Rapid Bovine Viral Diarrhea Virus Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ BVDV Ag SP Test Kit

[Catalogue Number: LGM-BVG-12]

Introduction

Bovine viral diarrhea virus (BVDV), a single-stranded positive-sense RNA virus, genus *Pestivirus* in the Flaviviridae family[1], is a highly contagious pathogen that causes significant economic losses around the world due to its impact on reproduction, respiratory health, and immunosuppression in cattle and other ruminants[2, 3].
BVDV is divided into two genotypes, BVDV 1 and BVDV 2, each with multiple subtypes, and exists in two biotypes, cytopathic (CP) and non-cytopathic (NCP)[4]. NCP BVDV is more common and can establish persistent infections (PI), while CP BVDV is rare but can cause more severe disease. The CP viruses arise by mutation of NCP viruses, and it is known that p80 is the marker protein for NCP viruses[5]. Calves are infected by NCP BVDV in utero during the first 125 days of gestation, when their immune systems have not fully developed[6]. Hemorrhagic disease and thrombocytopenia, and a disease resembling mucosal disease that is caused solely by NCP viruses. Fatal ulcerative enteritis arises when PI animals encounter CP viruses[4, 7].
BVDV can cause a range of clinical signs, including fever, diarrhea, respiratory distress, infertility, abortion, and in severe cases, mucosal disease, which is often fatal[7].
BVDV is spread through direct contact with infected animals, including nasal secretions, saliva, and feces, and indirectly through contaminated materials[8]. PI animals persistently shed high viral loads throughout their lives[8]. PI animals are a major source of infection for other cattle[9]. Therefore, rapid and accurate diagnosis and removal of PI animals from herds is essential for prevention, control, and extermination of the disease in affected countries[8].

Principle

The RIDX™ BVDV Ag SP Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of BVDV in bovine serum or plasma. This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the BVDV antigen exists in the sample, it binds to the gold-conjugated anti-BVDV antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the secondary anti-BVDV antibody on the test line, resulting in a red line. The control line indicates that the test is performed correctly and should appear when the test is complete.
Two different monoclonal antibodies against the recombinant conservative nonstructural NS3 protein[5] of BVDV are used as a capture and detector in the kit. The RIDX™ BVDV Ag SP Test Kit can detect BVDV in bovine serum or plasma with high accuracy.

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™ BVDV Ag SP Test	+	58	0	58
	-	2	92	94
	Total	60	92	152

Sensitivity: 96.67% (58/60, *95% CI: 88.64% ~ 99.08%)
Specificity: 100% (92/92, 95% CI: 95.99% ~ 100%)
Diagnostic Agreement: 98.68% (150/152, 95% CI: 95.33% ~ 99.64%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 1 x 10^4 $TCID_{50}$/mL

3. Cross-Reactivity
Potentially cross-reactive substances listed below have no effect on the performance of the RIDX™ BVDV Ag SP Test Kit.

Pathogen	Titer ($TCID_{50}$/mL)
Aino virus	1 x 10^5
Akabane virus	1 x 10^5
Bovine coronavirus (BCV)	1 x 10^4
Bovine rotavirus	1 x 10^3
Chuzan virus (CHUV)	1 x 10^4
Ibaraki virus (IBAV)	1 x 10^3

Kit Components

	Component	Quantity/kit
1	BVDV Ag test device	10
2	Disposable dropper	10
3	Sample dilution buffer	1
4	Instructions for use	1

Storage & Stability

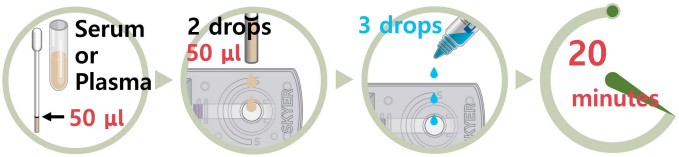
1. Store the test kit at 2~30℃ (35.6~86.0℉). **Do NOT freeze.**
2. Do not store the test kit in direct sunlight.
3. The test kit is stable within the expiration date marked on the package label.

Sample Preparation

1. **Serum or plasma from cattle of all ages should be used as specimens.**
2. Prepare bovine serum or plasma using the standard procedures.
3. Serum or plasma, either fresh or stored at 2~8°C (35.6~46.4℉) for up to 72 hours, can be used. For longer storage, freeze at −20°C (−4℉) or below. However, results from samples frozen for over one month may differ from those obtained before freezing.

Test Procedure

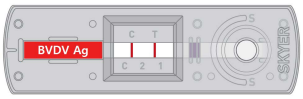
1. All samples and test components should be at room temperature (15~30°C/59~86℉) before use.
2. Take 50 µL of sample to the black line of the dropper.
3. Apply the taken sample into the sample hole (S).
4. Apply 3 drops (approximately 100 µL) of the dilution buffer into the sample hole (S).
5. Read test result at 20 minutes. **Do not read results that appear after 20 minutes.**



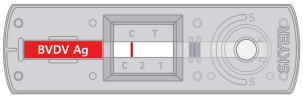
[Summary of Test Procedure]

Interpretation of Results

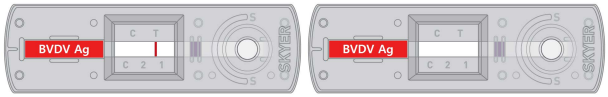
1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of BVDV antigens.



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.



Key Considerations When Judging Results

1. If the initial test result is positive, we recommend performing a second test after 3–4 weeks. Cattle that test positive on the initial test should be quarantined until the second test is performed to prevent the spread of BVDV.
2. In the case of transiently infected (TI) cattle, the virus titer usually drops significantly after 3 to 4 weeks as antibodies to BVDV are formed. Consequently, there is a high probability that the second test, conducted 3 to 4 weeks later, will yield a negative result. On the other hand, persistently infected (PI) cattle exhibit viremia and virus shedding throughout their lives, resulting in a positive result on the second test.

Precautions

1. This test kit is for veterinary *in vitro* diagnostic use only for cattle. Do not use this test kit for other animals.
2. This rapid kit is only for preliminary screening. The final decision should be made by a qualified veterinarian based on the results of this kit, clinical symptoms and evaluation by a veterinarian, and, if necessary, the results of additional detailed diagnostic procedures.
3. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
4. Do not touch the membrane in the sample hole on the device.
5. The device should not be used if the foil pouch is damaged or opened.
6. Do not use an expired test kit. The expiration date is marked on the package label.
7. Do not reuse the components of the kit.
8. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
9. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials following national and local regulations.
10. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.

References

1. International Committee on Taxonomy of Viruses. *Virus Taxonomy: 2024 Release*. Email Ratification February 2025 (MSL #40).
2. Scharnböck B, Roch FF, Richter V, Funke C, Firth CL, Obritzhauser W, Baumgartner W, A Käsbohrer, Pinior B. A meta-analysis of bovine viral diarrhoea virus (BVDV) prevalences in the global cattle population. *Scientific Reports* 2018; 8: 14420.
3. Ridpath JF. Bovine Viral Diarrhea Virus: Global Status. *Veterinary Clinics: Food Animal Practice* 2010; 26: 105–121.
4. Deregt D, Loewen KG. Bovine viral diarrhea virus: Biotypes and disease. *Canadian Veterinary Journal* 1995; 36: 371–378.
5. Donis RO. Molecular Biology of Bovine Viral Diarrhea Virus and Its Interactions with the Host. *Veterinary Clinics of North America: Food Animal Practice* 1995; 11(3); 393–423.
6. McClurkin AW, Littledike ET, Cutlip RC, Frank GH, Coria MF, Bolin SR. Production of Cattle Immunotolerant to Bovine Viral Diarrhea Virus. *Canadian Journal of Comparative Medicine* 1984; 48: 156–161.
7. Baker JC. The Clinical Manifestations of Bovine Viral Diarrhea Infection. *Veterinary Clinics of North America: Food Animal Practice* 1995; 11(3); 425–445.
8. Broersen BW. Bovine Viral Diarrhea Virus Infections: Manifestations of Infection and Recent Advances in Understanding Pathogenesis and Control. Veterinary Pathology 2014; 51(2): 453–464.
9. Houe H. Epidemiology of Bovine Viral Diarrhea Virus. *Veterinary Clinics of North America: Food Animal Practice* 1995; 11(3); 521–547.

Symbol Descriptions

LIC	License number
CAT	Catalogue number
LOT	Batch code, Lot number
	Consult instructions for use
Σ_n	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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