



Prodox Vital GmbH – Eichweberstr. 4 – 25821 Bredstedt

Technical File

Canine Giardia Antigen Rapid Test

Relative Sensitivity and Specificity Studies



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Specification

Product Name	Canine Giardia Antigen Rapid Test
Intended Use	Immunochromatographic assay for the qualitative detection of Giardia antigen (Giardia Ag) in dog's feces or vomit specimen
Specimens	dog's feces or vomit specimen
Reagents and Materials	<ul style="list-style-type: none">■ 1 test pouches, with cards and disposable droppers■ 1 vials 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

a. Study Design

Relative sensitivity, specificity, accuracy studies were performed to a panel of clinical specimen by comparing with a commercial ELISA method used in commercial laboratory. Records the results running by the Canine Giardia Antigen Rapid Test were photographed and stored on the hard disc. All the results were visually assessed and noted on the test sheet. All specimen were enrolled on May 2022. Result by Canine Giardia Antigen Rapid Test were performed In Laboratory of IAR&FR PAS at room temperature, while the specimen were collected by veterinarian clinic and ELISA test were performed in lab.

b. Calculation formulations

Specificity = $\text{VN test} / \text{Neg ref} \times 100\%$

Sensitivity = $\text{VP test} / \text{Pos ref} \times 100\%$

Accuracy = $(\text{VN test} + \text{VP test}) / \text{total sample amount}$

c. Acceptance Criteria

The relative sensitivity of Canine Giardia Antigen Rapid Test specimen in this study should be higher than 85%. The specificity of Canine Giardia Antigen Rapid Test in this study should be higher than 90%. study should be higher than 90%.

d. Result

Result		RT-PCR Test	
		Positive	Negative
Canine Giardia Antigen Rapid Test	Positive	46	0
	Negative	5	13
Relative Sensitivity		90.01%	
Relative Specificity		100%	
Relative Accuracy		92.18%	

e. Discussion

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

2) Specificity and Cross-reactivity Studies

i. Study Design

Specificity studies were performed to a panel of 20 cases negative secretions from dog's feces or vomit specimen. All specimen were prepared as they are described in the package insert. Record the result running by the Canine Giardia Antigen Rapid Test and fill the data into the result sheet. Cross-reactivity studies were performed to a panel of clinical positive specimen (Coronavirus, Rotavirus, Parvovirus, Cryptosporidium, Coccidia, Distemper virus, Toxoplasma) confirmed by PCR method. Record the result running by the Canine parvovirus Antigen Rapid Test and fill the data into the result sheet.

ii. Acceptance Criteria

All the clinical negative specimen should be negative by Canine Giardia Antigen Rapid Test. All other disease specimen should be negative tested by Canine Giardia Antigen Rapid Test. No false positive to any of the specimen.

iii. Results

Nr.	Specimen	Result	Nr.	Specimen	Result
1	Feces	-	11	Feces	-
2	Feces	-	12	Feces	-
3	Feces	-	13	Feces	-
4	Feces	-	14	Feces	-
5	Feces	-	15	Feces	-
6	Feces	-	16	Feces	-
7	Feces	-	17	Bloody feces	-
8	Feces	-	18	Bloody feces	-
9	Feces	-	19	Vomit	-
10	Feces	-	20	Vomit	-

Nr.	Specimen	Result	Nr.	Specimen	Result
1	Coronavirus positive	-	5	Coccidia positive	-
2	Rotavirus positive	-	6	Distemper virus positive	-
3	Parvovirus positive	-	7	Toxoplasma positive	-
4	Cryptosporidium positive	-	8		-

iv. Discussion

The specificity and cross-reactivity of the Canine Giardia Antigen Rapid Test is acceptable in the studies.

3) Precision/Reproducibility Studies

i. Study Design

Precision/reproducibility studies were performed to the Canine Giardia Antigen Rapid Test using diluted positive specimen to the following concentrations with the assay buffer: 1:2, 1:4, 1:8, 1:16, 1:32 and negative (assay buffer). The samples were aliquoted, coded, randomized and masked. Each specimen, at each concentration, was tested on a total of sixty (60) test devices from three different lots by three operators within four (4) times daily for five (5) consecutive days with a total 20 assays at each concentration. The results are displayed in the tables below.

ii. Acceptance Criteria

The precision (%) rate is higher than 95% when the negative and 1:2 dilution. The test device shows reproducible result in the tested three (3) lots.

iii. Result

	Concentration of sample	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	1:2	20	0/20	100
	1:4	20	0/20	100
	1:8	20	0/20	100
	1:16	20	2/18	90
	1:32	20	19/1	5
	0 (assay buffer)	20	20/0	100
Lot 2	1:2	20	0/20	100
	1:4	20	0/20	100
	1:8	20	0/20	100
	1:16	20	2/18	90
	1:32	20	19/1	5
	0 (assay buffer)	20	20/0	100
Lot 3	1:2	20	0/20	100
	1:4	20	0/20	100
	1:8	20	0/20	100
	1:16	20	1/19	95
	1:32	20	19/1	5
	0 (assay buffer)	20	20/0	100



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iv. Discussion

In the studies, the precision (%) rate of the Canine Giardia Antigen Rapid Test is higher than 95% when the negative and 1:2 dilution. The test device shows reproducible result in the tested three (3) lots.

4) Stability Studies

i. Study Design

Stability studies were performed to the Canine Giardia Antigen Rapid Test using negative (assay buffer), weak positive (1:16), and positive (1:2) specimen. The Canine Giardia Antigen Rapid Tests were placed at 15-25°C for 24 months (humidity is in normal state, approx. 20% to 90%) and tested its performance characteristics in a fixed day every 3 months. Each sample run a double check.

ii. Acceptance Criteria

All Tests must be stable in 2 years from manufacturing date.

iii. Result

	Negative specimen (assay buffer)		Weak positive (1:16)		Positive (1:2)	
	1	2	1	2	1	2
24th month	-	-	+	+	+	+
21st month	-	-	+	+	+	+
18th month	-	-	+	+	+	+
15th month	-	-	+	+	+	+
12th month	-	-	+	+	+	+
9th month	-	-	+	+	+	+
6th month	-	-	+	+	+	+
3rd month	-	-	+	+	+	+

iv. Discussion

The Canine Giardia Antigen Rapid Test was stable in 2 years from manufacturing date.

4. Packing Materials

1) Packing Size

10 Tests per kit (box), dimension: 15.5cm*10cm*8cm

100 Boxes per paper carton, dimension: 63cm*43cm*43cm