

Anigen Rapid Bovine TB Ab Test Kit

1. Explanation of the Test

Bovine Tuberculosis is a serious bacterial disease caused by *Mycobacterium bovis* that usually affects the respiratory system, and is capable of infecting most mammals. Bovine TB is a chronic disease that has affected animal health throughout recorded history.

The Anigen Rapid Bovine TB Test Kit is a chromatographic immunoassay for the qualitative detection of *Mycobacterium bovis* antibody in plasma and serum.

The Anigen Rapid Bovine TB Test Kit has a letter T and C as “Test Line” and “Control Line” on the surface of the kit. Both the “Test Line” and “Control Line” in the result window are not visible before applying any samples. The “Control Line” is used for procedural control. The Control line should always appear if this procedure is performed properly, and the test reagents of the control line are working. A purple “Test Line” will be visible in the result window if there are enough *Mycobacterium bovis* antibodies in the specimen.

The specially selected *Mycobacterium bovis* antigens are used in the test as both capture and detector materials. These enable Anigen Rapid Bovine TB Test Kit to identify *Mycobacterium bovis* antibodies in specimens with a high degree of accuracy.

2. Materials Provided

Anigen Rapid Bovine TB Ab Test Kit contains following items to perform the assay.

- 1) Ten (10) Anigen Rapid Bovine TB Ab Test Kits.
- 2) One (1) Bottle containing 4 ml of whole blood diluent.
- 3) One (1) Bottle containing 4 ml of developing buffer.
- 4) Two (10) Test tubes for whole blood diluent.
- 5) Two (10) K2 EDTA tube for whole blood.
- 6) One (1) Paper rack for test tube.
- 7) Two (10) Disposable capillary tubes for specimens.
- 8) Two (10) Disposable droppers for whole blood dispensing.
- 9) One (1) Instruction for use.

♣ A dark color score line on the capillary tube is the indicator line for 10 μ l.



3. Precautions

Anigen Rapid Bovine TB Test Kit should be stored at room temperature. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiry date.

4. Specimen Collection and Storage

- 1) [whole blood] Collect the whole blood using a suitable anti-coagulant. Use the whole blood within 1 day after collection. Do not use hemolysed blood.
- 2) [serum or plasma] Centrifuge whole blood to get plasma or serum specimen.
- 3) If specimens are not immediately tested they should be refrigerated at 2 ~ 8 °C. For storage periods greater than three days, freeze the specimen at – 20 °C or below. Bring specimens to room temperature prior to testing.
- 4) Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to testing.

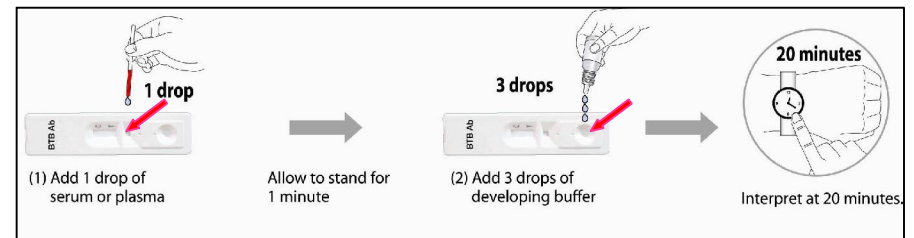
5. Warnings

- 1) For *in-vitro* diagnostic use only.
- 2) Do not eat or smoke while handling specimens.
- 3) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- 4) Avoid splashing or aerosol formation.
- 5) Clean up spills thoroughly using an appropriate disinfectant.
- 6) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- 7) Do not use the test kit if the pouch is damaged or the seal is broken.

6. Test Procedures

[Serum & Plasma specimen]

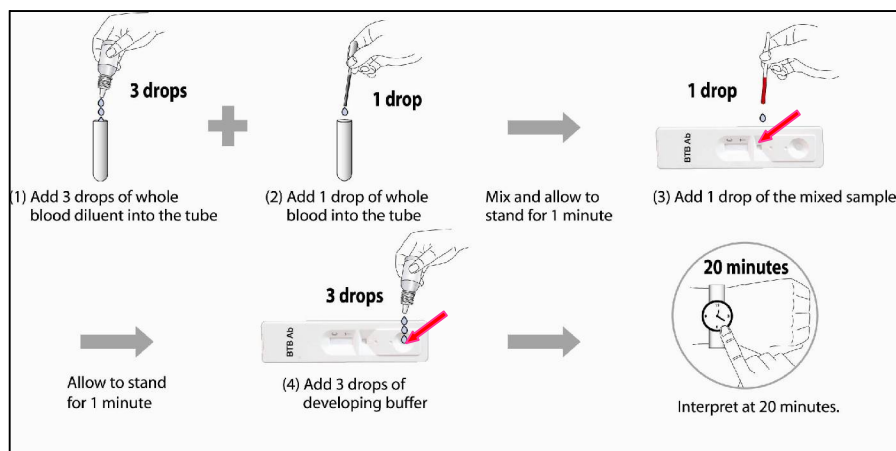
- 1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
- 2) Add 10ul of serum, or plasma to the sample hole marked “S” on the test device with a capillary tube and wait for 1 minute, then add 3 drops of the developing buffer into the developing hole
- 3) For the test result, you will see the purple band in the result window of the kit Interpret test results at 20minutes. Do not interpret after 30 minutes.



[Whole blood specimen]

- 1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
- 2) Dispense 3 drops of the whole blood diluent into the test tube for the whole blood dilution.
Add 1 drop (30ul) of a whole blood sample with a disposable dropper and mix them for 1 minute.
- 3) Add 10ul of the mixed sample to the sample hole marked "S" on the test device with a capillary tube and wait for 1 minute.
- 4) Dispense 3 drops of the developing buffer into developing hole
- 5) For the test result, you will see the purple band in the result window of the kit. Interpret test results at 20 minutes. Do not interpret after 30 minutes.

Caution: The above result interpreting time is based on reading test results at room temperature of 15 ~ 30°C. If your room temperature is not significantly more than 15°C, the result interpreting time should be properly increased.



7. Interpretation of the Test

- 1) A color band will appear in the left section of the result window to show that the test is working properly. This band is the Control line (C).
- 2) The right section of the result window indicates the test results. If another color band appears in the right section of the result window, this band is the Test line (T).
- 3) **Negative** : The presence of only one purple color band within the result window indicates a negative result.



- 4) **Positive** : The presence of two color bands ("T" band and "C" band) within the result window, no matter which band appears first, indicates a positive result.



- ⊗ Even if the intensity of the purple band color is faint, it should be interpreted as positive if it appears within 20 minutes

- 5) **Invalid** : If the purple color band is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



8. Limitations of the Test

- 1) Anigen Rapid Bovine TB Test Kit will only indicate the presence of antibodies against *Mycobacterium bovis* in the specimen.
- 2) As with all diagnostic tests, all results must be interpreted together with other clinical information available to the veterinarian.
- 3) If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Brucellosis.

9. Expected Values

Anigen Rapid Bovine TB Test Kit has been compared with a PPD tests. The overall accuracy is greater or equal to 85.5%

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