Rapid Transmissible Gastroenteritis Virus Antigen Test Kit

Document Number: SKR-IFU-PTG10049
Revised Date: 15 October 2025

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ TGEV Ag Test Kit
[Catalogue Number: LGM-PTG-11, LGM-PTG-12]

Introduction

Transmissible gastroenteritis (TGE) in swine is one of the most significant diarrhea-causing diseases in young pigs and is caused by transmissible gastroenteritis virus (TGEV). TGEV belongs to the genus *Alphacoronavirus*, family Coronaviridae and contains a single-stranded, positive-sense RNA genome of approximately 28.5 kb in length[1, 2].
The enteropathogenic coronavirus causes severe diarrhea, vomiting, and dehydration, with mortality rates of greater than 95% in piglets less than 2 weeks old[3]. TGEV infection damages the small intestine, impairs immune functions, and increases pathogenic bacterial loading, all of which may facilitate secondary infections by other pathogens[4]. The infection was usually mild to moderate and focal in the pigs without clinical signs of the disease and more severe and extensive in the pigs with clinical signs of the disease variable in severity[5].
TGEV spreads rapidly by aerosol or contact exposure and is infected through the oral or nasal route. The surviving pigs continue to shed the virus from their stool or nasal secretions for 2 to 8 weeks. Some pigs excrete the virus intermittently for up to 18 months[5, 6].

Principle

The RIDX™ TGEV Ag Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of TGEV antigens in porcine 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 TGEV antigen exists in the sample, it binds to the gold-conjugated TGEV monoclonal antibody. The antigen-antibody complex moves through the membrane by capillary force and responds to the TGEV monoclonal 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.
The highly selective and sensitive two monoclonal antibodies to TGEV are used as capture and detector in the kit. The RIDX™ TGEV Ag Test Kit can detect TGEV antigen in porcine feces with high accuracy.

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™ TGEV Ag Test	+	52	2	54
	-	1	150	151
	Total	53	152	205

Sensitivity: 98.11% (52/53, *95% CI: 90.06% ~ 99.67%)
Specificity: 98.68% (150/152, 95% CI: 95.33% ~ 99.64%)
Diagnostic Agreement: 98.54% (202/205, 95% CI: 95.79% ~ 99.50%)

* 95% CI: 95% Confidence Interval

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

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

Pathogen	Titer
Classical swine fever virus (CSFV)	1 x 10^2 $TCID_{50}$/mL
Japanese encephalitis virus (JEV)	1 x 10^2 $TCID_{50}$/mL
Porcine circovirus type 2 (PCV2)	1 x 10^2 $TCID_{50}$/mL
Porcine epidemic diarrhea virus (PEDV)	1 x 10^2 $TCID_{50}$/mL
Porcine reproductive and respiratory syndrome virus (PRRSV)	1 x 10^2 $TCID_{50}$/mL
Porcine rotavirus	1 x 10^2 $TCID_{50}$/mL
Salmonella spp.	1 x 10^2 CFU/mL

Kit Components

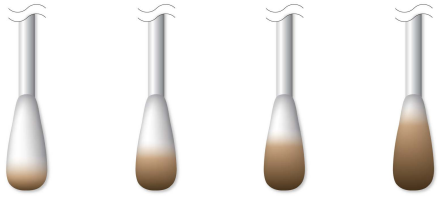
Component	Quantity/kit by CAT No.	
	LGM-PTG-11	LGM-PTG-12
1 TGEV Ag test device	10	2
2 Sample dilution buffer	10	2
3 Disposable swab	10	2
4 Disposable dropper	10	2
5 Instructions for use	1	1

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.

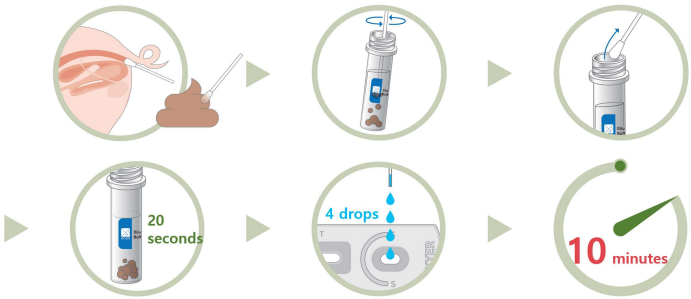
Sample Preparation

1. **Porcine fecal swabs** should be used for this test.
2. The samples should be tested immediately after collection.
3. If samples are not tested immediately, they should be stored at 2~8°C (35.6~46.4°F) for 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.
4. The amount of fecal sample with swab may affect the results. It is required to follow the swab amount of feces as shown in the picture below. The excessive fecal amount may induce a false positive result and slow migration.



Test Procedure

1. All reagents and samples must be at room temperature (15~30℃ /59~86℉) before use.
2. Collect fecal sample using a swab.
3. Put the swab into the sample dilution buffer and stir the solution with the swab to disperse the sample into the buffer (approximately 10 seconds).
4. Remove the swab from the sample dilution buffer.
5. Wait for 20 seconds to settle down the large particles.
6. Remove the test device from the pouch and place it on a flat and dry surface.
7. Take the supernatant sample in the tube by using a disposable dropper.
8. Apply 4 drops of the mixed sample into the sample hole (S), drop by drop vertically.
9. Read test result at 10 minutes. **Do not read results that appear after 10 minutes.**

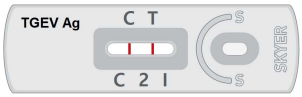


[Summary of Test Procedure]

Interpretation of Results

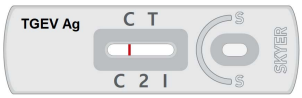
1. Positive result

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



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 pigs. 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.
6. Do not use an expired test kit. The expiration date is marked on the package label.
7. Do not reuse the components (device, buffer, dropper, and swab).
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. Brian DA, Dennis DE, Guy JS. Genome of porcine transmissible gastroenteritis virus. *J Virol.* 1980; 34(2): 410–415.
2. Jacobs L, Van Der Zeijst BAM, Horzinek MC. Characterization and translation of transmissible gastroenteritis mRNAs. *J. Virol.* 1986; 57: 1010–1015.
3. Doyle LP, Hutchings LM. A transmissible gastroenteritis in pigs. *J Am Vet Med Ass.* 1946; 108: 257–259.
4. Xia L, Yang Y, Wang J, Jing Y, Yang Q. Impact of TGEV infection on the pig small intestine. *Virol J.* 2018; 15: 102.
5. Morin M, Morehouse LG, Solorzano RF, Olson LD. Transmissible gastroenteritis in feeder swine: clinical, immunofluorescence and histopathological observations. *Can J Comp Med.* 1973; 37(3): 239–248.
6. Liu Q, Gerdts V. Transmissible Gastroenteritis Virus of Pigs and Porcine Epidemic Diarrhea Virus (Coronaviridae). *Encycl Virol.* 2021; 4(2): 850–853.

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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