Canine Borrelia Burgdorferi Antibody Test Kit

VetScan®

FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO *BORRELIA BURGDORFERI* IN CANINE WHOLE BLOOD, PLASMA OR SERUM

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE ASSAY

Abaxis, Inc.
3240 Whipple Road
Union City, CA 94587
800-822-2947
www.abaxis.com

EC REP
Abaxis Europe GmbH
Otto-Hesse-Strasse
19 D-64293 Darmstadt
Germany
+49 6151 350 790

U.S. Veterinary License No. 424
For patent information,
see www.abaxis.com/about_us/patents

INTENDED USE

The VetScan Canine Borrelia Burgdorferi Antibody Test Kit is a visual and rapid test for the qualitative detection of antibodies to *Borrelia burgdorferi* in canine whole blood, serum or plasma. This test is for veterinary use only. *B. burgdorferi* is a spirochete that causes Lyme disease in dogs, and some other animals. The disease is transmitted by ticks and it has a world-wide distribution. Clinical signs of Lyme disease include fever, arthritis and less commonly glomerulonephritis, uveitis, myocarditis and neurologic signs.

The VetScan Canine Borrelia Burgdorferi Antibody Test Kit uses peptides that bind antibodies elicited in response to certain *Borrelia* antigens in an amplified lateral flow sandwich assay. Antigen-coated colloidal gold particles bind to *B. burgdorferi* antibody in the sample. The bound antibody flows through the strip and is then 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 *Borrelia Burgdorferi* antibodies in canine samples.
- Refrigerated or frozen samples must be at room temperature 15° to 27°C (59° 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° to 8°C (35° to 46°F), may be used in this test. Serum or plasma may be stored for use up to 7 days at 2° to 8°C (35° 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.

⚠ Caution 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.
- The Test Device should be used in a horizontal position on a flat surface while the test is performed. The Test Device should not be moved or tilted during the test procedure.
- Use a separate Transfer Pipette for each test.
- The Chase Buffer is not interchangeable from serial (lot) to serial (lot).
- Do not use a Test Device from a pouch that is obviously torn or damaged.
- Do not use a Test Device if it appears cracked, broken, or otherwise damaged.
- The Kit Components must not be frozen.

STORAGE

- The Test Devices and Chase Buffer must be stored at 2° to 27°C (35° 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.
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.

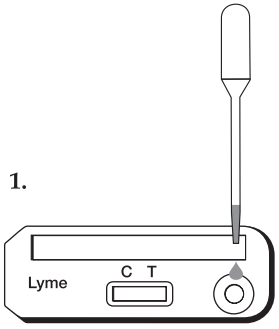
Invalid results
The test is invalid if no colored line appears at the Control line (C) area even if a colored line appears at the Test line (T) area. Colored lines that appear after 15 minutes are not diagnostic and should be ignored.

REFERENCES

Littman MP, Goldstein RE, Labato MA, Lappin MR, Moore GE. ACVIM small animal consensus statement on Lyme disease in dogs: diagnosis, treatment, and prevention. J Vet Intern Med. 2006 Mar-Apr;20(2):422-34.

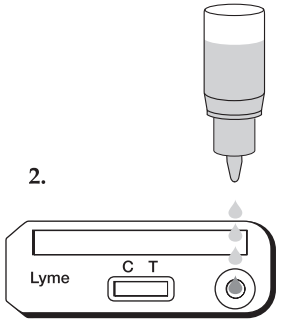
LYME TEST PROCEDURE

1.



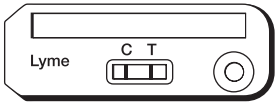
Add 1 drop of blood, serum or plasma to the sample well and wait 30-60 seconds.

2.



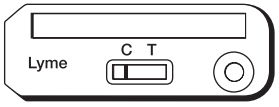
Add 3 drops of Chase Buffer to the sample well.

3. Results



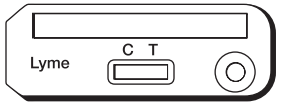
Read results within 8 to 10 minutes.

Positive Example



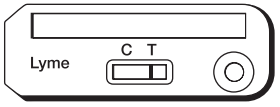
Read results within 8 to 10 minutes.

Negative Example



Read results within 8 to 10 minutes.

Invalid Example



Read results within 8 to 10 minutes.

Invalid Example

Use By

REF
Catalog Number

LOT
Batch Code

IVD
In Vitro Diagnostic Device

Consult Instructions for Use

Manufacturer

Do Not Reuse

X Number of Test Devices in Kit

BOX
Manufacturing Sequence

SN
Serial

EC REP
Authorized Representative in the European Community

Temperature Limitation

Caution
Precautions and Warnings

PN:
Part Number

For Veterinary Use Only

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