



**Biogal** | ACADEMY

## In-clinic Titer Test Study

Netherland & Belgium  
May 5<sup>th</sup>, 2021

# Objectives

1. Compare three commercial in-clinic titer tests:
  - **Canine VacciCheck (Biogal, Israel)**
  - RapidStatus Titer Test (Biotech Laboratories, USA)
  - FASTest CDV-CPV Ab (Megacor, Austria)
2. Evaluate the practicality of introducing the POC kits into a clinic.
3. Examine the performance of the kits at 5 veterinary clinics in the Netherlands **(4 Netherland, 1 Belgium)**.
4. Compare the accuracy of the kits by comparing to reference laboratory gold standard (Animal Health Diagnostic Laboratory, Cornell USA).

**\*\* The study was limited to sensitivity evaluation only due to the absence of non-vaccinated dogs. \*\***

# Background

Kit	RapidStatus	FasTest	VacciCheck
<b>Technology</b>	Lateral Flow	Lateral Flow	Solid phase ELISA (dot blot)
<b>Structure</b>	3 tests/cassette	2 tests/cassette	12 tests/comb – 3 tests/tooth
<b>Tests/unit</b>	CPV, CDV, CAV	CPV, CDV	CPV, CDV, CAV
<b>Hands-on time</b>	10 min	10 min	23 min
<b>Sample</b>	blood/serum	blood/plasma/serum	blood/serum/plasma
<b>Analysis</b>	Qualitative Visually by user	Semi quantitative Mobile hand-held reader	Semi quantitative CombCam

\*Manufacturers declare comparable performance with Gold-Standard Antibody titer assays VN (SN) and HI.

\*\*Only VacciCheck have been evaluated and approved by the USDA (USA) and MAFF (Japan).



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# Participants

	Name	Affiliation
<b>Principal investigator</b>	Dr. Tomer Keren, PhD	Biogal Galed Labs, Israel
<b>Study coordinator</b>	Ms. Zohar Shasha	Biogal Galed Labs, Israel
<b>Study coordinator</b>	Dr. Dietske Dijkman	NML Health, Netherlands
<b>Veterinary Clinic A</b>	Dr. Karin Salomon, DVM	Dierenkliniek Lunetten, Netherlands
<b>Veterinary Clinic B</b>	Dr. Thamar de Lange, DVM	A7 Noord Drachten, Netherlands
<b>Veterinary Clinic C</b>	Dr. Annemieke Calis, DVM	Annemieke Calis, Netherlands
<b>Veterinary Clinic D</b>	Dr. Odette Radier, DVM	Dap Den Bommel, Netherlands
<b>Veterinary Clinic E</b>	Dr. Jolanda Krosse, DVM	Jolanda Krosse, Belgium



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# Study Design

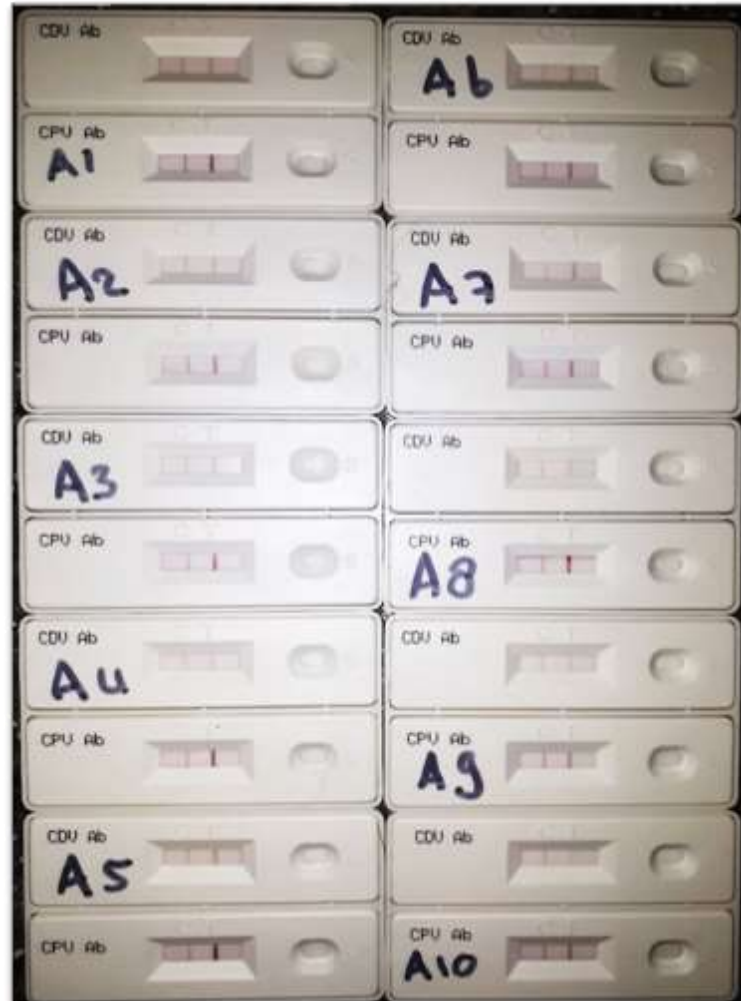
## **Prospective comparative study (fresh plasma samples)**

- 5 clinics (4 in the Netherland and 1 in Belgium).
- 7-10 healthy adult dogs with known vaccination history.
- Tests performed sequentially. Results recorded in results-form + photographic documentation.
- Aliquot of plasma sent frozen for gold standard titer tests (SN and HI) AHDC, Cornell University.



# Photographic Documentation (A1-10)

FasTest

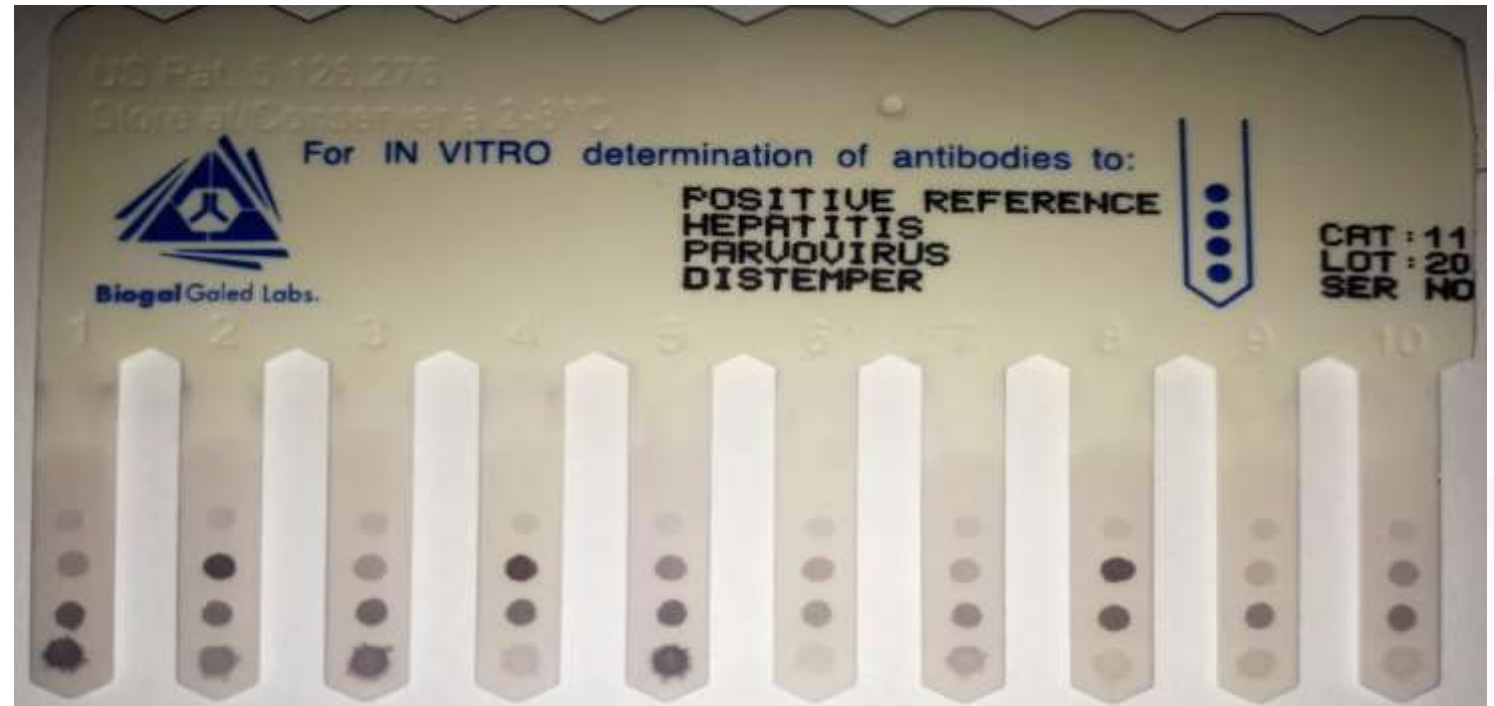


RapidStatus



# Photographic Documentation (A1-10)

**VACCI**Check<sup>®</sup>  
by **Biogal** Galed Labs.





# Results



Sample	Patient information			VacciCheck Visual			VacciCheck CombCam			RapidStatus			FASTest		Cornell					
	Age	Last Vaccination Date	Vaccine	CAV	CPV	CDV	CAV	CPV	CDV	CAV	CPV	CDV	CPV	CDV	CAV	CAV SN Titer	CPV	CPV HI Titer	CDV	CDV SN Titer
A1	2.5	19/07/2018	Nobivac DHP	4	5	5.5	5	6	6	N	P	P	PH	PH	Pos	128	Pos	2560	Pos	4096
A2	6	11/05/2016	Nobivac DHP	5.5	5	4.5	6	6	6	P	P	WP	PH	PC	Pos	2048	Pos	1280	Pos	512
A3	7	07/01/2013	Nobivac DHPPi	5	5.5	5.5	5	6	6	N	P	P	PH	PH	Pos	512	Pos	2560	Pos	512
A4	3.5	23/06/2017	Nobivac DHP	6	5	3	6	6	4	P	WP	N	PH	PC	Pos	4096	Pos	2560	Pos	32
A5	2	29/12/2018	Nobivac DP	5	5.5	5.5	6	6	6	WP	P	P	PH	PH	Pos	128	Pos	5120	Pos	1024
A6	5	13/01/2016	Eurican DHPPi	4.5	4.5	2	5	6	3	P	P	N	PH	PH	Pos	32	Pos	320	Pos	32
A7	9	28/01/2019	Nobivac DHP	4	5	4	5	6	5	N	WP	WP	PC	PH	Pos	512	Pos	640	Pos	128
A8	3.5	23/06/2017	Nobivac DHP	6	5	3	6	6	3	WP	P	N	PH	PC	Pos	2048	Pos	5120	Pos	16
A9	6	25/03/2016	Nobivac DHP	4	5	3	4	6	4	N	P	N	PH	PW	Pos	64	Pos	1280	Pos	64
A10	8	25/03/2016	Nobivac DHP	4.5	5	3	5	6	3	N	P	N	PH	PW	Pos	256	Pos	1280	Pos	32
B1	2.5	10/11/2019	Nobivac DHP+L4	4.5	5	5	4	6	6	N	WP	WP	PC	PW	Pos	128	Pos	640	Pos	256
B2	8	29/06/2017	Nobivac DHP+L4	4	5	4.5	4	6	6	N	N	N	PC	PW	Pos	64	Pos	640	Pos	128
B3	3	20/07/2018	Nobivac DHP+L4	5	5.5	5	6	6	6	WP	N	P	PH	PH	Pos	64	Pos	2560	Pos	256
B4	3	27/05/2019	Nobivac DHP+L4	4	5.5	6	5	6	6	WP	WP	WP	PH	PC	Pos	32	Pos	2560	Pos	256
B5	6	30/01/2019	Nobivac DHP+L4	4.5	5	6	6	6	6	N	WP	WP	PH	PC	Pos	256	Pos	2560	Pos	32
B6	10	28/09/2017	Nobivac DHP+L4	4	5	2	4	5	3	N	N	N	PW	PC	Pos	32	Pos	80	Pos	16
B7	6	17/06/2020	Nobivac DHP+L4	5.5	5.5	6	6	6	6	WP	N	WP	PH	PW	Pos	1024	Pos	1280	Pos	256
B8	9	12/07/2018	Nobivac DHP+L4	4	5	4	5	6	6	N	WP	WP	PH	PC	Pos	64	Pos	1280	Pos	128
B9	7.5	03/05/2013	Nobivac DHP+L4	4	5.5	5	5	6	6	N	N	WP	PH	PC	Pos	64	Pos	2560	Pos	128
C1	9	24/03/2013	Nobivac DHPPi	1	0	2	1	1	2	WP	N	N	PW	PH	Pos	8	Pos	40	Pos	32
C2	9	01/03/2013	Nobivac DHPPi	6	6	6	6	6	6	WP	WP	N	PH	PH	Pos	128	Pos	640	Pos	32
C3	4	01/11/2016	Vanguard 7	5	4	6	4	4	6	WP	N	P	PC	PH	Pos	32	Pos	80	Pos	256
C4	7	21/12/2016	Veriscan DHPPi	6	6	5	6	6	5	WP	P	WP	PH	PH	Pos	32	Pos	640	Pos	32
C5	4	03/02/2017	Nobivac DHP	6	6	6	6	6	6	WP	P	WP	PH	PH	Pos	128	Pos	1280	Pos	128
C6	1	30/01/2020	Veriscan DHPPi+Nobivac P	6	6	3	6	6	3	P	P	WP	PH	PH	Pos	1024	Pos	1280	Pos	128
C7	1	25/02/2020	Veriscan DHPPi	6	6	5	6	6	5	WP	P	WP	PH	PH	Pos	32	Pos	640	Pos	64
D1	12	30/11/2010	Nobivac DHP	5	5	4	6	6	4	N	P	WP	PH	PC	Pos	32	Pos	1280	Pos	16
D2	12.5	26/02/2015	Nobivac DHP	4	4	4	5	4	4	N	WP	N	PC	PH	Pos	32	Pos	80	Pos	16
D3	3	04/12/2017	Nobivac DHP	5	6	5	6	6	6	N	P	WP	PH	PC	Pos	256	Pos	640	Pos	256
D4	12	07/06/2011	Nobivac DHP	3	5	4	5	6	6	N	P	N	PH	PC	Pos	32	Pos	640	Pos	64
D5	5.5	31/12/2015	Nobivac DHP	6	5	4	6	5	5	P	P	WP	PH	PH	Pos	2048	Pos	640	Pos	256
D6	13	19/09/2019	Nobivac DHP	4	5	4	4	5	4	N	N	N	PW	PC	Pos	8	Pos	160	Pos	16
D7	10	18/07/2015	Nobivac DHP	5	5	4	6	5	5	P	N	WP	PH	PH	Pos	256	Pos	640	Pos	256
D8	7.5	24/07/2015	Nobivac DHP	5	5	4	6	6	6	WP	N	N	PC	PC	Pos	64	Pos	320	Pos	64
D9	3	06/01/2019	Nobivac DHP	5	5	5	6	6	6	P	P	N	PH	PH	Pos	1024	Pos	1280	Pos	1024
D10	3.3	25/11/2017	Nobivac DHP+PC	3	5	5	3	6	6	P	P	N	PH	PH	Pos	8	Pos	2560	Pos	4096
E1	5	05/09/2016	Nobivac DHP	4.5	6	4	6	6	6	WP	P	P	PH	PH	Pos	256	Pos	2560	Pos	2048
E2	1	22/10/2020	Versican DHP	4	6	2	4	6	3	N	P	N	PH	PH	Pos	64	Pos	1280	Pos	128
E3	9	09/07/2015	Nobivac DHP	5	6	3	6	6	4	N	P	P	PH	PH	Pos	512	Pos	2560	Pos	64
E4	11	01/12/2015	Nobivac DHP	3	4	3	4	6	5	WP	P	WP	PH	PH	Pos	128	Pos	640	Pos	128
E5	7	01/12/2015	Nobivac DHP	5	6	3	6	6	4	WP	P	N	PH	PH	Pos	256	Pos	2560	Pos	128
E6	3	24/02/2018	Nobivac DHP	4	6	4	5	6	5	N	WP	WP	PH	PH	Pos	256	Pos	2560	Pos	256
E7	6	23/10/2018	Nobivac DHPPi	6	6	3	6	5	4	N	P	N	PC	PC	Pos	256	Pos	640	Pos	16
E8	10	10/05/2017	Nobivac DHP	6	6	3	6	6	4	P	P	WP	PH	PH	Pos	1024	Pos	5120	Pos	256
E9	4	18/05/2020	Nobivac DHP	3.5	5.5	4.5	4	6	6	N	P	P	PH	PC	Pos	512	Pos	1280	Pos	512
E10	1	06/04/2020	Virbac CAN DHPPi/L	6	6	3	6	6	3	WP	P	N	PH	PH	Pos	64	Pos	1280	Pos	128

# Results

Sensitivity compared to the gold standards (SN/HI) performed at AHDC Cornell

	Canine Distemper Virus (N=46)		
	VacciCheck	FasTest	RapidStatus
True Positive	45	45	26
True Negative	0	0	1
False Positive	1	1	0
False Negative	0	0	19
Sensitivity (CI) %	100 (CI 92.1-100)	100 (CI 92.1-100)	58 (CI 42.2-72.3)

	Canine Parvovirus (N=46)		
	VacciCheck	FasTest	RapidStatus
True Positive	45	45	36
True Negative	0	0	0
False Positive	0	0	0
False Negative	1	1	10
Sensitivity (CI) %	97.8 (CI 88.5-99.9)	97.8 (CI 88.5-99.9)	78.3 (CI 63.6-89.1)

	Canine Adenovirus (N=46)	
	VacciCheck	RapidStatus
True Positive	43	24
True Negative	0	1
False Positive	2	1
False Negative	1	20
Sensitivity (CI) %	97.7 (CI 88.0-99.7)	54.6 (CI 38.9-69.6)

# Results

**RESULTS:** The Gold Standard tests determined that:



**46**  
**CPV**



**46**  
**CDV**



**46**  
**CAV**



**SENSITIVITY**



**VACCI**Check<sup>®</sup>  
by **Biogal** Coated Labs.

(Biogal, Israel)

**98%**

**100%**

**98%**

**RapidStatus Titer Test**

(Biotech Laboratories USA)

**78%**

**58%**

**55%**

**FASTest CDV-CPV Ab**

(Megacor, Austria)

**98%**

**100%**

Does not  
test for **CAV**

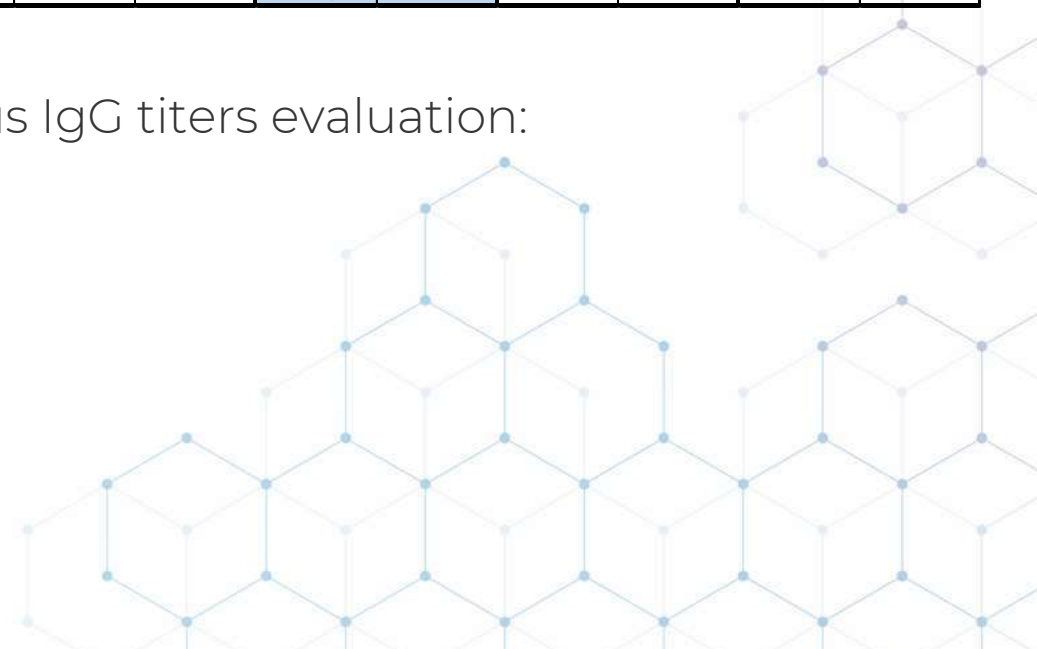
# Results

Interpretation of 3 discrepant results between the rapid tests and gold standards

Sample ID	Patient information			VacciCheck visual score			RapidStatus			FASTest		Cornell					
	Dog Age	Last vaccination Date	Last vaccine type	CAV	CPV	CDV	CAV	CPV	CDV	CPV	CDV	CAV	CAV SN	CPV	CPV HI	CDV	CDV SN
D1	12	30/11/2010	Nobivac DHP	5	5	4	N	P	WP	PH	PC	Pos	32	Pos	1280	Neg	16
D6	13	19/09/2019	Nobivac DHP	4	5	4	N	N	N	PW	PC	Neg	8	Pos	160	Pos	16
D10	3.3	25/11/2017	Nobivac DHP+PC	3	5	5	P	P	N	PH	PH	Neg	8	Pos	2560	Pos	4096

Serum Neutralization: Distemper Virus and Adenovirus IgG titers evaluation:

- 8-32 Low
- 64-128 Medium
- 268 -512 High
- >1024 Very High



# Summary

**46**  
Vaccinated  
Dogs



The accuracy of the **three in-clinic test kits** was evaluated against the Gold Standards

- FasTest kit - all of the 46 samples all were positive for CDV and 45 samples were positive for CPV. \*\*Note that few tests showed clear visible line but weaker than the control line hence if strictly follow the FasTest IFU should be considered as not protected\*\*.
- VacciCheck - all of the 46 samples all were positive for CDV and 45 samples were positive for CPV, providing 100% agreement with the **FasTest** kit.
- Both the VacciCheck and **FasTest** showed excellent sensitivity compared to the gold standard CDV SN (100%) and CPV HI (98%).
- VacciCheck also identified 43 samples positive for CAV, a target test not available on the FasTest kit. When compared to the gold standard CAV SN the sensitivity was 98% (2 false positive and 1 one false negative).

# Summary - RapidStatus

- When RapidStatus results were compared to the gold standards, the sensitivities were **58%, 78% and 55% for CDV, CPV and CAV respectively**. The performance of the RapidStatus was relatively low compared to **VacciCheck** and FasTest.
- On many of the reactive RapidStatus tests, the visual appearance of the test lines was very weak and hard to define as positive or negative. The appearance of all of the **VacciCheck spots and the FasTest test line were easily interpreted.**
- For RapidStatus:- 10 samples showed positive results for all 3 antigens (CDV, CPV and CAV)
- 22 samples were positive for both CDV and CPV (24 cases would be interpreted as requiring revaccination due to negative CDV or CPV or both).
- The Duration of Immunity:- 13 dogs with 3 - 6 years since last vaccine 7 dogs with 7 - 9 years since last vaccination.
- According to the trial: 17 of these dogs were negative for CDV or CPV only on the RapidStatus. If this test was used, a question would arise as to revaccinate or not.

## Conclusions from this trial

- **VacciCheck** and FasTest kits had excellent agreement between themselves and with the gold standard laboratory methods.
- RapidStatus kit generated results different to those of **VacciCheck**, FasTest and the reference laboratory gold standard test.
- High rate of false negatives could lead to unnecessary revaccination of dogs.





# VacciCheck is more complex to operate than FasTest!

Added value for using **VacciCheck**

- 1. VacciCheck** measures CAV Ab while the FasTest does not. Some veterinarian dismisses the importance of CAV, it is still part of the recommendation by the **WSAVA Guidelines and this disease is still relevant.**
- 2. VacciCheck** test spots are permanently stable, while the FasTest results have no diagnostic value after 20 min. This is especially important when there is a need for a second review of the results.
- 3. Only VacciCheck** have been evaluated and **approved by the USDA (USA) and MAFF (Japan)** i.e the correlation between the titers values **generated by VacciCheck and the gold standard tests have been validated .**

# When to Use Titer Testing

## VACCINATION GUIDELINES - AAHA and WSAVA

- ✓ Determine whether a puppy/adult has responded to vaccination (Maternal antibodies, genetic non responders, faulty vaccine).
- ✓ Test newly adopted adult dogs of unknown vaccination history.
- ✓ Protect from side effects of over vaccination. Titer Test **INSTEAD** of automatic core revaccination for adult dogs.
- ✓ Management of outbreaks in shelters. Who to quarantine.
- ✓ Geriatric dogs



# Puppy Titer Testing

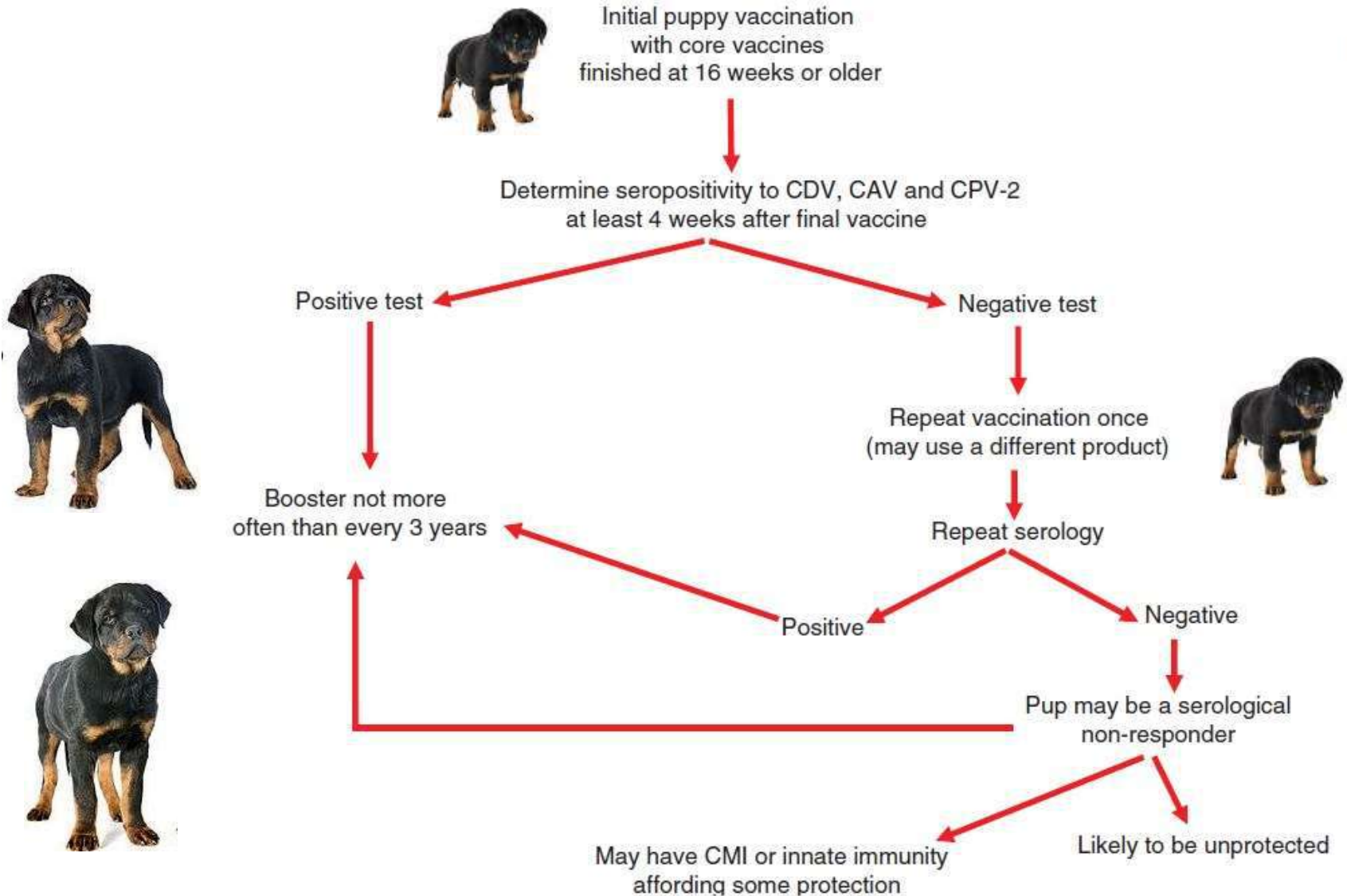


Fig 1. Flow chart for serological testing of puppies



**Biogal** Galed Labs.

**Thank You**



**VACCI**Check<sup>®</sup>  
by **Biogal** Galed Labs.

