# Brucella Antigen Rapid Test

REF KINER5084

Ver 1.0

IVT For In-Vitro Test Only

1 x 40 tests



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**Introduction:**

Brucella infection is a contagious bacterial disease of livestock caused by Brucella species, primarily affecting cattle, goats, sheep, and other domestic animals. The disease is commonly associated with reproductive disorders such as abortions, infertility, retained placenta, and reduced milk production, leading to significant economic losses in animal husbandry. Brucellosis is also an important zoonotic disease, posing a risk to human health through direct contact with infected animals or consumption of contaminated animal products. Early and accurate detection of Brucella antigen is essential for timely diagnosis, effective disease control, and implementation of eradication and surveillance programs.

**Intended Use:**

The Brucella Antigen Rapid Test is used for qualitative detection of Brucella antigen in animal clinical samples such as whole blood, serum, plasma, or milk.

**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 2ºC to 8ºC 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 (18-25ºC). 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 venipunctu re. Allow the blood to clot. Separate by centrifugation.

Milk Samples: Milk samples should be collected aseptically into clean, sterile containers, preferably during mid-milking to reduce contamination. Samples should be mixed gently before testing to ensure homogeneity. Milk samples are recommended to be tested immediately after collection. If immediate testing is not possible, samples may be stored at 2–8°C for up to 24–48 hours. For longer storage, milk samples can be frozen at −20°C or below, avoiding repeated freeze–thaw cycles.

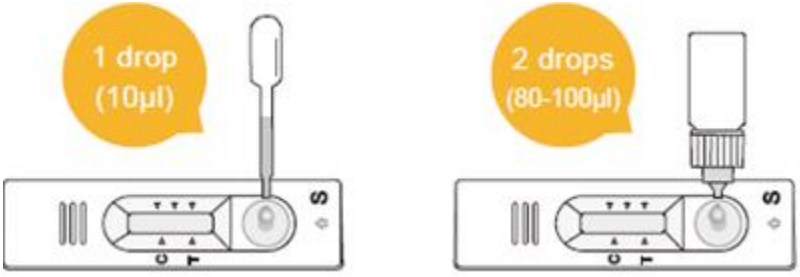
**Preparation Before Use:**

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

**Assay Procedure:**

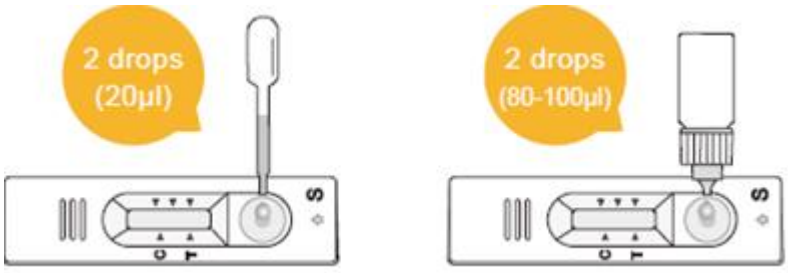
**For Serum / Plasma or Milk**

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/ plasma or Milk (10 ul) vertically into the sample well.
3. Add two (2) drops (80-100 ul) 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 ul) vertically into the sample well.
3. Add two (2) drops (80-100 ul) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.

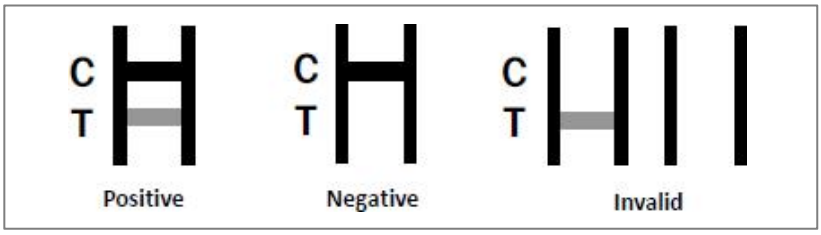



**Interpretation of Results:**

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: ≥ 97%, Positive coincident rate with Molecular testing: ≥ 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.
- 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

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