

Cattle and Goat Tuberculosis Antibodies Rapid - Cattle, Goat, sample type = serum, whole blood

REF

KINER5011

Ver 1.0

IVT

For In-Vitro Test Only



1 x 40 tests

Purchase does not include or carry the right to resell or transfer this product either as a stand-alone product or as a component of another product. Any use of this product other than the permitted use without the express written authorization of KINETIC BIOTECH FZCO is strictly prohibited.



KINETIC BIOTECH FZCO

Building A1,
Dubai Digital Park,
Dubai Silicon Oasis, Dubai,
UAE
Tel: +44-186-5522721
Email: info@kineticbiotech.ae

Ste#619,
606 S Hill Street,
Los Angeles, CA 90014.
USA

Introduction:

Tuberculosis Antibodies are host-produced immunoglobulins generated in response to infection with *Mycobacterium tuberculosis* complex organisms. Detection of tuberculosis-specific antibodies in serum or whole blood provides supportive serological evidence of exposure or infection and may be used as a supplementary tool for screening and epidemiological studies, in conjunction with clinical evaluation and other diagnostic methods.

Intended Use:

The Cattle and Goat Tuberculosis Antibodies Rapid - Cattle, Goat, sample type = serum, whole blood is used for qualitative detection of the antibodies against *Mycobacterium* spp. associated with tuberculosis in serum or whole blood samples of cattle and goats.

Principle:

This Rapid Test is an immuno-chromatographic test, using colloidal gold immunoassay method to detect the indicated antigen/antibody. After the addition of the sample, as per the instruction for use (IFU), the sample moves along with the colloidal gold labeling protein. If the relevant protein is present, it will develop a reddish color line near the space marked as "T". This indicates the sample is Positive and if a line is not developed or seen, it indicates the sample is Negative for the tested antigen/antibody.

Materials Provided:

1. Cassette: with a pad in the device.
2. Sample Diluent - 3 ml

Materials to be provided by the End-User:

1. Adjustable pipettes and multichannel pipettor to measure volumes ranging from 25 ul to 1000ul
2. Alcohol prep-pad
3. Clock or timer
4. Specimen collection container
5. Centrifuge
6. Biohazard waste container
7. Sterile gauze or cotton

Handling / Storage:

1. All reagents should be stored at 2°C to 8°C for stability.
2. All the reagents and wash solutions should be used within 12 months from manufacturing date.
3. Before using, bring all components to room temperature (18-25°C). Upon assay completion ensure all components of the kit are returned to appropriate storage conditions.

Health Hazard Warnings:

1. Reagents that contain preservatives may be harmful if ingested, inhaled or absorbed through the skin.
2. For Research Use Only.

Sample Preparation and Storage:

Whole blood samples: Clean the site with Alcohol Prep Pad. Collect the blood from vein. Using

Disposable Pipette, collect blood from the puncture site. Alternatively - draw blood following laboratory procedure for obtaining venous blood. Do not test whole blood samples if older than 3 days.

Serum/Plasma samples: Fresh serum or plasma samples can be used. No special patient preparation required. Care should be taken to ensure blood full clotting and any visible particulate matter in the sample should be removed by centrifugation or filtration. Avoid the use of highly hemolytic, turbid, microorganism contaminated samples or samples stored for over 30 days at 2-8°C.

Store samples at 2-8°C. Samples not required for assay within 3 days should be stored frozen (-20°C or lower). Avoid sample deterioration by multiple freeze-thaw cycles.

Plasma: Collect whole blood into a collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture. Separate the plasma by centrifugation.

Serum: Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture. Allow the blood to clot. Separate by centrifugation.

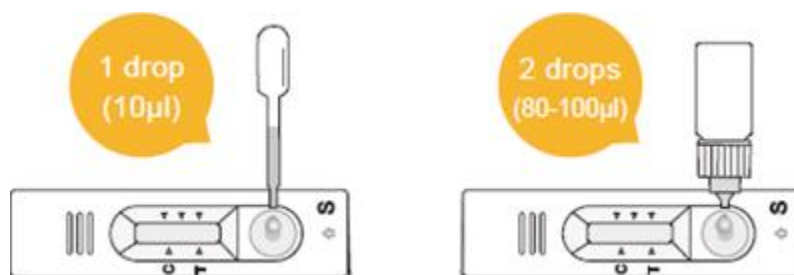
Preparation Before Use:

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20°C - 30°C) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (humidity ≤ 60%, temp: 20°C - 30°C). Please use immediately when the humidity > 60%.

Assay Procedure:

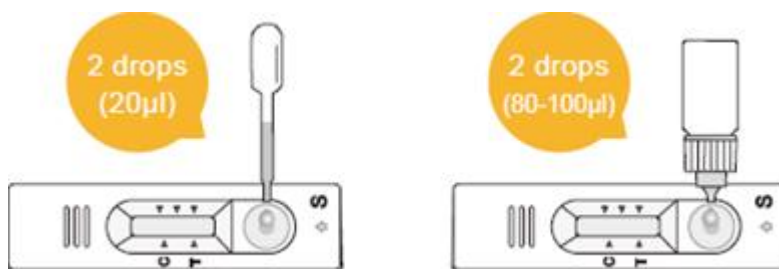
For Serum / Plasma

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add one (1) full drop of serum or plasma (10 μ l) vertically into the sample well.
3. Add two (2) drops (80-100 μ l) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.



For Whole Blood

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add two (2) full drops of whole blood (20 μ l) vertically into the sample well.
3. Add two (2) drops (80-100 μ l) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.

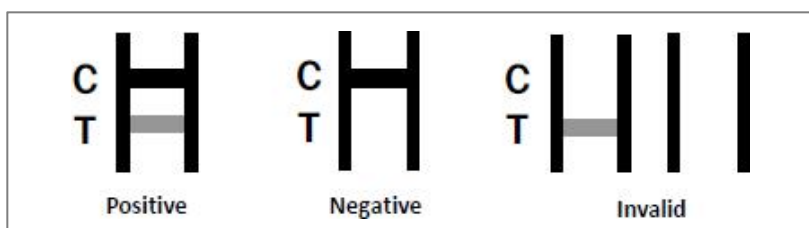


Interpretation of Results:

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



Quality Control:

It is recommended that for each laboratory assay appropriate quality control samples in each run to be used to ensure that all reagents and procedures are correct.

Performance Characteristics of the Kit:

Sensitivity:

Negative coincident rate with Molecular testing: $\geq 97\%$, Positive coincident rate with Molecular testing: $\geq 75\%$.

Limitations of Method

Any diagnosis should not be based on the results of in vitro methods alone. Veterinarians are suggested to consider all clinical and laboratory findings possible to state a diagnosis. This reagent is designed for the qualitative screening test.

Safety Precautions:

- Follow the working instructions carefully.
- The expiration dates stated on the kit are to be observed. The same relates to the stability stated for reagents
- Do not use or mix reagents from different lots.
- Do not use reagents from other manufacturers.

- Avoid time shift during pipetting of reagents.
- All reagents should be kept in the original shipping container.
- Some of the reagents contain small amount of sodium azide (< 0.1 % w/w) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Since the kit contains potentially hazardous materials, the following precautions should be observed
 - Do not smoke, eat or drink while handling kit material
 - Always use protective gloves
 - Never pipette material by mouth
 - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.

Symbols



Use by



Lot/Batch



Catalog number



Temperature limitation



Caution, consult accompanying documents



Manufacturer



LIMITED WARRANTY

KINETIC BIOTECH FZCO does not warrant against damages or defects arising in shipping or handling, or out of accident or improper or abnormal use of the product; against defects in products or components not manufactured by KINETIC BIOTECH FZCO, or against damages resulting from such non-KINETIC BIOTECH FZCO made products or components. KINETIC BIOTECH FZCO passes on to customer the warranty it received (if any) from the maker thereof of such non-KINETIC BIOTECH FZCO made products or components. This warranty also does not apply to product to which changes or modifications have been made or attempted by persons other than pursuant to written authorization by KINETIC BIOTECH FZCO.

THIS WARRANTY IS EXCLUSIVE. The sole and exclusive obligation of KINETIC BIOTECH FZCO shall be to repair or replace the defective product in the manner and for the period provided above. KINETIC BIOTECH FZCO shall not have any other obligation with respect to the products or any part thereof, whether based on contract, tort, strict liability or otherwise. Under no circumstances, whether based on this Limited Warranty or otherwise, shall KINETIC BIOTECH FZCO be liable for incidental, special, or consequential damages.

This Limited Warranty states the entire obligation of KINETIC BIOTECH FZCO with respect to the product. If any part of this Limited Warranty is determined to be void or illegal, the remainder shall remain in full force and effect.

KINETIC BIOTECH FZCO. 2026

THANK YOU FOR USING KINETIC BIOTECH PRODUCT!