



For Veterinary Use Only

Leptospira IgM/IgG Ab Test

Leptospira IgM/IgG Antibody Test



Bioguard Leptospira IgM/IgG Ab Test is a sandwich lateral flow immunochromatographic assay, developed and manufactured by Bioguard Corporation, for rapid and qualitative detection of *Leptospira* spp. IgM and IgG Antibody in dog's blood. The test device has a testing window, coated by two invisible test band (T1-IgM and T2-IgG) and control band (C band). When sample is applied into the sample well on the device, the reagent will laterally flow on the surface of the test strip. If there is enough Leptospira Ab in the sample, a visible T band will appear. The C band should always appear after a sample is applied, indicating a valid result. By this means, the device can accurately indicate the presence of Leptospira Ab in the specimen.

KIT COMPONENTS

COMPONENTS	5 TESTS /Kit	10 TESTS /Kit
Leptospira IgM/IgG Ab test device	5	10
Disposable dropper	5	10
EDTA blood collection tube	5	10
Assay buffer bottle	1	1
Instruction manual	1	1

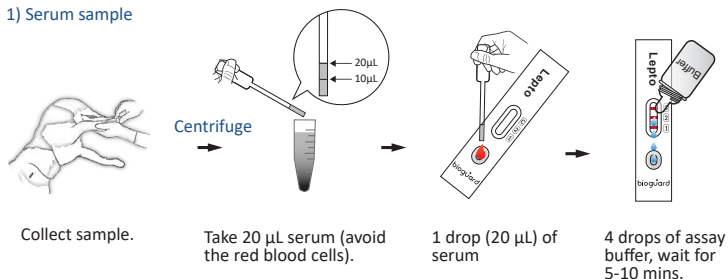
SPECIMEN

Dog's whole blood, serum or plasma.

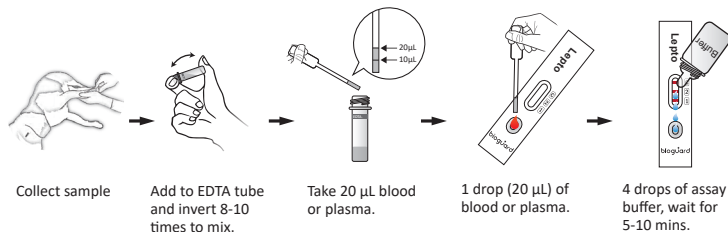
TEST PROCEDURE

- Remove the sealed pouch, assay buffer bottle and EDTA blood collection tube from the box.
- Take out the cassette from the foil pouch and place it horizontally on a clean surface.
- Take dog's whole blood, serum or plasma (centrifugation from EDTA tube) as sample.
- Take sample by disposable dropper, drip 1 drop (20µL) of sample and immediately drip 4 drops (100µL) of assay buffer into the well.
- Interpret the result in 5-10 minutes. The result after 10 minutes is not allowed to be read.

1) Serum sample

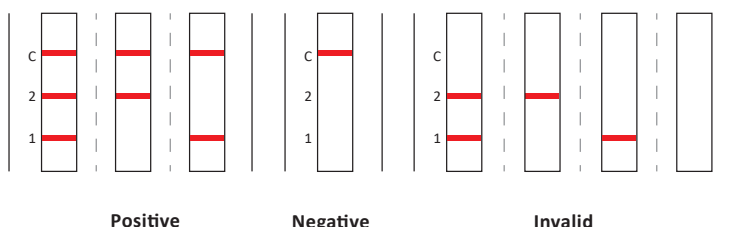


2) Whole blood or plasma sample



INTERPRETATION OF RESULTS

- Positive:** The presence of both C and IgM(1)/ IgG(2) band, no matter IgM(1)/ IgG(2) band is clear or vague.
- Negative:** Only clear C band appears.
- Invalid:** No colored band appears in C zone, no matter whether IgM(1)/ IgG(2) band appears.



STORAGE

- The kits should be stored between 2-30°C. DO NOT FREEZE. If they are stored under cold circumstance, keep them at room temperature for 15~30 minutes before use.
- Do not store the test kit in direct sunlight.
- The test kits are stable through the expiration date (24 months) marked on the foil pouch.

PRECAUTIONS

- For best results, please strictly adhere to these instructions.
- Please pay attention to the expiration date marked on the foil pouch before using. Do not use the expired kits.
- Do not remove the kit from the foil pouch until the test is ready to be carried out in case that the kit is overly exposed to the air and affected by humidity, and all the manipulating process should be finished within 10 minutes after the foil pouch is opened.
- All the test devices in the box, including test kit, dropper, assay buffer and EDTA tube are all disposable. Do not reuse. Once the test is finished, please properly discard all specimens and kits in accordance with Good Laboratory Practice (GLP).
- Do not move the test strip after samples applied into the sample wells in cause of abnormal occurrence on the test strips.
- The components in this kit have been quality-controlled as a standard batch unit. Do not mix components from different lot number units.

LIMITATION

The test is for veterinary use and in vitro diagnosis only, and it is **not able to exclude all the possibility of false negative and false positive results caused by various factors**. Hence, besides the results from test kits, veterinarians should also consider other clinical information and laboratory diagnostic methods to make the definite diagnosis in practice.

