Canine Parvovirus Antigen Test Kit
Product Code 5024.01

Research Report: Product Validation Study

November 24, 2015

SafePath Laboratories, LLC

U.S. Veterinary License No. 430

Canine Parvovirus Antigen Test Kit
Product Code 5024.01

I. OBJECTIVE: SafePath Laboratories, LLC, U.S. Veterinary License No. 430, has carried out the study described within this report to validate the overall performance of the SafePath Canine Parvovirus Antigen Test Kit, Product Code 5024.01, as compared to the gold standard testing method of Hemagglutination (HA) / Hemagglutination-Inhibition (HI).

II. PERSONNEL: Testing for this study was performed at SafePath Labs, LLC in Carlsbad, CA by Diane Quan from November 11, 2015 through November 13, 2015.

III. MATERIALS:

a) Canine Parvovirus Antigen Test Kit Serial LN1187 was made per the current accepted Outline of Production dated November 13, 2013.

b) 200 Canine Parvovirus (CPV) positive and negative canine fecal samples were provided by the RD Schultz Lab Testing Services, University of Wisconsin School of Vet Med, Madison, WI 53706 where they were characterized using Hemagglutination (HA) / Hemagglutination-Inhibition (HI) by Dr. Laurie Larson.

Note: See Appendix A for the procedure used at the Schultz Lab.

IV. METHOD: All 200 samples were run on Canine Parvovirus Antigen Test Kit serial LN1187. The study was conducted by a qualified technician following Section V.C. of the Outline of Production, with the exception that tests were read only visually, not using the Un-Scan-It instrument.

a) All samples were aliquoted, randomized and given identification numbers of 1-200 by Dr. Larson so that their characterization would be unknown to the testing technician at SafePath Labs.

b) Randomized and blinded samples were split into 2 boxes, each containing 100 samples, and shipped on dry ice to SafePath Labs. The samples did not arrive with any paperwork showing their positive or negative status.

c) Dr. Larson provided the gold standard results to Chris Lambillotte at SafePath Labs via email; Ms. Quan did not have access to these results.

V. RESULTS: All testing results of a positive or negative sample were determined by a visual reading of the test and control lines. There will be three possible interpretations of the testing results:

1. Positive: A line will be visible in the test and control line area of the device.
2. Negative: A line will be visible in only the control line area of the device.

3. Invalid: A line will be visible in only the test line area of the device or if no lines are visible in both the test and control line areas of the device.

See Appendix B under the "Incoming Core Documents" folder of the electronic submission for the data generated for this report. False positive results are highlighted in yellow; there were no false negative results. Additionally, a .csv version of the same data is provided under the "Statistical Data" folder of the electronic submission.

A summary of the results is as follows:

	Serial LN1187	
	HA/HI Positive	HA/HI Negative
SafePath Positive	100	1
SafePath Negative	0	99

Sensitivity: 100% (100/100) 95% CI = 96.3% to 100%
Specificity: 99% (99/100) 95% CI = 94.6% to 99.8%

VI. DISCUSSION:

a) Serial LN1187 showed a high degree of sensitivity and specificity as compared to the gold standard methods of HA/HI. The sensitivity when compared to the gold standard was 100% while the specificity was 99%.

b) All 200 tests gave a valid result as all control lines were clearly visible.

VII. CONCLUSION: The results of this study demonstrate that the SafePath Canine Parvovirus Antigen Test Kit, Product Code 5024.01, has the required ruggedness, sensitivity and specificity to be license by the USDA and is suitable for use in veterinary diagnostic laboratories.

Chris Lambillotte

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APHIS Liaison

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TEST REPORT

NO.: SD-190503X
Date: 2021.08.24

1. Product name : CPV Ag Test (canine parvovirus Ag Test)
2. Company : Bioguard
3. Test period : 2021.05.03-2021.08.23
4. Date issued : 2021.08.24
5. Test result

Sample:

47 CPV infected-positive specimens.
35 CPV non-infected-negative specimens.

Procedure:

a) Collect dog's feces with the swab. Insert and mix the specimen swab into the assay buffer tube.
b) Add 4 drops of specimen extraction into test cartridge slowly by dropper.
c) Results interpretation.
Positive: the appearance of control and test line.
Negative: the appearance of control line only.
Invalid: no appearance of control line.

	Real time PCR (+)	Real time PCR (-)	Total
CPV Ag Test (+)	45	0	45
CPV Ag Test (-)	2	35	37
Total	47	35	82

6. Statistical analysis

Sensitivity: 95.74%
Specificity: 100.00%
Accuracy: 97.56%

7. Condition

Temperature 25±10℃, Relative Humidity 65±15%

8. Reference

a. Vet Microbiol. 2005 Jan 5;105(1):19-28.
b. Journal of virological methods, 2005, 126(1): 179-185.

The requirements of the specification are only for reference, veterinarians should consider other clinical information to make the definitive diagnosis in practice.

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