Rapid Bovine Leukemia Virus Antibody Test Kit

Document Number: SKR-IFU-BLB10031
Revised Date: 14 October 2025

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ BLV Ab Test Kit

[Catalogue Number: LGM-BLB-11]

Introduction

Enzootic bovine leukosis is a contagious disease caused by bovine leukemia virus (BLV, the synonym of bovine leukosis virus). BLV contains two copies of a single-stranded genomic RNA and belongs to the genus *Deltaretrovirus* in the family Retroviridae. The *Deltaretrovirus* genus also includes human T-cell lymphotropic virus types I and II (HTLV-I and HTLV-II)[1].

Domestic cattle are the natural hosts for BLV. 70% of animals infected with BLV develop a B-cell lymphoproliferative syndrome with altered productive traits and 1 to 5% die from B-cell lymphosarcoma[2].

BLV is transmitted horizontally by direct contact, iatrogenic procedures, or insect bites by transferring infected cells from the milk, blood, and body fluids of heavily infected cattle[3, 4]. The BLV-infected cattle may act as a reservoir for infectious BLV, and the BLV infection can be a risk factor for breast cancer in humans[5].

Principle

The RIDX™ BLV Ab Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of bovine leukemia virus antibodies in bovine serum.

This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the BLV antibody exists in the sample, it binds to the gold-conjugated BLV antigen. The antibody-antigen complex moves through the membrane by capillary force and responds to the BLV antigen 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.

The high-quality recombinant BLV envelope glycoprotein (gp51) antigen is used as a capture and detector in the kit[6, 7]. The RIDX™ BLV Ab Test Kit can detect BLV antibodies in bovine blood with high accuracy.

Performance

1. Sensitivity & Specificity

[AGID]

		AGID		
		+	-	Total
RIDX™	+	100	7	107
BLV Ab	-	0	152	152
Test	Total	100	159	259

Sensitivity: 100% (100/100, *95% CI: 96.30% ~ 100%)
Specificity: 95.60% (152/159, 95% CI: 91.19% ~ 97.85%)
Diagnostic Agreement: 97.30% (252/259, 95% CI: 94.53% ~ 98.68%)

* 95% CI: 95% Confidence Interval

[Blocking ELISA]

		Blocking ELISA		
		+	-	Total
RIDX™	+	105	2	107
BLV Ab	-	0	152	152
Test	Total	105	154	259

Sensitivity: 100% (105/105, 95% CI: 96.47% ~ 100%)
Specificity: 98.70% (152/154, 95% CI: 95.39% ~ 99.64%)
Diagnostic Agreement: 99.23% (257/259, 95% CI: 97.23% ~ 99.79%)

2. Cross-Reactivity

Potentially cross-reactive substances listed below have no effect on the performance of the RIDX™ BLV Ab Test Kit.

Antiserum to	Result
Bovine herpesvirus type 1 (BHV-1)	Negative
Bovine respiratory syncytial virus (BRSV)	Negative
Bovine viral diarrhea virus (BVDV)	Negative
Parainfluenza virus 3 (PI-3)	Negative
Yersinia enterocolitica O:9	Negative

Kit Components

	Component	Number/Kit
1	BLV Ab test device	10
2	Dilution buffer	1
3	Disposable capillary tube	10
4	Instructions for use	1

Storage & Stability

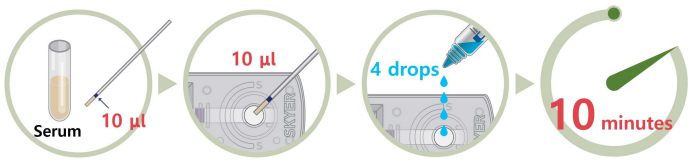
1. Store the test kit at 2~30℃ (35.6~86.0℉). **Do not freeze.**
2. Do not store the test kit in direct sunlight.
3. The test kit is stable within the expiration date marked on the package label.

Sample Preparation

1. Prepare serum using a standard procedure of clinical laboratory.
2. Samples either fresh or stored at 2~8°C (35.6~46.4℉) for up to 14 days, can be used. For longer storage (up to 15 months), freeze at -20°C (-4℉) or below. But, results from samples frozen for over one month may differ from those obtained before freezing.

Test Procedure

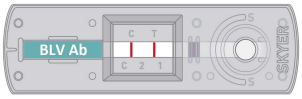
1. All samples and test components should be at room temperature (15~30°C/59~86℉) before use.
2. Take the bovine serum using a capillary tube.
3. Apply 10 μL of the serum into the sample hole (S).
4. Apply 4 drops of dilution buffer into the sample hole (S).
5. Read test result at 10 minutes. **Do not read results that appear after 10 minutes.**



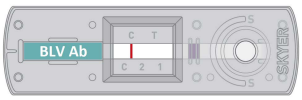
[Summary of Test Procedure]

Interpretation of Results

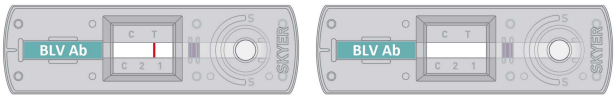
1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of BLV antibodies.



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* 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 of the test 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 test components (device and capillary tube).
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. Gillet N, Florins A, Boxus M, Burteau C, Nigro A, Vandermeers F, Balon H, Bouzar AB, Defoiche J, Burny A, Reichert M, Kettmann R, Willems L. Mechanisms of leukemogenesis induced by bovine leukemia virus: prospects for novel anti-retroviral therapies in human. *Retrovirol*. 2007; 4: 18.
2. Schwartz I, Levy D. Pathobiology of bovine leukemia virus. *Vet Res*. 1994; 25(6): 521–536.
3. Ferrer JF, Piper CE. An evaluation of the role of milk in the natural transmission of BLV. *Ann Rech Vet*. 1978; 9(4): 803–807.
4. Hopkins SG, DiGiacomo RF. Natural transmission of bovine leukemia virus in dairy and beef cattle. *Vet Clin North Am Food Anim Pract*. 1997; 13(1): 107–128.
5. Buehring GC, Sans HM. Breast Cancer Gone Viral? Review of Possible Role of Bovine Leukemia Virus in Breast Cancer, and Related Opportunities for Cancer Prevention. *Int J Environ Res Public Health*. 2020; 17(1): 209.
6. Jun MH, Chung UI, An SH. Studies on bovine lymphosarcoma. III. Preparation of bovine leucosis virus antigen and its biological properties. *Res Rep ORD*. 1983; 25: 68–75.
7. Kim EJ, Cheong KM, Jung HK, Kim BH, Song JY, Cho IS, Lee KK, Shin YK. Development and evaluation of an immunochromatographic assay using a gp51 monoclonal antibody for the detection of antibodies against the bovine leukemia virus. *J Vet Sci*. 2016; 17(4): 479–487.

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

SKYER, INC.
#532, 416, Hwagok-ro, Gangseo-gu, Seoul, 07548,
Republic of Korea
TEL: +82-2-706-6801, FAX: +82-50-4096-6988
Technical support: marketing@skyer.co.kr
www.skyerdiagnostics.com
Korean Veterinary Diagnostics Manufacturer License No. 300