

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ BVDV Ag FE Test Kit

[Catalogue Number: LGM-BVG-11]

Introduction

Bovine viral diarrhea virus (BVDV), a single-stranded positive-sense RNA virus, genus *Pestivirus* in the *Flaviviridae* family¹, 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 viruses⁵. Calves are infected by NCP BVDV in utero during the first 125 days of gestation, when their immune systems have not fully developed⁶. 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 fatal⁷.

BVDV is spread through direct contact with infected animals, including nasal secretions, saliva, and feces, and indirectly through contaminated materials⁸. PI animals persistently shed high viral loads throughout their lives⁹. PI animals are a major source of infection for other cattle⁹. Therefore, rapid and accurate diagnosis and removal of PI animals from herds is essential for prevention, control, and extermination of the disease in affected countries⁸.

Principle

The RIDX™ BVDV Ag FE Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of BVDV in bovine feces or ear notches. 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 protein⁵ of BVDV are used as a capture and detector in the kit. The RIDX™ BVDV Ag FE Test Kit can detect BVDV in bovine feces or ear notches with high accuracy.

Performance

1. Sensitivity & Specificity with fecal specimen

		RT-PCR		
		+	-	Total
RIDX™	+	36	0	36
BVDV Ag FE	-	4	80	84
Test	Total	40	80	120

Sensitivity: 90.00% (36/40, *95% CI: 76.95% ~ 96.04%)

Specificity: 100% (80/80, 95% CI: 95.42% ~ 100%)

Diagnostic Agreement: 96.67% (116/120, 95% CI: 91.74% ~ 98.70%)

* 95% CI: 95% Confidence Interval

2. Sensitivity & Specificity with ear notch specimen

		RT-PCR		
		+	-	Total
RIDX™	+	14	0	14
BVDV Ag FE	-	0	71	71
Test	Total	14	71	85

Sensitivity: 100% (14/14, 95% CI: 78.47% ~ 100%)

Specificity: 100% (71/71, 95% CI: 94.87% ~ 100%)

Diagnostic Agreement: 100% (85/85, 95% CI: 95.68% ~ 100%)

3. Limit of Detection: 1 x 10⁴ TCID₅₀/mL

4. Cross-Reactivity

Potentially cross-reactive substances listed below have no effect on the performance of the RIDX™ BVDV Ag FE 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

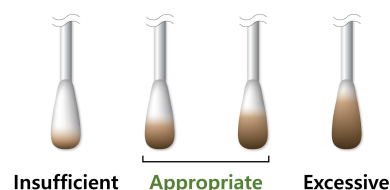
Component	Quantity/kit
1 BVDV Ag test device	10
2 Sample dilution buffer	10
3 Disposable swab	10
4 Dropper cap with filter	10
5 Paper rack for standing buffer tubes	1
6 Instructions for use	1

Storage & Stability

1. Store the test kit at 2~30°C (35.6~86.0°F). **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 label.

Sample Preparation

1. Feces or ear notches from cattle of all ages should be used as specimens.
2. The size of the ear notch specimen should be **2~3 mm in diameter**.
3. The amount of fecal sample may affect the results. It is required to follow the swab amount of feces as shown in the picture below. The excessive sample may induce a false positive result and slow migration.

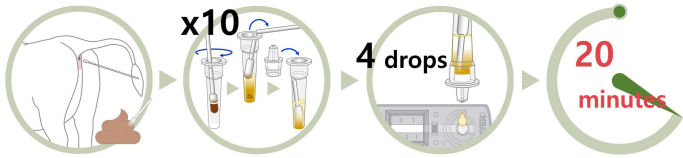


4. The samples should be tested immediately after collection.
5. If samples cannot be tested promptly, they should be stored at 2~8°C (35.6~46.4°F) for up to 24 hours. For longer storage, freeze at -20°C (-4°F) or below. But, results from samples frozen for over one month may differ from those obtained before freezing. Frozen samples should be brought to room temperature (15~30°C/59~86°F) before use.

◆ Test Procedures

[Fecal Specimen]

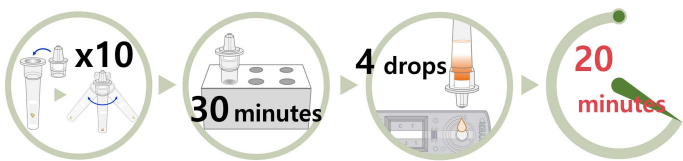
1. All samples and test components should be at room temperature (RT: 15~30°C/59~86°F) before use.
2. Using a swab to collect specimen.
3. Put the swab into the sample dilution buffer tube and stir the solution 10 times with the swab to disperse the specimen into the buffer.
4. Break the head of the cotton swab and discard the rod.
5. Attach a dropper cap to the top of the buffer tube.
6. Apply 4 drops (approximately 100 µL) of the processed solution in the sample hole on the device.
7. Read test result at 20 minutes. **Do not read results that appear after 20 minutes.**



[Summary of Test Procedure: Fecal specimen]

[Ear Notch Specimen]

1. All samples and test components should be at RT before use.
2. Collect an ear notch from cattle using an ear notcher.
3. Put the ear notch into the sample dilution buffer tube, attach a dropper cap to the top of the buffer tube, and shake 10 times.
4. Incubate the ear notch in the buffer for 30 minutes at room temperature (15~30°C/59~86°F). **Do not leave it on for more than 30 minutes at this step.**
5. Apply 4 drops (approximately 100 µL) of the processed solution in the sample hole on the device.
6. Read test result at 20 minutes. **Do not read results that appear after 20 minutes.**

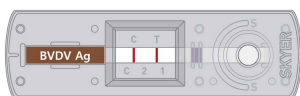


[Summary of Test Procedure: Ear notch specimen]

◆ Interpretation of Results

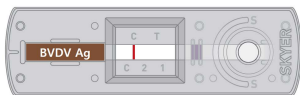
1. Positive result

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



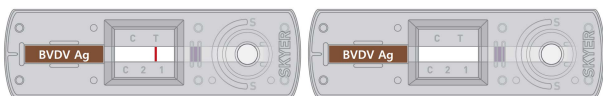
2. Negative result

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.
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.
7. Do not reuse the components of the kit except the paper rack.
8. Do not mix components from different lot numbers because the components 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.

◆ References

1. International Committee on Taxonomy of Viruses. *Virus Taxonomy: 2024 Release*. Email Ratification February 2025 (MSL #40).
2. Scharnböck B *et al.*, 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 *et al.*, Bovine viral diarrhoea virus: Biotypes and disease. *Canadian Veterinary Journal* 1995; 36: 371-378.
5. Donis RO. Molecular Biology of Bovine Viral Diarrhoea Virus and Its Interactions with the Host. *Veterinary Clinics of North America: Food Animal Practice* 1995; 11(3): 393-423.
6. McClurkin AW *et al.*, Production of Cattle Immunotolerant to Bovine Viral Diarrhoea Virus. *Canadian Journal of Comparative Medicine* 1984; 48: 156-161.
7. Baker JC. The Clinical Manifestations of Bovine Viral Diarrhoea Infection. *Veterinary Clinics of North America: Food Animal Practice* 1995; 11(3): 425-445.
8. Broersen BW. Bovine Viral Diarrhoea 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 Diarrhoea Virus. *Veterinary Clinics of North America: Food Animal Practice* 1995; 11(3): 521-547.

◆ Symbol Descriptions

	License number
	Catalogue number
	Batch code, Lot number
	Consult instructions for use
	Contains sufficient for <n> tests
	Do not reuse
	<i>In vitro</i> diagnostic medical device
	Temperature limitation
	Do not use, if the package is damaged
	Upper side
	Manufacturer



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