Rapid Porcine Epidemic Diarrhea Virus Antigen Test Kit

Document Number: SKR-IFU-PPG10219
Revised Date: 15 October 2025

For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ PEDV Ag Test Kit

[Catalogue Number: LGM-PPG-11, LGM-PPG-12]

Introduction

Porcine epidemic diarrhea virus (PEDV), the etiological agent of PED (porcine epidemic diarrhea), is an approximately 28 kb, positive-sense, single-stranded, enveloped RNA virus, which is a member of the genus *Alphacoronavirus* in the family Coronaviridae of the order Nidovirales[1].

PEDV can infect pigs of all ages, causing watery diarrhea and vomiting accompanied by anorexia and depression. Morbidity approaches 100 % in piglets but can vary in sows. The incubation period of PEDV is approximately 2 days, ranging from 1 to 8 days depending on field conditions. The interval between the onset and cessation of clinical signs is 3 to 4 weeks[2, 3].

The disease severities and mortality rates are inversely associated with the age of the pigs[4]. The mortality rate averages 50 %, often approaching 100 % in 1- to 3-day-old piglets, and decreases to 10 % thereafter. In older animals, including weaner to finisher pigs, clinical signs are self-limiting within 1 week after the onset of the disease[2].

The main means of PEDV transmission is the direct or indirect fecal-oral route[3, 4]. Fecal shedding of PEDV can be detected within 48 hours and may last for up to 4 weeks. Diarrheal feces and/or vomitus and other contaminated fomites, such as transport trailers and feed, can be major transmission sources of the virus[5]. Asymptomatic infected older pigs can be a possible reservoir and carrier. PEDV can become airborne, remain contagious while suspended in the air, and the genetic material of the virus can be transported long distances following natural infections[6].

Principle

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

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	-	Total
RIDX™ PEDV Ag Test	+	228	4	232
	-	4	276	280
	Total	232	280	512

Sensitivity: 98.28% (228/232, *95% CI: 95.65% ~ 99.33%)
Specificity: 98.57% (276/280, 95% CI: 96.39% ~ 99.44%)
Diagnostic Agreement: 98.44% (504/512, 95% CI: 96.95% ~ 99.21%)

* 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™ PEDV Ag Test Kit.

Pathogen	Titer ($TCID_{50}$/mL)
Bovine viral diarrhea virus (BVDV)	1 x 10^5
Classical swine fever virus (CSFV)	1 x 10^5
Porcine circovirus type 2 (PCV2)	1 x 10^4
Porcine reproductive and respiratory syndrome virus (PRRSV)	1 x 10^3
Porcine rotavirus	1 x 10^3
Transmissible gastroenteritis virus (TGEV)	1 x 10^3

Kit Components

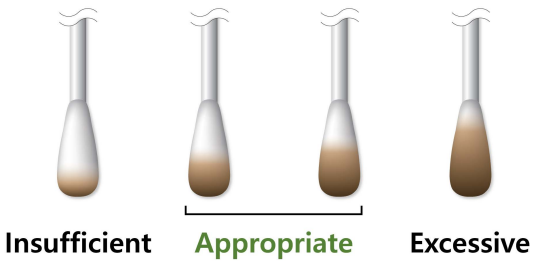
Component	Quantity/kit by CAT No.	
	LGM-PPG-11	LGM-PPG-12
1 PEDV Ag test device	10	2
2 Sample dilution buffer	10	2
3 Disposable swab	10	2
4 Disposable dropper	10	2
5 Instructions for use	1	1

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.

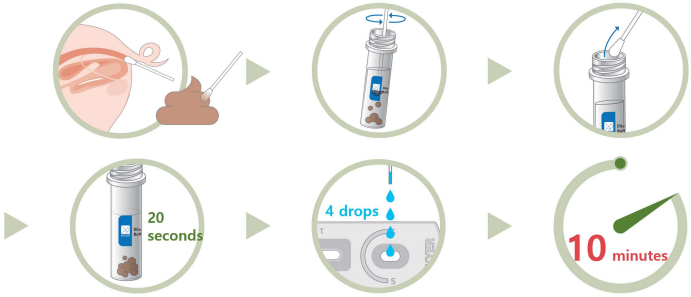
Sample Preparation

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

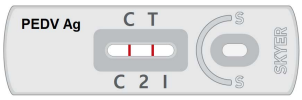
1. All reagents and samples must be at room temperature (15~30℃ /59~86℉) before use.
2. Collect fecal sample using a swab.
3. Put the swab into the sample dilution buffer and stir the solution with the swab to disperse the sample into the buffer (approximately 10 seconds).
4. Remove the swab from the 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.**



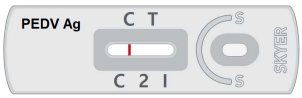
[Summary of Test Procedure]

Interpretation of Results

1. Positive result
Test (T) line and control (C) line within the result window indicate the presence of PEDV 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 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 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 (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. Kocherhans R, Bridgen A, Ackermann M, Tobler K. Completion of the porcine epidemic diarrhoea coronavirus (PEDV) genome sequence. *Vir Gen*. 2001; 23(2): 137–144.
2. Lee C. Porcine epidemic diarrhea virus: An emerging and re-emerging epizootic swine virus. *Virol J*. 2015; 12: 193.
3. Jung K, Saif LJ, Wang Q. Porcine epidemic diarrhea virus (PEDV): An update on etiology, transmission, pathogenesis, and prevention and control. *Vir Res*. 2020; 286: 198045.
4. Shibata I, Tsuda T, Mori M, Ono M, Sueyoshi M, Uruno K. Isolation of porcine epidemic diarrhea virus in porcine cell cultures and experimental infection of pigs of different ages. *Vet Microbiol*. 2000; 72: 173–182.
5. Jung K, Saif LJ. Porcine epidemic diarrhea virus infection: Etiology, epidemiology, pathogenesis and immunoprophylaxis. *Vet J*. 2015; 204: 134–143.
6. Alonso C, Goede DP, Morrison RB, Davies PR, Rovira A, Marthaler DG, Torremorell M. Evidence of infectivity of airborne porcine epidemic diarrhea virus and detection of airborne viral RNA at long distances from infected herds. *Vet Res*. 2014; 45: 73.

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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