INTENDED USE

The O.FMDV-A Ab Test is a lateral flow immunochromatographic assay for the qualitative detection of serotype-A FMDV antibodies in sheep's serum, plasma. VP1 protein recombinant was applied in this assay, for the monitoring of FMDV-A antibody level and providing an important reference for the vaccination plan.

Assay Time: 5-10 minutes

Specimen: serum, plasma

PRINCIPLE

The O.FMDV-A Ab Test is based on sandwich lateral flow immunochromatographic assay. The test device has a testing window for the observation of assay running and result reading. The testing window has an invisible T (test) zone and a C (control) zone before running the assay. When the treated sample was applied into the sample well on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated FMDV-A antigens. If there are anti-A FMDV antibodies in the specimen, a visible T line will appears. The C line should always appear after a sample is applied, which indicates a valid result.

REAGENTS AND MATERIALS

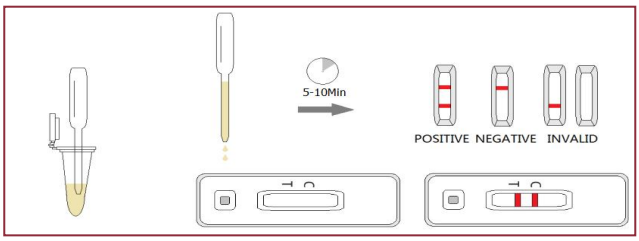
- 10 test pouches, with cards and disposable droppers
- 1 package insert

STORAGE AND STABILITY

The kit can be stored at room temperature (2-30°C). The test kit is stable through the expiration date (18 months) marked on the package label. DO NOT FREEZE. Do not store the test kit in direct sunlight.

TEST PROCEDURE

- Collect sheep's fresh whole blood, and get the serum or plasma specimen for use. Immediately apply the testing once collected the specimen.
- Take out the test device from the foil pouch and place it horizontally.
- Place 2-3 drop (around 70-100uL) of serum or plasma specimen into the sample well. Start timer and wait for result.
- Interpret the result in 5-10 minutes. Result after 15 minutes is considered as invalid.



INTERPRETATION OF RESULTS

Positive (+): The presence of both "C" line and zone "T" line, no matter T line is clear or vague. The density of color T line is related with the level of FMDV-A antibody titer of the specimen.

- Strong signal is explained as high titer and vaccination should not be carried.
- Weak signal is explained as low titer. Vaccination might not be necessary right now. It is suggested to be re-checked the antibodies few days later.

Negative (-): Only clear C band appear. No T band.

- No signal is explained as the level of antibody titer is lower than protective limit.

Invalid: No colored band appears in C zone. No matter if T band appears. Repeat the testing at once.

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PRECAUTIONS

- All reagents must be at room temperature before running the assay.
- Do not remove test cassette from its pouch until immediately before use.
- Do not use the test beyond its expiration date.
- The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.
- All specimens are of potential infection. It must be strictly treated according to the rules and regulations by local states.

LIMITATION

O.FMDV-A Ab Test is for in vitro veterinary diagnosis use only. All result should be considered with other clinical information available with veterinarian.

Manufacturer:
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