VDRG® FMDV 3Diff/PAN Ag Rapid kit

CAT. NO. PM-FMD-16



GENERAL DESCRIPTION

VDRG® FMDV 3Diff/PAN Ag Rapid kit is a lateral flow chromatographic immunoassay for universal detection of all seven serotypes (PAN) of Foot-and-mouth disease virus (FMDV) antigen and simultaneous typing of O, A and Asia 1 serotypes (3Diff) in saliva, tissue or vesicular fluid around lip, tongue, gums, nose, hoof of porcine or bovine.

PAN strip of the device detecting all seven FMDV serotypes using a pan-serotype detection antibody conjugate and capture antibody line determines the existence of detectable level of FMDV in specimens diluted in sample dilution buffer. 3Diff strip of the device specifically determines FMDV O, A and Asia 1 serotype antigens in specimens diluted in sample dilution buffer using a pan-serotype detection antibody conjugate and three serotype-specific capture antibody lines.

FMDV antigen bound to antibody-gold particle conjugate will flow through nitrocellulose membrane by capillary action to be captured at test line coated with pan-serotype or serotype O, A and Asia-1 specific antibodies. The accumulation of gold particle on the test line will form a red colored line. The test procedures can be completed within 15 minutes after application of specimens.

KIT COMPONENTS

Reagents	10 tests/kit
① FMDV 3Diff/PAN Ag Rapid Test Device	10 tests
② Sample Dilution Buffer	1 bottle
③ Test Tube	10 ea
④ Swabs	10 ea
⑤ Dropper	10 ea
Instruction Manual	1 сору

DEVICE APPEARANCE

Specimen application holes (S1 and S2) are located at right side of test device: diluted specimens will be applied to these positions. The test (T) and control (C) lines in rectangular open display are marked on the both sides of the device. The sample pad, conjugate pad, nitrocellulose membrane, and absorption pad are assembled inside cassette of the test device.

SAMPLE PREPARATION

1. Specimen collection

 Collection of fluid from intact vesicle: Draw vesicular fluid using a syringe.

SAMPLE PREPARATION

- Collection of fluid from ruptured vesicles: Soak vesicular fluid using a cotton swab.
- 3) Tissue sampling from ruptured lesions.
 - ① Follow the instruction manual in **VDRG® Tissue Sample Extraction kit** (CAT. NO. EXT-TIS-11, not provided).
 - ② Collect 0.2g of fresh and friable epithelium (size of little finger nail) from surface or margin of vesicles or other tissues of interest.
- 4) Saliva: Collect saliva from porcine or bovine using appropriate method
 - ① For bovine, collect saliva directly from tongue using disposable plastic gloves.
 - ② For swine, collect saliva using chewing rope or other oral fluid collection kit.
- 5) Cultured virus: Collect virus culture media using micropipette.

2. Sample processing

- 1) Syringe-collected fresh vesicular fluid
 - ① Add 1 scale (approximately 250 μ l) of Sample Dilution Buffer to the test tube using dropper.
 - 2 Add 250µl of syringe-collected vesicular fluid to the test tube and mix gently.
- 2) Swab-collected fluid from ruptured vesicles
 - (1) Add 2 scales (approximately 500 µl) of Sample Dilution Buffer to the test tube using dropper.
 - ② Soak the swab in the dilution buffer, mix by swirling and extract the vesicular lesion fluid by pressing the cotton bud against the tube wall.
 - 3 Remove the swab from the test tube after extraction.
- 3) Tissue-extracted fluid
 - ① Follow the instruction manual in VDRG® Tissue Sample Extraction Kit (Cat. No. EXT-TIS-11, not provided).
 - ② Add 4 scales (1ml) of Sample Dilution Buffer to the extraction vial
 - 3 Add tissue sample to the extraction vial
 - ① Cut the tissue into pieces using scissors and grind using pestle and sand included in the kit.
 - (5) Leave the homogenate for 2~3 minutes to settle down tissue fraction.
 - 6 Use the clarified fluid for testing.
- 4) Saliva
 - ① Add 2 scales (approximately $500\mu\ell$) of Sample Dilution Buffer to the test tube using the dropper.
 - ② Centrifugate(6,000rpm, 10min) the collected saliva and soak the swab with supernatant of centrifugated saliva.
 - 3 Soak the swab in the dilution buffer, mix by swirling and extract the saliva by pressing the cotton bud against the tube wall.

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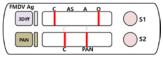
- Remove the swab from the test tube after extraction.
- Use the diluted and clarified saliva for testing.
- 5) Virus culture media
 - ① Add 200 pl of Sample Dilution Buffer to the test tube, Eppendorf tube or microplates.
 - 2 Add 200 µl of virus culture media to the test tube and mix by several times of swirling.

TEST PROCEDURE

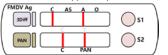
- Remove a VDRG® FMDV 3Diff/PAN Rapid Test Device from the foil pouch and place on a flat surface.
- 2. Slowly add 4 drops (100 μℓ) of the processed sample solution to position "S1" and "S2" on the test device using a dropper (provided) or micropipette (not provided).
- 3. Read results within 15 minutes exactly. Reading later than 15 minutes may cause inaccurate results.

INTERPRETATION OF RESULT

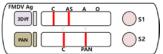
- 1. Positive when both control and test lines are red.
 - 1) FMDV serotype O positive result



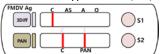
2) FMDV serotype A positive result



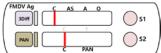
3) FMDV serotype Asia-1 positive result



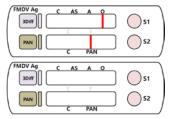
4) FMDV serotypes SAT-1, -2, -3 or C positive result



2. Negative when only control lines are red.



3. Re-test when control lines are not visible.



PRECAUTIONS

- 1. For *in-vitro* animal diagnostic use only.
- 2. Read this instruction manual thoroughly and follow all steps strictly for successful use of the product.
- 3. Extended exposure of this Rapid Test Device to moisture may decrease test performance. Therefore, open the device right before use (<10 minutes).
- 4. Make sure to use a separate test tube, dropper, and cotton swab for each sample.
- 5. Do not touch the membrane in the device. The results may be affected if touched.
- 6. Do not use test device and reagents after expiration date.
- Wear personal protective equipment (PPE) such as lab coat, goggle, and disposable gloves while performing the assay. Wash hands thoroughly afterwards.
- 8. All test samples should be considered potentially infectious and all items contacting the samples should be considered contaminated.
- 9. After use, all wastes should be sterilized with highpressure steam at 121 degrees Celsius for ≥15 minutes or comparable methods.
- 10. This Rapid Kit is considered as a preliminary test. The result should be confirmed by other laboratory tests for confirmatory diagnosis.
- 11. Sometimes, if the sample has low titer of O, A or Asia1 FMDV, the result may be shown as positive in strip PAN and negative in strip 3Diff. In this case, additional tests should be done.

STORAGE AND STABILITY

Store all reagents at 2~30°C. Do not freeze. Reagents remain stable through the expiration date when stored as instructed.



MEDIAN Diagnostics Inc.

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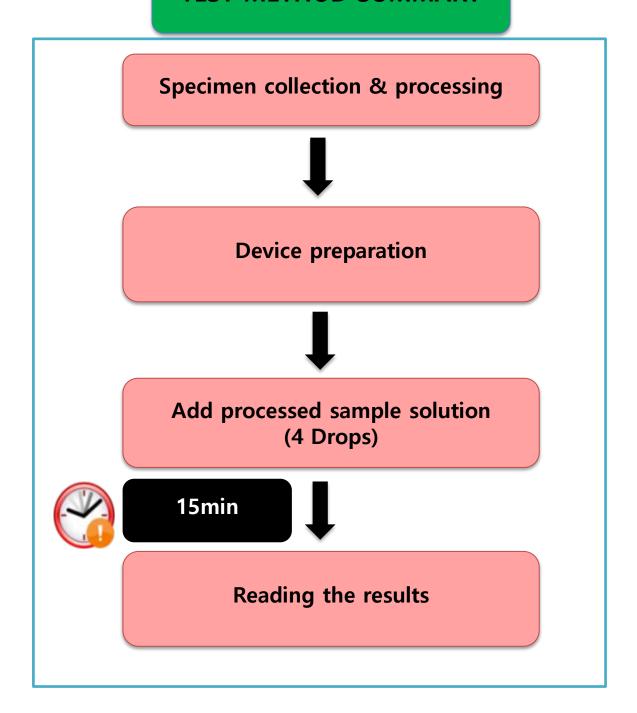
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TEST METHOD SUMMARY





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