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Product Information (30.10.07)

Name of Kit: **ImmunoComb[®] Canine VacciCheck IgG Antibody Test Kit**

Catalog No: 50CVV101/50CVV110

No of Tests: Standard Size: 12 samples X 3 antigens = 36 Tests
Lab Size: 120 samples X 3 antigens = 360 Tests

Intended Use: The ImmunoComb[®] Canine VacciCheck Test Kit is intended to evaluate the IgG antibody response to vaccination or infection by Infectious Canine Hepatitis (ICH), Canine Parvovirus (CPV) and Distemper Virus (CDV). A high antibody level is associated with immunity to infection (in well dogs) and is helpful for diagnosis of clinical cases.

Diagnostic Method: The ImmunoComb[®] test is based on solid phase "dot"-ELISA technology. Antigens are applied to test 'spots' on the solid phase, which is a comb-shaped plastic card. (The Comb has 12 teeth-sufficient for 12 test samples.)

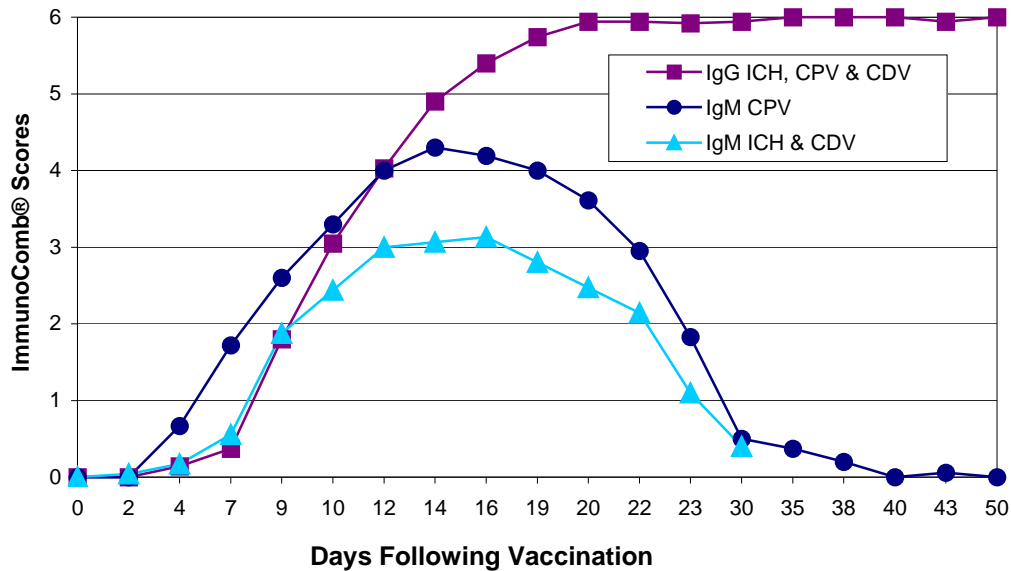
The samples to be tested are mixed with diluent in the first row of wells of a multi-chamber developing plate. The test spots on the Comb are then incubated with the sample in the developing plate. Specific IgG antibodies from the samples, if present, bind to the antigens at the test spots.

The Comb is then transferred to a well, where unbound antibodies are washed from the antigens spots. In the next step, the Comb is allowed to react with an anti-dog IgG Alkaline Phosphates conjugate, which will bind to antigen-antibody complexes at the test spots. After 2 more washes, the Comb is moved to the last well, where a color result develops via an enzymatic reaction. The intensity of the color result of test spots corresponds directly to the antibody level in the test sample.

Immunology: Serology can provide the veterinarian with information about the dog's immune status regarding previous vaccination or infection by particular disease agents. The humoral immune response is largely composed of 2 classes of antibodies, IgM and IgG. In immuno-competent dogs, IgM antibodies are initially produced in response to infection or following vaccination. IgM levels begin to decline within approximately 2 weeks and IgG

antibody levels start to rise. IgG remain elevated for months to years. Thus, high IgG titers may indicate recent vaccination or previous infection (See Fig. 1).

Fig. 1. Levels of IgG and IgM in Days Following Vaccination



Main Application: Provides information about humoral immune response to previous vaccination (or infection) with Infectious Hepatitis, Parvovirus and Distemper virus.

Infectious Hepatitis (IgG):	Specificity: 86%	Sensitivity: 98%
Parvovirus (IgG):	Specificity: 100%	Sensitivity: 97%
Distemper (IgG):	Specificity: 100%	Sensitivity: 95%

Other Diagnostic Methods:

- a) Hematology/ Blood chemistry – Routine hematologic tests (such as CBC) are helpful when abnormal results are present (e.g., lymphopenia), however, these tests are not specific for individual disease.
- b) Antigen Detection – Immunofluorescence, Fecal antigen, PCR.
- c) Other serologic methods – IFA, HI, VN.

Interpretation: The level of antibodies (i.e., antibody titer) is determined according to the intensity of the test color result. Thus, no or a trace of grey color indicates an absence of antibodies (negative). A faint color result that is lighter than the positive reference spot is considered low positive. On the ImmunoComb® Canine VacciCheck Test Kit a reference spot is provided on each comb tooth (top spot), that is calibrated to develop a distinct grey color. This is the same color that is generated by a significant¹ positive result. Please refer to Table 1.

Table 1. Interpretation of Results

ImmunoComb® Score	Color Result	Interpretation
0	White or trace of grey	Negative. No detectable antibodies to ICH, CPV or CDV.
1 – 2	Faint grey	Low Positive. Not considered to be a protective level of antibodies to ICH, CPV or CDV.
3 – 4	Distinct grey	Significant Positive. Consistent with protective level of antibodies to ICH, CPV or CDV. Revaccination is not needed.
5 – 6	Dark grey	High Positive. High level of humoral immunity to ICH, CPV or CDV. Revaccination is not needed.

¹ ‘Cut-off’ positive values (**S3**): ICH 1:40 VN, CPV 1:80 HI, CDV 1:80 VN.

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