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Product Information (1.4.07)

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

Catalog No: 50CLC201/50CLC210

No of Tests: 12 (Standard-size Kit)/ 120 (Lab-size Kit)

Intended Use: The Kit is designed to determine dog serum IgG antibody titer to *Leptospira* serovars mix: *canicola*, *icterohaemorrhagiae* (*copenhageni* and RGA), *pomona* and *grippotyphosa*.

Diagnostic Method: The ImmunoComb[®] test is based on solid phase "dot"-ELISA technology. Antigen is 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 samples in the developing plate. Specific IgG antibodies from the samples, if present, bind to the antigen at the test spots.

The Comb is then transferred to a well, where unbound antibodies are washed from the antigen spots. In the next step, the Comb is allowed to react with an anti-dog IgG alkaline phosphate 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.

Sensitivity: 80%

Specificity: 60%

Pathophysiology: Leptospirosis is an infectious disease of animals and humans, which is caused by a spirochete of the genus *Leptospira*. Widespread vaccination of dogs with a bacterin of the 2 major canine *Leptospira* serovars (*canicola* and *icterohemorrhagiae*) has reduced but not eliminated the incidence of canine leptospirosis.

Leptospira invade the body through mucous membranes, wounds or intact skin. Within a week, organisms can spread via the blood to all parts of the body stimulating an early antibody response. The liver and kidney are the organs, which are primarily affected and death may result from acute septicemia or hemolytic anemia. In cases that survive, Leptospira may localize in the renal tubules, damage the kidneys and be shed in the urine for prolonged period.

Clinical Signs: Leptospiral infections in dogs are associated with both acute disease and a mild subclinical state. Typical acute signs include fever, jaundice, mucous membrane congestion and hemoglobinuria. The acute form is more common in puppies and frequently results in death. Vomiting and diarrhea associated with intestinal intussusception have been noted with some frequency in dogs with subacute infections. In subclinical infections, Leptospira typically localize in the renal tubules resulting in a carrier state whereby organisms are shed in the urine. Leptospira in healthy vaccinated dogs has been reported. This represents a potential health risk to pet owners and caretakers.

Diagnostic Methods: Thrombocytopenia is a common hematologic finding in canine leptospirosis. White blood cell counts fluctuate, depending upon the stage and severity of infection.

A leukocytosis with a left shift develops after a leukopenia that is seen in the leptospiremic stage. Elevated levels of BUN, creatinine, ALT and AST are associated with insult to the kidney and liver.

The microscopic agglutination test (MAT) is the standard laboratory method to serologically diagnose leptospirosis. The MAT has several significant limitations: (1) It requires a dark field microscopy, (2) It is relatively non-specific, so numerous antigens are required to identify the etiologic serovar, and (3) MAT antibody titers are often negative during the first week of illness.

Preferred Method of Diagnosis: Biogal's ImmunoComb[®] Antibody Test Kit is an enzyme immunoassay for serologic diagnosis of canine leptospira. The ImmunoComb[®] is very sensitive although not serovar specific, and is more user-friendly than the conventional ELISA or the MAT; it requires no additional laboratory equipment to process. Results, which can be read by eye, are obtained within 20 minutes.

Main Application: Provides information about natural exposure to Leptospira.

References:

Langston, C. E. and Heuter, K. J. (2003). Leptospirosis: A re-emerging zoonotic disease. *Veterinary Clinics Small Animals*, **33**, 791-807.