Rapid Bovine Brucella Antibody Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ Bovine Brucella Ab Test Kit

[CAT No. LGM-BBB-11]

Introduction

Brucellosis is one of the most common contagious zoonotic diseases with high rates of morbidity and high economic losses. Bovine brucellosis is a widespread reproductive disease, commonly causing abortion, death of young ones, stillbirth, retained placenta or birth of weak calves, delayed calving, male infertility, and marked reduction in milk yield[1].

Bovine brucellosis is caused by a Gram-negative aerobic coccobacillus, *Brucella abortus* and occasionally by *Brucella melitensis* and *Brucella suis*[2]. Natural transmission of the pathogen in cattle occurs by ingestion, inhalation, conjunctiva, and pregnancy. Pregnant cows usually abort in the last trimester of pregnancy. Abortion rate may vary from 30 to 80 percent in susceptible herds[3]. Aborted fetus, placenta, and secretion from uterus act as the source of infection to other animals. Infected bulls serve as the lifelong source of infection. Milk and milk products can be source of infection to man, if consumed unpasteurized[4].

Humans act as the dead-end hosts for *Brucella*, and brucellosis occurs as a more serious clinical symptom in humans[5]. The most common symptoms of human brucellosis include undulant fever, night sweats, chills, weight loss, fatigue, insomnia, constipation, joint/muscle pain, headaches, sexual impotence, nervousness, and depression[2].

Principle

The RIDX™ Bovine Brucella Ab Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of brucella antibody in bovine blood.

This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. The control line indicates that the test is performed correctly and should appear when the test is complete. If the brucella antibody exists in the sample, it binds to the gold-conjugated anti-bovine IgG. The complex moves through the membrane by capillary force and responds to bovine brucella antigen on the test line, resulting in a red line.

The high-quality antigen to *B. abortus* antibody is used as capture in the kit. The RIDX™ Bovine Brucella Ab Test Kit can detect bovine brucella antibodies in bovine blood with high accuracy.

Performance

1. Sensitivity & Specificity

[Rose Bengal Plate Test]

		Rose Bengal Plate Test		
		+	-	Total
RIDX™ Bovine Brucella Ab Test	+	105	0	105
	-	0	600	600
	Total	105	600	705

Sensitivity: 100% (105/105, 95% CI*: 96.47% ~ 100%)
Specificity: 100% (600/600, 95% CI: 99.36% ~ 100%)
Diagnostic Agreement: 100% (705/705, 95% CI: 99.46% ~ 100%)

* CI: Confidence Interval

[Enzyme-Linked Immunosorbent Assay]

		ELISA		
		+	-	Total
RIDX™ Bovine Brucella Ab Test	+	105	0	105
	-	0	600	600
	Total	105	600	705

Sensitivity: 100% (105/105, 95% CI: 96.47% ~ 100%)
Specificity: 100% (600/600, 95% CI: 99.36% ~ 100%)
Diagnostic Agreement: 100% (705/705, 95% CI: 99.46% ~ 100%)

2. Cross-Reactivity

Below potential cross-reactivity substances do not affect the performance of the RIDX™ Bovine Brucella Ab Test Kit.

Pathogen	Result
Bovine herpesvirus type 1 (BHV-1)	Negative
Bovine leukosis virus (BLV)	Negative
Bovine respiratory syncytial virus (BRSV)	Negative
Bovine viral diarrhea virus (BVDV)	Negative
Parainfluenza virus 3 (PI-3)	Negative

Kit Components

	Component	Number/Kit
1	Bovine brucella antibody test device	10
2	Anticoagulant tube with EDTA	10
3	Disposable capillary tube	10
4	Dilution buffer	1
5	Instructions for use	1

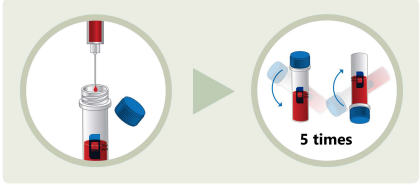
Storage & Stability

1. Store the test kit at 2~30℃ (35.6~86℉). Do not freeze.
2. Do not store the test kit in direct sunlight.
3. The test kit is stable within the expiration date marked on the package label.

Sample Preparation

[Whole blood]

1. Collect 1mL (0.5~1.5mL) of the whole blood sample and put it into an anticoagulant tube.
2. Close the cap on the anticoagulant tube and invert the tube 5 times to mix blood sample and ethylene diamine tetra acetic acid (EDTA).

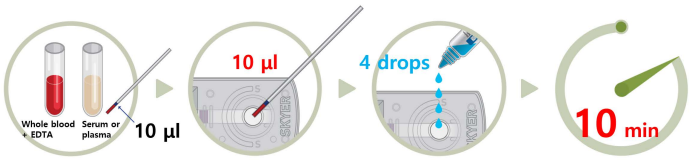


3. The anticoagulated whole blood samples should be used instantly after collection. If you cannot use the samples immediately, store them refrigerated (2~8℃/35.6~46℉) or keep them on ice. Do not freeze the anticoagulated whole blood samples. If you cannot use the samples within 24 hours, store them in a form of serum or plasma.

[Serum or plasma]
1. Prepare serum and plasma using a standard procedure of clinical laboratory.
2. Serum or plasma, either fresh or stored at 2~8°C (35.6~46℉) for up to 72 hours, can be used. For longer storage, freeze at −20°C (−4℉).

Test Procedure

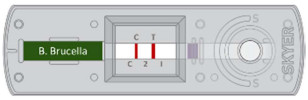
1. All samples and test components should be at room temperature (15~30°C/59~86℉) before use.
2. Take a sample (anticoagulated whole blood, serum, or plasma) using a capillary tube.
3. Add 10μL of the sample into the sample hole (S).
4. Add 4 drops of dilution buffer into the sample hole (S).
5. Read test results at 10 minutes.



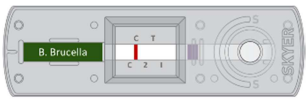
[Summary of Test Procedure]

Interpretation of Results

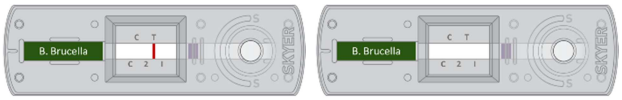
1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of bovine brucella antibody.



2. Negative result
Only control (C) line appears in the result window.



3. Invalid results
If the control (C) line does not appear, the result might be considered invalid. The sample should be retested.



Precautions

1. This test kit is for veterinary *in vitro* diagnosis only especially bovine. Do not use this test kit for other animals.
2. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
3. Do not touch the membrane of the test device.
4. Do not use the test device if the foil pouch is damaged or the seal is open.
5. Do not use an expired test kit. The expiration date is marked on the package label.
6. Do not reuse the test components (device, capillary tube).
7. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
8. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials following national and local regulations.
9. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.

References

1. Khan MZ, Zahoor M. An Overview of Brucellosis in Cattle and Humans, and its Serological and Molecular Diagnosis in Control Strategies. *Trop. Med. Infect. Dis.* 2018; 3(2): 65.
2. Mantur BG, Amarnath SK, Shinde RS. Review of clinical and laboratory features of human brucellosis. *Indian J Med Microbiol.* 2007; 25(3): 188–202.
3. Kiros A, Asgedom H, Abdi RD. A review on bovine brucellosis: epidemiology, diagnosis and control options. *ARC J Anim Vet Sci.* 2016; 2(3): 8–21.
4. Khurana SK, Sehrawat A, Tiwari R, Prasad M, Gulati B, Shabbir MZ, Chhabra R, Karthik K, Patel SK, Pathak M, Yatoo MI, Gupta VK, Dhama K, Sah R, Chaicumpa W. Bovine brucellosis – a comprehensive review. *Vet. Quart.* 2021; 41(1): 61–88.
5. Moreno E. Retrospective and prospective perspectives on zoonotic brucellosis. *Front Microbiol.* 2014; 5: 213.

Symbol Descriptions

LIC	License number
CAT	Catalogue number
LOT	Batch code, Lot number
	Consult instructions for use
Σn	Contains sufficient for ⟨n⟩ tests
	Do not reuse
IVD	*In vitro* diagnostic medical device
	Temperature limitation
	Do not use, if the package is damaged
	Upper side
	Manufacturer

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