Rapid Foot-and-Mouth Disease Virus Antibody Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ FMDV 3ABC Ab Test Kit

[Catalogue Number: LGM-VFB-73]

Introduction

Foot-and-mouth disease (FMD) is an acute systemic disease of cloven-hooved animal species and is caused by Foot-and-mouth disease virus (FMDV), a nonenveloped positive-sense single-stranded RNA virus, the prototype member of the genus *Aphthovirus* of the family Picornaviridae[1]. FMDV occurs as seven distinct serotypes [Euroasiatic serotypes A, O, C, and Asia1 and South African Territories (SAT) serotypes SAT1, SAT2, and SAT3] and multiple subtypes reflecting significant genetic variability[1, 2].

All domestic cloven-hoofed animals are susceptible to FMDV, including cattle, pigs, sheep, goats, and buffalo. Cattle are usually the main host, although some strains appear to be specifically adapted to domestic pigs, sheep and goats[2].

FMD is characterized by fever (pyrexia) and vesicles in the mouth and on the muzzle, teats, and feet and is spread through direct contact or aerosolized virus via respiratory secretions, milk, semen, and ingestion of feed from infected animals[3]. In a susceptible population, morbidities reach 100% and mortalities are rare except in young animals[4, 5].

Principle

The RIDX™ FMDV 3ABC Ab Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies to FMDV in bovine or porcine blood specimens.

This kit shows two letters which are the test (T) line and the control (C) line on the surface of the device. If the FMDV antibodies exist in the samples, that bind to the cellulose nano beads-conjugated recombinant 3ABC non-structural polyprotein of FMDV. The antigen-antibody complexes move through the membrane by capillary force and respond to the Protein A on the test line, resulting in a blue line. The control line indicates that the test is performed correctly and should appear when the test is complete.

The high-quality recombinant 3ABC non-structural polyprotein antigen of FMDV is used as a detector in the kit. As the 3ABC non-structural polyprotein is very conservative protein in all FMDV serotypes[6], the RIDX™ FMDV 3ABC Ab Test Kit can detect FMDV antibodies to all seven serotypes of FMDV in bovine or porcine whole blood, serum, or plasma with high accuracy.

Performances

1. Sensitivity & Specificity

[Bovine specimens]

		ELISA		
		+	−	Total
RIDX™ FMDV 3ABC Ab Test	+	30	2	32
	−	0	498	498
	Total	30	500	530

Sensitivity: 100% (30/30, *95% CI: 88.65% ~ 100%)
Specificity: 99.60% (498/500, 95% CI: 98.55% ~ 99.89%)
Diagnostic Agreement: 99.62% (528/530, 95% CI: 98.63% ~ 99.90%)

*95% CI: 95% Confidence Interval

[Porcine specimens]

		ELISA		
		+	−	Total
RIDX™ FMDV 3ABC Ab Test	+	25	4	29
	−	5	496	501
	Total	30	500	530

Sensitivity: 83.33% (25/30, *95% CI: 66.44% ~ 92.66%)
Specificity: 99.20% (496/500, 95% CI: 97.96% ~ 99.69%)
Diagnostic Agreement: 98.30% (521/530, 95% CI: 96.80% ~ 99.10%)

*95% CI: 95% Confidence Interval

2. Limit of Detection (LOD)

FMDV serotype	Virus Neutralization Test (VNT) Titer
O	64
A	5.5
Asia1	177
SAT2	512

Kit Components

	Component	Number/Kit
1	FMDV NSP Ab test device	10
2	Anticoagulant tube with EDTA	10
3	Capillary tube (with line for 5 μL)	10
4	Dilution buffer	1
5	Instructions for use	1

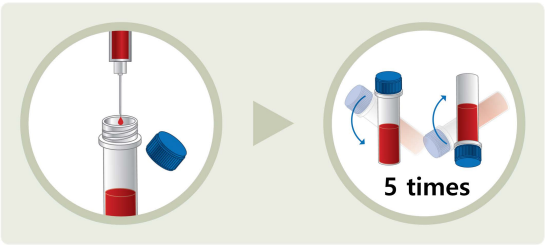
Storage & Stability

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 pouch for device and package label.

Sample Preparation

[Whole blood]

1. Collect 1 mL (0.5~1.5 mL) of the whole blood sample and put it into an anticoagulant tube.
2. Close the cap on the anticoagulant tube and invert the tube 5 times to mix blood sample and ethylene diamine tetra acetic acid (EDTA).



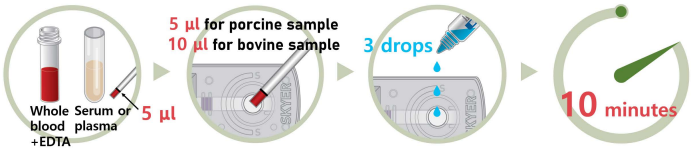
3. The anticoagulated whole blood samples should be used instantly after collection. If you cannot use the samples immediately, store them refrigerated (2~8℃/35.6~46.4℉) or keep them on ice. Do not freeze the anticoagulated whole blood samples. If you cannot use the samples within 24 hours, store them in a form of serum or plasma.

[Serum or plasma]

1. Prepare serum and plasma using a standard procedure of clinical laboratory.
2. Serum or plasma, either fresh or stored at 2~8°C (35.6~46.4℉) for up to 72 hours, can be used. For longer storage, 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 specimens and test components should be at room temperature (15~30°C/59~86℉) before use.
2. Using a capillary tube, take a specimen (anticoagulated whole blood, serum or plasma) and apply it to the sample hole (S). For porcine specimens, fill the dropper up to the 5 μL line and apply once; for bovine specimens, since 10 μL is required, **repeat this process twice**.
3. Apply 3 drops (approximately 100 μL) of dilution buffer into the sample hole (S).
4. Read test results at 10 minutes. **Do not read results that appear after 10 minutes.**

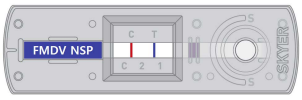


[Summary of Test Procedure]

Interpretation of Results

1. Positive results

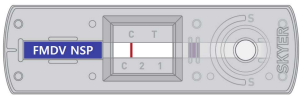
Test (T) line and control (C) line within the result window indicate the presence of FMDV antibodies.



※ If the whole blood specimen is too viscous or hemolyzed, flow along the membrane may be impeded, resulting in nonspecific false-positive results. Therefore, the results observed after the designated time are deemed unreliable.

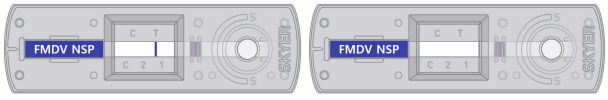
2. Negative result

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 and 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 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, dropper, and EDTA 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. Carrillo C, Tulman ER, Delhon G, Lu Z, Carreno A, Vagnozzi A, Kutish GF, Rock DL. Comparative genomics of foot-and-mouth disease virus. *J Virol*. 2005; 79(10): 6487–6504.
2. Klein J. Understanding the molecular epidemiology of foot-and-mouth-disease virus. *Inf Gen Evol*. 2009; 9: 153–161.
3. Arzt J, Baxt B, Grubman MJ, Jackson T, Juleff N, Rhyan J, Waters R, Rodriguez LL. The pathogenesis of foot-and-mouth disease II: viral pathways in swine, small ruminants, and wildlife; myotropism, chronic syndromes, and molecular virus-host interactions. *Transbound Emerg Dis*. 2011; 58(4): 305–326.
4. Kitching RP. Clinical variation in foot and mouth disease: cattle. *Rev Sci Tech Off Int Epiz*. 2002; 21(3): 499–504.
5. Kitching RP, Alexandersen S. Clinical variation in foot and mouth disease: pigs. *Rev Sci Tech Off Int Epiz*. 2002; 21(3): 513–518.
6. De Diego M, Brocchi E, Mackay D, De Simone F. The non-structural polyprotein 3ABC of foot-and-mouth disease virus as a diagnostic antigen in ELISA to differentiate infected from vaccinated cattle. *Arch Virol*. 1997; 142: 2021–2033.

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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