M. Bovis Ab Rapid Test Kit

Cat No. S045-01

In vitro Diagnostics

INTENDED USE

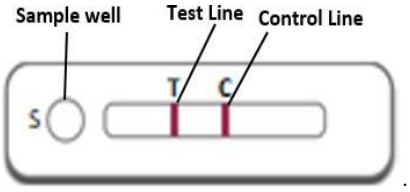
Sensit M.Bovis Ab Rapid test is an Immuno- chromatographic assay for the detection of antibodies to Mycobacterium tuberculosis and Mycobacterium bovis in serum, plasma or whole blood in animals. The test is used as an aid in the diagnosis of active tuberculosis (TB) in conjunction with other diagnostic methods.If specific antibodies are present in the sample, the expected test result is reactive. A reactive result is suggestive of active TB. In the absence of antibodies, the expected test result is nonreactive.

SUMMARY & TEST DESCRIPTION

Mycobacterium bovis is the causative agent of bovine tuberculosis (TB) in animals, and it also has the potential to induce disease in humans. An unknown proportion of TB cases are caused by M. bovis. Zoonotic TB, caused by M. bovis, is present in animals in most developing countries where control measurements are not or sporadically applied, and pasteurization is rarely practiced. In countries where bovine TB is uncontrolled, most infections in human result from drinking or handling contaminated milk.In industrialized countries, veterinary TB control and elimination programs, together with milk pasteurization, have drastically reduced the incidence of disease caused by M. bovis in both cattle and humans, but the control programs have not completely eliminated infection in cattle because of wild animal reservoirs.

TEST DESCRIPTION & PRINCIPLE

The animal TB rapid Test is a membrane-based screening test for the rapid detection of antibodies to M. bovis in samples from animals. The innovative and rapid screening test is based on lateral flow immunochromatography and is among the easiest point of care assay diagnostics. The rapid test kit is suitable to test for antibodies in both serum and plasma



After the serum or whole blood sample and diluent are put into the well on the test card using a pipette, the diluted sample passes through the gold-marked antibody binding protein (conjugate).The conjugate attaches to the immunoglobulins contained in the sample. This antibody-conjugate complex then flows through the membrane. Two specific recombinant antigens from M. bovis (test line 1 and 2) and one highly purified cell wall antigen (test line 3) are immobilized on the membrane in the "T" region (test zone).If the sample contains antibodies to one or all of these antigens, then the antibody-conjugate complex attaches itself to one or more of the test lines: one or more pink- purple bands then appears in the "T" zone of the test card. The remaining antibody-conjugate complex then passes through the card until it reaches the control zone "C". Again, a pink-purple band appears, indicating that the test has been performed properly

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MATERIALS PROVIDED

1.Each sealed in a foil pouch containing following items:

a. One Test card
b. Dropper
c. Desiccant

2.Assay Diluent- In dropper bottle

3.Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTION & WARNING

1) Use within 10 minutes after opening pouch.
2) Do not touch result window.
3) Use only the buffer supplied along with the kit.
4) Do not mix components from different kits.
5) Do not reuse the test device; each test can be used ONLY SINGLE TIME.
6) Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION

Whole Blood:

- Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.

Serum:

- Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.

Note:

- *If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.*
- *For storage period longer than 5 days, freezing is recommended. Store at -20^{0}C*
- *The specimen should be brought to room temperature prior to use.*

Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

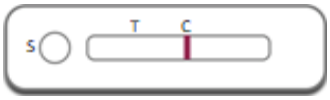
1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 10 µl of specimen without air bubble to the Sample well "S".
3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample hole.
4. Wait for 10-15 minutes and interpret results. Do not read the result after 15 minutes. All results where control band does not appear are considered invalid.

INTERPRETATION OF TEST RESULT

(IMPORTANT NOTE: INTERPRET THE RESULTS WITH RESPECT TO THE WRITINGS 'C' & 'T' ON THE DEVICE AS SHOWN BELOW.)

Positive: Color bands at position C and T. M Bovis Antibody is present in the sample

Negative: Color band at position C. M.Bovis Antibody is not present in the sample.



Invalid: Color band at C does not appear

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in M Bovis Rapid Test for single-step detection of M Bovis are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

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ubio Biotechnology Systems Pvt Ltd
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