Bovine Brucella Antigen Rapid Test Device

(Whole Blood/Serum/Plasma)

Package Insert

REF VR-BB-AG-10	English

INTENDED USE

The Bovine Brucella Antigen Rapid Test Device is a lateral flow immunochromatographic assay for the qualitative detection of Bovine Brucella antigens in bovine whole blood/serum/ plasma.

PRINCIPLE

The Bovine Brucella Antigen Rapid Test is based on sandwich lateral flow immunochromatographic assay. The test device has a testing window for the observation of assay running and result reading. The testing window has an invisible T (test) line region and a C (control) line region before running the assay. When the treated sample was applied into the sample well on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated Brucella antibody. If there are anti-Brucella antigens in the specimen, a visible T line will appear in the T region. The C line should always appear after a sample is applied, which indicates a valid result. By this means, the device can accurately indicate the presence of Bovine Brucella antigens in the specimen.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

PRECAUTIONS

- Do not use after expiration date.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- Do not remove test device from its pouch until immediately before use.
- Do not reuse the test kit.
- Do not mix components from different lot and different products.

MATERIALS

Materials Provided

・Test devices ・Droppers ・Buffer ・Package insert

Materials Required but Not Provided

・Timer ・Sample containers ・Centrifuge (for plasma)

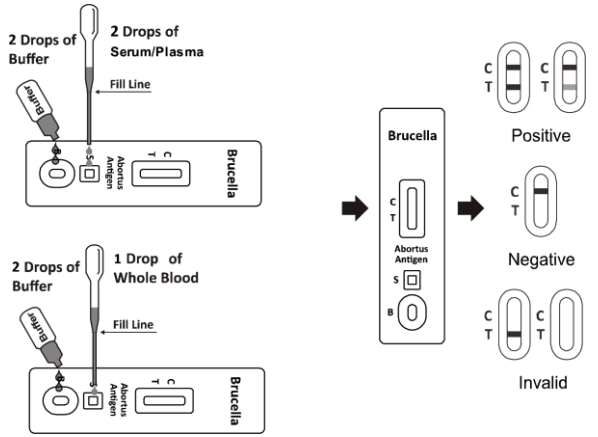
DIRECTIONS FOR USE

Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

1. Collect fresh whole blood, or separate serum or plasma from blood as soon as possible to avoid hemolysis. Only use clear, non-hemolyzed specimens. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long term storage, serum and plasma specimens should be kept below -20 °C.
2. Place the test device on a clean and level surface.

   For serum and Plasma: Hold the dropper vertically, draw the specimen about 1cm above the Fill Line, and transfer **2 drops of serum or plasma** (approximately 40µl) to the specimen well (S), then add **2 drops of buffer** (approximately 120 µl) into the buffer well (B). See illustration below and start the timer.

   For whole blood specimen: Hold the dropper vertically, draw the specimen about 1cm above the Fill Line, and transfer **1 drop of whole blood** (approximately 20µl) to the specimen well (S), then add **2 drops of buffer** (approximately 120 µl) into the buffer well (B). See illustration below and start the timer.
3. **Read the result at 10 minutes**. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS

Positive: The presence of both C line and T line, no matter T line is clear or vague.

Negative: Only clear C line appears.

Invalid: No colored line appears in C region no matter whether T line appears

PERFORMANCE CHARACTERISTICS

Relative Sensitivity: 95.45% (95%CI*: 84.53%-99.44%)

Relative Specificity: 97.70% (95%CI*: 91.94%-99.72%)

Accuracy: 96.95% (95%CI*: 92.37%-99.16%)

*CI = confidence interval compared to PCR method

LIMITATION

The Bovine Brucella Antigen Rapid Test is for in vitro veterinary diagnosis use only. All result should be considered with other clinical information available with veterinarian. It is suggested to apply a further confirmative method when positive result was observed.

Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	2	Do not reuse
IVD	For in vitro diagnostic use only	⌛	Use by	REF	Catalog #
2°C 30°C	Store between 2-30°C	LOT	Lot Number	i	Consult Instructions For Use
	Do not use if package is damaged		Manufacturer		

Manufactured by Rapid Labs Ltd.

Unit 2 and 2a Hall Farm Business Centre, Church Road, Little Bentley

Colchester, Essex CO7 8SD

Revision 1: 2018-07-13