■ *INTENDED USE*

The B.Lepto Ab Test (Lepto Ab) is a lateral flow immunochromatographic assay for the qualitative detection of Leptospira antibodies in cattle's serum, plasma or whole blood specimen.

Assay Time: 5-10 minutes

Specimen: serum, plasma or whole blood

■ *PRINCIPLE*

The B.Lepto Ab Test is based on sandwich lateral flow immunochromatographic assay. The test device has a testing window for the observation of assay running and result reading. The testing window has an invisible T (test) zone and a C (control) zone before running the assay. When the treated sample was applied into the sample well on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated Lepto antigens. If there are Lepto antibodies in the specimen, a visible T line will appear. The C line should always appear after a sample is applied, which indicates a valid result.

■ *REAGENTS AND MATERIALS*

- 10 test pouches, with cards and desiccants
- 10 Capillary droppers
- 1 Bottle of Assay buffer
- 1 package insert

■ *STORAGE AND STABILITY*

The kit can be stored at room temperature (2-30°C). The test kit is stable through the expiration date (18 months) marked on the package label. DO NOT FREEZE. Do not store the test kit in direct sunlight.

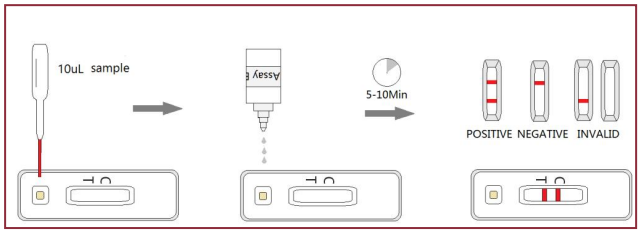
■ *SPECIMEN PREPARATION AND STORAGE*

1. Specimen should be obtained and treated as below.

- Whole blood: collect fresh blood for use directly or make anticoagulant blood for storage at 2-8°C.
- Serum: Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate), allow to settle for 30 minutes for blood coagulation and then centrifuge to obtain serum supernatant.
- Plasma: Collect the whole blood into the collection tube (containing anticoagulant) such as heparin, EDTA and sodium citrate) and then centrifuge to get plasma.
- If serum or plasma samples are not tested immediately, they should be refrigerated at 2~8°C. For longer storage, serum or plasma can be frozen (-20°C or colder). Frozen samples should be brought to room temperature (15~30°C) prior to use.
- Samples containing precipitate may yield inconsistent test results. Such samples must be clarified prior to assaying.
- The use of hemolytic, lipaemic, icteric or bacterially contaminated samples should be avoided. Erroneous results may occur.

■ *TEST PROCEDURE*

- Allow all materials, including specimen and test device, recover to 15-30°C before running the assay.
- Take out the test device from the foil pouch and place it horizontally.
- Using the capillary dropper to place 1 drop (approx. 10μL) of specimen into the sample well "S" of the test device. Then drop 3 drops of the assay buffer into the sample well immediately.
- Interpret the result in 5-10 minutes. Result after 15 minutes is considered as invalid.



■ *INTERPRETATION OF RESULTS*

- Positive (+): The presence of both "C" line and zone "T" line, no matter T line is clear or vague.
- Negative (-): Only clear C line appear. No T line.
- Invalid: No colored line appears in C zone. No matter if T line appears.

■ *PRECAUTIONS*

- All reagents must be at room temperature before running the assay.
- Do not remove test cassette from its pouch until immediately before use.
- Do not use the test beyond its expiration date.
- The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.

- All specimens are of potential infection. It must be strictly treated according to the rules and regulations by local states.

LIMITATION

The B.Lepto Ab Test is for in vitro veterinary diagnosis use only. All result should be considered with other clinical information available with veterinarian. It is suggested to apply a further confirmative method when positive result was observed.

Manufacturer:
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