

Foot and Mouth Disease Virus Type O Antibody (FMD-O Ab) Rapid Test Kit

Technical Manual (GICA)



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| Product Information |

Intended Use

Foot and Mouth Disease (FMD) is an acute, febrile, highly contagious disease of cloven-hoofed animals caused by the Foot and Mouth Disease Virus (FMDV). It is characterized by the formation of vesicles and erosions on the oral mucosa, feet, and mammary skin.

This assay is designed to detect antibodies against Foot and Mouth Disease Virus Type O (FMD-O) in the serum or whole blood of swine, bovine, sheep and goat. It can be employed for evaluating the immunological efficacy of the FMD-O vaccine.

Principle

The kit uses colloidal gold immunochromatography assay (GICA). After being added to sample hole ("S"), the sample will move along the nitrocellulose membrane with the gold markers. If there are

antibodies against FMD-O in the sample, they will bind with the gold markers as well as antigens on the test ("T") line, resulting in the appearance of a colored test ("T") line. If not, no color reaction will be produced.

Content

Package specification	20T/Kit	40T/Kit
Test device (with disposable dropper)	20	40
Antibody Titration Color Card	1	1
Instruction	1	1

Storage Conditions

The kit shall be stored at 2°C to 30°C (35.6°F to 86°F) in dry environment. Avoid freezing.

Shelf life: 24 months. The date of manufacture is presented in the label of the box.

I Preparation of Sample I─

Whole blood: Collect blood samples using anticoagulant tubes (containing anticoagulants such as EDTA or heparin) or use disposable syringes. The anticoagulated blood collected can be used within 24 hours, and the syringe samples should be used immediately after collection.

Serum: Collect 2-3mL of blood using a collection tube without anticoagulant, let it stand for 1 hour, and then centrifuge at 4000 rpm for 10 minutes. (Alternatively, the blood can be left undisturbed at 25-40°C for about 2 hours, allowing the serum to naturally separate.) Collect the supernatant as the prepared sample. Short-term storage can be done at 2-8°C, while long-term storage requires -20°C (return to room temperature before use). Serum should be clear and bright, free from hemolysis and contamination.

Please note that sample should be return to room temperature (15-30°C) before use.

| Test Methods |-

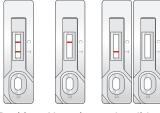
- 1. Open the foil pouch, take out the test card and put it on a flat and clean work surface.
- 2. Using the provided dropper, aspirate the prepared sample and slowly add 6 drops (approximately 120 μ L) of serum (for whole blood samples, use 7 drops.) vertically into the sample hole("S").
- 3. Read the result at room temperature in 10 to 20 minutes. Results are invalid after more than 30 minutes.



| Results Judgement |

Negative: Only control ("C") line appears in the result window.

Positive: Both test("T") line and control("C") line appear in the result window. The higher the



Positive Negative

Invalid

antibody titer, the darker the color of the test("T") line.

Invalid: If the control("C") line does not appear, the result might be considered invalid.

| Results Interpretation |

If the animal has not been vaccinated against Foot-and-mouth disease:

The negative result indicates that there are no antibodies against FMD-O in the tested sample. If the animal is healthy, FMD-O vaccination should be carried out promptly. The presence of acute symptoms cannot

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be ruled out as indicative of FMD-O infection.

A positive test result indicates that the animal may potentially have a wild-type infection or a past infection. Further analysis should be conducted, taking into account clinical observations and employing other methods.

If the animal has been vaccinated against Foot-and-mouth disease:

When the color of the test("T") line is darker than the color corresponding to the 1:32 HI titer on the Antibody Titration Color Card, it indicates that the titer of FMD-O antibodies is higher, reaching a protective level.

When the color of the test("T") line is lighter than the color corresponding to the 1:32 HI titer on the Antibody Titration Color Card, it indicates that the FMD-O antibody titer has not reached the protective level. It is recommended to administer the relevant vaccine.

| Limitation of the Test Method |-

This test result is for screening purposes only and is not sufficient for confirmation.

Although this kit is highly accurate in detecting antibodies against FMD-O, there is still a possibility of occasional false results. If uncertain or questionable results are obtained, additional clinical or laboratory tests may be necessary. As with other diagnostic tests, a definitive clinical diagnosis should not rely solely on the outcome of a single test. Instead, it should be made by the veterinarian after evaluating all clinical and laboratory findings. By considering a comprehensive assessment, veterinarians can ensure a more reliable and accurate diagnosis and provide appropriate care and treatment for the animal.

| Notice |-

- 1. Please read the instruction carefully before testing. And a variety of reagents are only used for this experiment.
- 2. Do not use Liquids that do not meet the requirements of Preparation of Sample (such as water, PBS, other animal serum) as negative controls.
- 3. The kit should be allowed to return to room temperature after being removed from the refrigerator before opening. Once opened, it should be used as quickly as possible to avoid becoming ineffective due to moisture.
- 4. Avoid using expired or damaged products.
- 5. Avoid using samples that are contaminated, turbid, severely hemolytic, and have a large amount of blood lipids.
- 6. Avoid touching the white nitrocellulose membrane in the middle of the detection card.
- 7. The waste shall be regarded as pollutants. Please dispose of them properly in accordance with the relevant local regulations.