

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

 RIDX™ Bovine Cryptosporidium Ag Test Kit

[Catalogue Number: LGM-BCG-11]

 **Introduction**

Bovine cryptosporidiosis, a gastrointestinal disease of cattle, is caused by the protozoan parasite *Cryptosporidium*¹. It's a major cause of neonatal calf diarrhea and can be fatal if not managed properly.

Cryptosporidium parvum is the primary species responsible for clinical illness in young calves. Other species, including *C. bovis*, *C. ryanae*, and *C. andersoni*, have been observed to infect older animals, though they typically manifest as subclinical or mild infections^{1,2}.

Calves ingest sporulated oocysts through contaminated feed, water, or bedding³. Within the small intestine, oocysts release sporozoites that invade epithelial cells and undergo both asexual and sexual reproduction. Thin-walled oocysts enable autoinfection, amplifying parasite load⁴. Clinically, affected calves develop diarrhea (mild to severe, watery, and potentially containing mucus or blood), dehydration, lethargy, anorexia, and weight loss⁵. Severe infections may lead to villous atrophy and crypt hyperplasia on histopathology. The prevalence of infection has been observed to peak in calves within the first four weeks of life³.

The fecal-oral route is the primary means of transmission⁶. Oocysts, the infective stage of the parasite, are shed in feces and have been known to survive for months in cool, moist conditions. They are easily disseminated through contaminated environments, equipment, and even by people^{3,6}.

Furthermore, cattle act as a zoonotic reservoir for this parasite, with the potential to induce severe diarrhea in young children and immune-compromised individuals⁷. The infection constitutes a pervasive global phenomenon that results in substantial economic losses within the beef and dairy industries⁸.

 **Principle**

The RIDX™ Bovine Cryptosporidium Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of *Cryptosporidium* in bovine feces. This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the *Cryptosporidium* antigen exists in the sample, it binds to the gold-conjugated anti-*Cryptosporidium* antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the secondary anti-*Cryptosporidium* 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 to the oocyst of *Cryptosporidium parvum* are used as a capture and detector in the kit. The RIDX™ Bovine Cryptosporidium Ag Test Kit can detect *Cryptosporidium* in bovine feces with high accuracy.

 **Performance**

1. Sensitivity & Specificity

		PCR			Total
		+	-		
RIDX™ Bovine	+	43	1	44	
Cryptosporidium	-	2	278	280	
Ag Test	Total	45	279	324	

Sensitivity: 95.56% (43/45, *95% CI: 85.17% ~ 98.77%)
Specificity: 99.64% (278/279, 95% CI: 98.00% ~ 99.94%)
Diagnostic Agreement: 99.07% (321/324, 95% CI: 97.31% ~ 99.68%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 10² oocysts/mL

3. Cross-Reactivity

Potentially cross-reactive substances listed below have no effect on the performance of the RIDX™ Bovine Cryptosporidium Ag Test Kit.

Pathogen	Titer
Aino virus	1 x 10 ⁵ TCID ₅₀ /mL
Akabane virus	1 x 10 ⁵ TCID ₅₀ /mL
Bovine coronavirus (BCV)	1 x 10 ⁴ TCID ₅₀ /mL
Bovine herpesvirus (BHV-1)	1 x 10 ⁷ TCID ₅₀ /mL
Bovine respiratory syncytial virus (BRSV)	1 x 10 ⁸ TCID ₅₀ /mL
Bovine rotavirus	1 x 10 ³ TCID ₅₀ /mL
<i>Escherichia coli</i> K99	1 x 10 ⁷ CFU/mL
<i>Giardia lamblia</i>	1 x 10 ⁷ cysts/L
Parainfluenza virus SF-4	1 x 10 ⁸ TCID ₅₀ /mL

 Kit Components

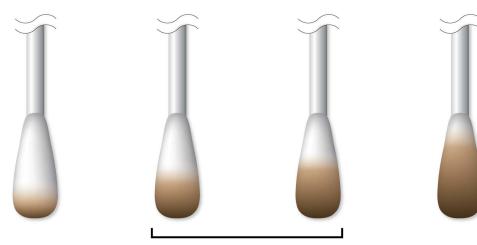
Component	Quantity/kit
1 Cryptosporidium Ag test device	10
2 Sample dilution buffer	10
3 Disposable swab	10
4 Dropper cap with filter	10
5 Paper rack for standing buffer tubes	1
6 Instructions for use	1

 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 kit is stable within the expiration date marked on the label.

 Sample Preparation

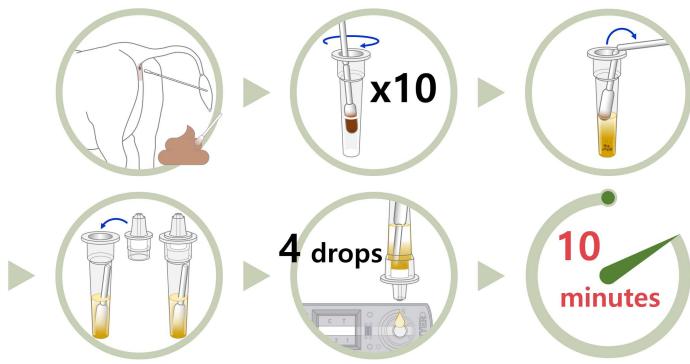
1. **Feces from cattle of all ages should be used as specimens.**
2. The amount of fecal sample may affect the results. It is required to follow the swab amount of feces as shown in the picture below. The excessive sample may induce a false positive result and slow migration.



3. The samples should be tested immediately after collection.
4. 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 Procedure

1. All samples and test components should be at room temperature (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 10 minutes. **Do not read results that appear after 10 minutes.**

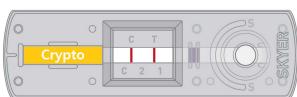


[Summary of Test Procedure]

◆ Interpretation of Results

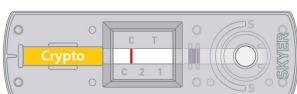
1. Positive result

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



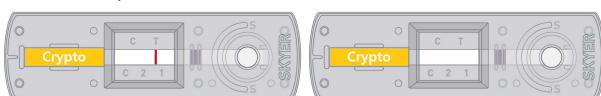
2. Negative result

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.



◆ 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 except the paper rack.
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. Fayer R, Ungar BLP. *Cryptosporidium* spp. and Cryptosporidiosis. *Microbiological Reviews* 1986; 50(4): 458–483.
2. Xiao L, Fayer R, Ryan U, Ryan U, Upton SJ. *Cryptosporidium* Taxonomy: Recent Advances and Implications for Public Health. *Clinical Microbiology Reviews* 2004; 17(1): 72–97.
3. Carey CM, Lee H, Trevors JT. Biology, persistence and detection of *Cryptosporidium parvum* and *Cryptosporidium hominis* oocyst. *Water Research* 2004; 38: 818–862.
4. Lendner M, Daugschies A. *Cryptosporidium* infections: molecular advances. *Parasitology* 2014; 141(11): 1511–1532.
5. Bouzid M, Hunter PR, Chalmers RM, Tyler KM. *Cryptosporidium* Pathogenicity and Virulence. *Clinical Microbiology Reviews* 2013; 26(1): 115–134.
6. Fayer R, Morgan U, Upton SJ. Epidemiology of *Cryptosporidium*: transmission, detection and identification. *International Journal for Parasitology* 2000; 30: 1305–1322.
7. Ryan U, Fayer R, Xiao L. *Cryptosporidium* species in humans and animals: current understanding and research needs. *Parasitology* 2014; 141: 1667–1685.
8. Buchanan R, Wieckowski P, Matechou E, Katzer F, Tsatsou AD, Farre M. Global prevalence of *Cryptosporidium* infections in cattle: A meta-analysis. *Current Research in Parasitology & Vector-Borne Diseases* 2025; 7: 100264.

◆ Symbol Descriptions

	License number
	Catalogue number
	Batch code, Lot number
	Consult instructions for use
	Contains sufficient for $\langle n \rangle$ 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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