2-30°C, 18 months
Interpretation of Results	<ul style="list-style-type: none">■ 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.

1. Technical Data

1) Relative Sensitivity and Specificity Studies

i. Study Design

Relative sensitivity and specificity studies were performed to a panel of clinical specimen by comparing with a commercial PCR kit. Record the result running by the Canine parvovirus Antigen Rapid Test and the PCR result into a sheet. Count the amount of positive and negative result by Canine parvovirus Antigen Rapid Test and RT-PCR kit. Fill the data into the result sheet. All specimen were enrolled from November 2017 to April 2018. Result by Canine parvovirus Antigen Rapid Test were performed on site at room temperature, while the specimen were collected and performed in lab for RT-PCR.

ii. Calculation formulations

Specificity = VN test/Neg ref X 100%

Sensitivity = VP test/Pos ref X 100%

Accuracy = (VN test + VP test)/total sample amount

iii. Acceptance Criteria

The relative sensitivity of Canine parvovirus Antigen Rapid Test specimen in this study



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should be higher than 85%. The specificity of Canine parvovirus Antigen Rapid Test in this study should be higher than 90%.

iv. Result

Result		RT-PCR Test	
		Positive	Negative
Canine parvovirus Antigen Rapid Test	Positive	81	0
	Negative	2	114
Relative Sensitivity		97.6%	
Relative Specificity		100%	
Relative Accuracy		99.0%	

v. Discussion

The relative sensitivity and specificity of the Canine parvovirus Antigen Rapid Test is acceptable compared with RT-PCR result.