

INTRODUCTION

Mycobacterium bovis causes bovine tuberculosis, a chronic and contagious bacterial disease in cattle. It mainly affects the respiratory system, leading to weight loss, coughing, and decreased productivity. It is a zoonotic disease and can be transmitted to humans, causing tuberculosis.

INTENDED USE

Diagno Bovine Tuberculosis Ab Rapid Test is used to detect specific antibodies against *Mycobacterium bovis* in bovine blood samples.

Assay Time: 10 minutes

Specimen: Whole blood, serum or plasma

METHOD

The Diagno Bovine Tuberculosis Ab Rapid Test is a lateral flow immunochromatographic assay based on the sandwich method.

KIT COMPONENTS

- 1 box contains 10 aluminum foil pouches, each with a Tuberculosis Ab rapid test cassette
- 1 diluent tube
- 10 capillary droppers
- 1 instructions for use (IFU)

STORAGE AND STABILITY

- The kit should be stored at room temperature (2- 30°C).
- Test is stable until the expiration date if stored in the aluminum pouch.
- DO NOT FREEZE.**
- Avoid direct exposure to sunlight.
- The test kit should be stored in a dry and cool environment.

IMPORTANT NOTES

- **DO NOT USE IF THE PACKAGE CONTAINING THE TEST CASSETTE IS DAMAGED OR OPENED.**
- All reagents should be at room temperature before using the test.
- Do not remove the test cassette from its pouch until just before use.
- Do not use the test after the expiration date.
- The materials in this kit have been quality control tested according to serial number. Do not mix materials of different LOT numbers.
- All specimens are of potential infection. It must be strictly treated according to the rules and regulations by local states.
- **Once contaminated, veterinary diagnostic kits, including used plates, samples, processed components, equipment, and consumables need to be disposed of as "medical waste". They should be handled by proper decontamination methods and must be destroyed in accordance with the legislation established for medical waste.**
- Uncontaminated packaging materials can be treated as household waste/recycling.

SAMPLE PREPARATION AND STORAGE

After collecting a blood sample from cattle (whole blood, serum, or plasma can be used), prepare as follows:

- 1.To obtain serum from whole blood, centrifuge the blood sample.
- 2.To obtain plasma from whole blood, place the blood into an anticoagulant tube and centrifuge.
- 3.The sample should be tested immediately for the most reliable results. If not tested immediately, it can be stored at 2–8 °C for up to 24 hours. For longer storage, samples should be frozen at –20 °C or below.

Delayed testing may reduce the sensitivity of the test kit.

PROCEDURE

- 1.Before use, all materials, including the sample and test cassette, should be kept at 15–25 °C for 5 minutes.
- 2.Open the foil pouch by tearing and place the test cassette on a flat surface.
 1. Add 1 drop of the prepared serum or plasma sample into the sample well marked "S" on the test cassette.
- 2.Open the cap of the diluent dropper bottle.
- 3.Add 3 drops of diluent into the same sample well marked "S". Do not let the tip of the bottle touch the sample in the well (**risk of contamination**).
- 4.Read the result within 10 minutes. Results after 25 minutes are considered invalid.

INTERPRETATION OF RESULTS

Positive: The band appears in the C and T regions of the cassette's large window. The T band appearing light colored or unclear does not make the result negative.

Negative: Only C band appears on the test cassette.

Invalid: Test result is considered as invalid if C band does not appear regardless of the appearance of the T band.

PERFORMANCE DATA

RESULT		ELISA	
		Positive	Negative
Tuberculosis Ab Rapid Test	Positive	36	5
	Negative	2	43
Relative Sensitivity		98,6%	
Relative Specificity		97,8%	
Relative Accuracy		98,2%	

The Diagno Bovine Tuberculosis Ab Rapid Test is intended for *in vitro* veterinary diagnostic use only. All results should be evaluated together with other clinical findings by a veterinarian. In case of a positive result, confirmation with an advanced method such as ELISA is recommended.

REFERENCES

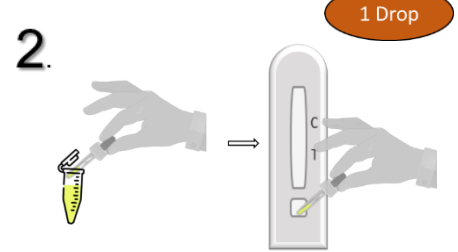
- 1.S. Izadi, A. Feizi (2024) Bovine brucellosis, associated risk factors and preventive measures in industrial cattle farms. <https://doi.org/10.1016/j.heliyon.2024.e40180>
- 2.Koczula, K. M., & Gallotta, A. (2016). Lateral flow assays. *Essays in Biochemistry*, 60(1), 111-120. <https://doi.org/10.1042/EBC20150012>

Symbol	Meaning	Symbol	Meaning
	Expiration date		LOT no
	Fragile, handle with care		Number of tests in one box
	Catalog no		Attention (see instructions for use)
	Instructions for use (IFU)		<i>in vitro</i> diagnostic medical device
	Temperature limitation		This side up
	Keep dry		Keep away from direct sunlight
	Do not reuse		Keep out of reach of children

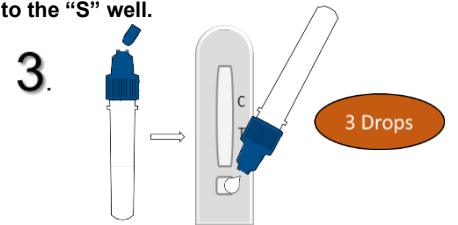
QUICK USER GUIDE



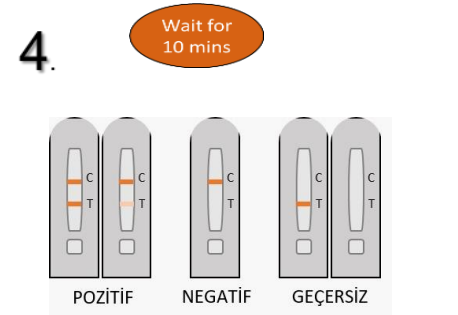
Collect a blood sample from the bovine. Use whole blood, serum, or plasma as the test sample.



Using a dropper, add 1 drop of the sample into the "S" well.



Open the cap of the diluent dropper bottle and add 3 drops of diluent into the "S" well. Do not allow the tip of the diluent bottle to touch the sample (**risk of contamination**).



Interpretation of results

MANUFACTURER AND OCCUPATION PERMIT HOLDER

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