Rapid Porcine ROTA Antigen Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ Porcine ROTA Ag Test Kit

[CAT No. LGM-PRG-11]

Introduction

Rotavirus is a genus of double-stranded RNA viruses in the family Reoviridae. There are nine species of rotavirus, referred to as A, B, C, D, F, G, H, I, and J, depending on serotypes[1].
Rotaviruses cause serious gastrointestinal diseases mainly in children under five years of age and children of other mammalian species. Children in the poorest countries account for 82% of rotavirus deaths[2].
Rotaviruses are pathogens that infect the mature enterocytes of the villi in the small intestine, and infection appears to be limited to these highly differentiated cells in immunologically competent hosts. In these hosts, infections are generally acute, yet diarrheal disease can be severe and life-threatening[3].
Rotaviruses are founded globally throughout swine populations. Five different serotypes (A, B, C, D, and H) affect pigs[4]. Porcine rotavirus A is a major cause of neonatal diarrhea in suckling and recently weaned piglets worldwide. The most common clinical symptom of the infections is diarrhea, usually white to yellow in color, for a few days until the pigs develop active immunity. Moderate dehydration is followed. Vomiting occurs but is not a major clinical sign. Prevalence, morbidity, and mortality are various depending on husbandry conditions[4]. The main transmission of porcine rotaviruses is the fecal-oral route. The Infection occurs through contact either with swine shedding the viruses in their feces or with a contaminated environment[5]. Porcine rotavirus A strains are commonly demonstrated to possess zoonotic potential[6].

Principle

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

Performance

1. Sensitivity & Specificity

		RT-PCR		
		+	−	Total
RIDX™ Porcine ROTA Ag Test	+	272	8	280
	−	20	420	440
	Total	292	428	720

Sensitivity: 93.15% (272/292, 95% CI*: 89.66% ~ 95.52%)
Specificity: 98.13% (420/428, 95% CI: 96.36% ~ 99.05%)
Diagnostic Agreement: 96.11% (692/720, 95% CI: 94.44% ~ 97.30%)

* CI: Confidence Interval

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

3. Cross-Reactivity
Below potential cross-reactivity substances do not affect the performance of the RIDX™ Porcine ROTA Ag Test Kit.

Pathogen	Titer
Classical swine fever virus (CSFV)	1 x 10^5 $TCID_{50}$/mL
Encephalomyocarditis virus (EMCV)	1 x $10^{4.1}$ $TCID_{50}$/mL
Japanese encephalitis virus (JEV)	1 x 10^5 $TCID_{50}$/mL
Porcine epidemic diarrhea virus (PEDV)	1 x 10^4 $TCID_{50}$/mL
Transmissible gastroenteritis virus (TGEV)	1 x 10^3 $TCID_{50}$/mL
Salmonella spp.	1 x 10^6 CFU/mL

Kit Components

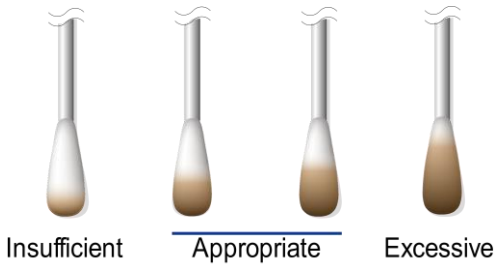
	Component	Number/Kit
1	Porcine ROTA Ag Test device	10
2	Sample dilution buffer (1mL)	10
3	Disposable swabs	10
4	Disposable dropper	10
5	Instructions for use	1

Storage & Stability

1. Store the test kit at 2~30℃ (35.6~86℉). 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 feces 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°F) for 24 hours. For longer storage, freeze at −20°C (−4°F) or below. 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 feces samples 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. Add 4 drops of the mixed sample into the sample hole (S), drop by drop vertically.
9. Read test results at 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 porcine rotavirus 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* diagnosis only especially swine. Do not use this test kit for other animals.
2. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
3. Do not touch the membrane of the test device.
4. Do not use the test device if the foil pouch is damaged or the seal is open.
5. Do not use an expired test kit. The expiration date is marked on the package label.
6. Do not reuse the test components (device, buffer, dropper, swab).
7. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
8. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials following national and local regulations.
9. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.

References

1. International Committee on Taxonomy of Viruses (ICTV). Virus Taxonomy: 2019 Release. Ratification March 2020 (MSL #35).
2. Parashar UM, Hummelman EG, Bresee JS, Miller MA, Glass RI. Global illness and deaths caused by rotavirus disease in children. *Emerg Infect Dis*. 2003; 9(5): 565–572.
3. Estes MK, Kang G, Zeng CQY, Crawford SE, Ciarlet M. Pathogenesis of rotavirus gastroenteritis. *Gastroenteritis Viruses: Novartis 238*. Wiley, Chichester 2001; 238: 82–100.
4. Vlasova AN, Amino JO, Saif LJ. Porcine Rotaviruses: Epidemiology, Immune Responses and Control Strategies. *Vir*. 2017; 9(3): 48.
5. Benfield DA, Stotz I, Moore R, McAdaragh JP. Shedding of rotavirus in feces of sows before and after farrowing. *J Clinic Microbiol*. 1982; 16(1): 186–190.
6. Martella V, Banyai K, Matthijnssens J, Buonavoglia C, Ciarlet M. Zoonotic aspects of rotaviruses. *Vet Microbiol*. 2010; 140(3–4): 246–255.

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