

## Lateral Flow Test for detection antibodies to Mycobacterium tuberculosis «LTFLOW TB»

### Operating instruction

**REF** LT-LF-TB-01  
Version: 001-2017-04

«LTFLOW TB» is a one-step qualitative immunochromatographic assay for the detection Mycobacterium tuberculosis antibodies in bovine serum or plasma.

Assay time: 10-15 min  
Sample: serum or plasma

#### PRINCIPLE OF THE ASSAY

«LTFLOW TB» is a sandwich lateral flow immunochromatographic assay for detection antibodies to Mycobacterium tuberculosis in bovine serum or plasma. The test device composed of a pad containing colloidal gold particles coated with Mycobacterium tuberculosis antigens. A second area of the test device has a membrane that is coated with the same Mycobacterium tuberculosis antigens. During the test, if Mycobacterium tuberculosis specific antibodies are present in the sample they bind to the antigens on the colored particles. The complex of antibody-antigen then migrates through the membrane and is captured by the antigens immobilized in the test region. This captured complex shows up as a purple line.

Absence of a line in the test region (T) suggests a negative result. The test contains an internal control in the control region (C) that should always show up as a purple line regardless of the test line result.

#### KIT COMPONENTS

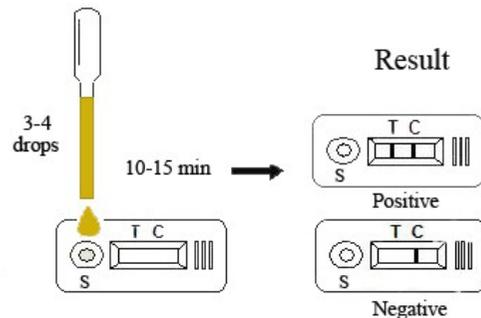
1. Test device
2. Pipette
3. Desiccant
4. Product Manual

#### SAMPLE PREPARATION

Collect bovine serum or plasma for assay according to standard procedure. Do not use sample showing hemolysis or being contaminated with microbes.

#### TEST PROCEDURE

1. In the case samples and test kits have been stored in a refrigerator, allow them to reach room temperature (18-25) °C before use.
2. Take out a device from a pouch and place it on a horizontal surface.
3. Using a dropper as a pipette, obtain the sample and dispense 3-4 drops (100-120µl) of the fluid into the sample well (S) of device.
4. Read the test results between 10-15 minutes.



#### INTERPRITATION OF RESULTS

A purple band should appear on the control line regardless of the test result. The presence of another band on the test line determines the result.

**Control Line (C):** The line should always appear regardless of the presence of the antibodies of Mycobacterium tuberculosis. If this line does not appear, the test should be considered invalid. This might be because of impure or the lack of sample. It should be tested again with another kit.

**Test Line (T):** The presence of antibodies of Mycobacterium tuberculosis the test line.

1. **Negative:** Control line only appear.
2. **Positive:** Both Test and Control lines appear.



#### 3. Retesting:

- a) Both Test and Control lines do not appear.
- b) Test line only appear



#### PRECAUTIONS

1. For the best results please strictly adhere to this instruction.
2. Use for in-vitro diagnostic purposes only.
3. Use within 10 minutes after opening the pouch because the test kit is very sensitive to moisture and its effect may diminish.
4. Do not use the kit when its pouch is torn, sealing is not good in shape or expiration date is passed.
5. Be careful of not touching the result window.
6. Every specimen should be used with different droppers.
7. Do not use sample showing hemolysis or being contaminated with microbes, which may cause false positive or false negative result.
8. Use disposable gloves when you suspect the infection caused by sample. And wash your hands later.
9. Dispose solid wastes after sterilizing them at 121 °C for over 1 hour.

#### STORAGE

The kit should be stored at temperature (8- °C). The test kit is stable during the expiration date (24 months) marked on the foil pouch. Do not freeze. Do not store the kit in direct sunlight.