INTENDED USE
The VetScan Canine Ehrlichia Antibody Test Kit is a visual and rapid test for the qualitative detection of antibodies to *E. canis*, *E. chaffeensis* and/or *E. ewingii* in canine whole blood, serum or plasma. This test is for veterinary use only. Gram negative bacteria belonging to these *Ehrlichia* spp. are obligatory intracellular parasites and cause the disease known as Ehrlichiosis in man, dogs and some other animals. This disease is transmitted by a variety of tick species and has a world-wide distribution. Clinical signs of Ehrlichiosis differ in acute, sub-acute and chronic phases. The acute phase may be characterized by fever, anorexia, lethargy, lymphadenopathy and thrombocytopenia. Hypergammaglobulinemia (polyclonal or sometimes monoclonal gammopathy), thrombocytopenia and anemia are common occurrences in the sub-acute phase. Lethargy, weight loss, pancytopenia, bone marrow suppression and hemorrhage eventually leading to death may occur in the chronic phase of Ehrlichiosis. Signs and symptoms as well as the outcome of disease may differ somewhat with the species of *Ehrlichia* causing the infection.

The VetScan Canine Ehrlichia Antibody Test Kit uses synthetic peptides that bind antibodies produced in dogs in response to certain dominant antigens of the above three *Ehrlichia* spp. Co-polymers of these synthetic peptides with bovine serum albumin are coated on colloidal gold particles and used in a double antigen sandwich assay to visualize the presence of antibodies binding to such peptides. The antibodies bound to antigen-coated gold particles flows through the strip and are captured by immobilized antigen on the test strip. The accumulation of the captured gold particle/antibody complex causes a color to become visible on the Test line (T). The intensity of the colored line is further enhanced by an amplification mechanism. A procedural Control line (C) will always appear whether the sample is positive or negative.

INSTRUCTION FOR USE
- This Test is for the detection of *Ehrlichia* spp. antibodies in canine samples.
- Refrigerated or frozen samples must be at room temperature 15°C to 27°C (59°F to 80°F) before running the assay—DO NOT HEAT.
- Whole canine blood collected in any type of EDTA, heparin, or citrate tubes may be used within one day of collection, provided no visual clotting has occurred. Do not freeze whole blood or use whole blood that has been frozen. If whole blood is not used within two hours of draw, store refrigerated.
- Serum or plasma, either fresh, previously frozen, or stored at 2°C to 8°C (35°F to 46°F), may be used in this test. Serum or plasma may be stored for use up to 7 days at 2°C to 8°C (35°F to 46°F). For longer storage, sample should be frozen at -20°C (-4°F) or colder.
- Previously frozen or older serum or plasma samples must be centrifuged at >1600g to remove any particulate material before use.
- Excessive hemolysis may obscure the results.
- EDTA, heparin, or ACD in plasma will not affect the results.

STORAGE
- The Test Devices and Chase Buffer must be stored at 2°C to 27°C (35°F to 80°F) and never frozen.
- Test Devices and Chase Buffer are stable until expiration when stored at recommended temperatures.

KIT COMPONENTS
1. Test Devices
2. Chase Buffer Bottle
3. Transfer Pipettes
4. Instruction for Use

TEST PROCEDURE
1. Remove the Test Device from the protective pouch and place on a flat surface. Label the Test Device with the patient I.D. or control identification.
2. Gently mix the sample by inverting.
3. Using the Transfer Pipette provided, transfer one drop of sample (whole blood, serum or plasma) in to the sample well.
4. Let the sample absorb for 30-60 seconds.

PRECAUTIONS AND WARNINGS
- **Important:** Do not remove Test Device from the pouch until ready for use.
- Test Device must be used as soon as possible after removing from pouch and within a maximum of 15 minutes.
- For veterinary use only.
- Do not use components after expiration date.
5. Holding the Chase Buffer Bottle vertically, add 3 drops of the chase buffer into the sample well. Read the results within 8-10 minutes. High positive results may appear as soon as 1 minute, and low positive results may take up to 8-10 minutes to appear. Do not read results after 15 minutes. Colored lines which appear after 15 minutes are not diagnostic and should be ignored.

INTERPRETATION OF TEST RESULTS

Positive results
The test is positive if two colored lines appear. One colored line will appear at the Test line (T) area and other in the Control line (C) area. Any intensity of the Test line (T) should be considered positive. Colored lines may be lighter or darker than each other.

Negative results
The test is negative if only one line appears at the Control line (C) area.

Invalid results
The test is invalid if no colored line appears at the Control line (C) area even if a colored line appears at the Test line (T) area. Colored lines that appear after 15 minutes are not diagnostic and should be ignored.

REFERENCES