INTENDED USE

Bovine tuberculosis is a chronic infectious disease caused by Mycobacterium bovis. The BTB Ag Test is a lateral flow immunochromatographic assay for the qualitative detection of Bovine Tuberculosis antigen (BTB Ag) with interferon-gamma (IFN- γ) in cattle's whole blood specimen.

Assay Time: 5-10 minutes

Specimen: whole blood

PRINCIPLE

The BTB Ag Test is based on sandwich lateral flow immunochromatographic assay for the qualitative detection of Bovine Tuberculosis antigen (BTB Ag) with interferon-gamma (IFN- γ). The test is based on the principle that lymphocytes in cattle's blood are able to immunologically remember the stimulating antigen after stimulation by exogenous or endogenous antigens. 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 monoclonal antibodies. If there is IFN-γ in the specimen, a visible T line will appears. The C line should always appear after a sample is applied, which indicates a valid result. By this means, the device can accurately indicate the presence of Bovine Tuberculosis Antigen with IFN-γ in the specimen.

REAGENTS AND MATERIALS

- 10 test pouches, with cards and disposable droppers
- 10 centrifuge tubes (1.5ml)
- 1 bottle of assay buffer
- 1 cell culture plate
- 1 package insert

STORAGE AND STABILITY

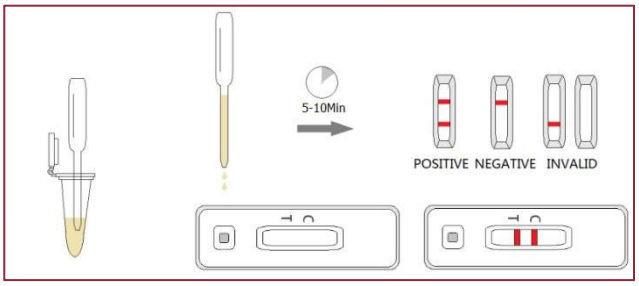
The kit can be stored at room temperature (2-30°C). The test kit is stable through the expiration date (18 months) marked on the package label. DO NOT FREEZE. Do not store the test kit in direct sunlight.

SPECIMEN PREPARATION AND STORAGE

- Collect the whole blood in heparin tubes from the cattle. Store the specimen at room temperature (15-25°C).
- Add 1.0 ml of the prepared whole blood to cell culture plate.
- Then add 4 drops of assay buffer to the cell culture plate, mix well and incubate at 37°C for 16-24 hours in a CO2 incubator. (The supply of CO2 is not required, but humidity control of the incubator is required to prevent drying.)
- Centrifuge the sample in a centrifuge tube for 15 minutes at RCF 2,200~2,300 xg.
- After centrifugation, collect the plasma. The collected plasma can be used immediately for the test.
- If not for immediate testing, the plasma should be stored at 2-8°C or -20°C for longer.

TEST PROCEDURE

- Allow all materials, including specimen and test device, recover to 15-25°C before running the assay.
- Take out the test device from the foil pouch and place it horizontally.
- Take 3 to 4 drops (approx.90μL) of prepared plasma with a disposable dropper into the sample well "S" of the test card. Start the timer.
- 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.
- Use fresh sample. Hemolyzed or contaminated sample might cause false results.

- 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 BTB Ag 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:
Hangzhou Evegen Biotech Co., LTD.
1st Floor, Building#1 No.578, 20th Street, Baiyang Subdistrict, Qiantang District, Hangzhou, Zhejiang Province