REF

AKIT-FMD-AB-01

FMD (Foot and Mouth Disease) Ab - Instructions For Use (IFU)

For in vitro diagnostic use only.

Sample Collection Method

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Intended Use

The Rapid Antibody Test for Foot and Mouth Disease (FMD) is an immunochromatographic assay intended for the visual qualitative detection or machine read quantitative detection of antibodies for FMDV in blood or serum. Foot and Mouth Disease (FMD) is a highly contagious viral disease that affects cloven-hoofed animals, including cattle, pigs, sheep, goats, deer, and bison. It is not related to hand, foot, and mouth disease in humans. FMD is not a threat to human health. The virus does not cause disease in humans. However, people can carry the virus on their clothing, shoes, and vehicles and spread it to animals. FMD can have significant economic and agricultural impacts due to its ability to spread rapidly among livestock herds and the trade restrictions it can trigger. Timely and accurate detection of FMD is essential for effective disease management and containment. FMD is caused by the FMD virus (FMDV), a member of the Picornaviridae family. It spreads through direct contact with infected animals or their saliva, milk, or manure, contaminated equipment, clothing, aerosols containing the virus, or contaminated feed and water.

FMD is characterized by a range of clinical symptoms, including high fever, blisters and sores on the mouth, tongue, nostrils, or feet, excessive salivation, weight loss, and reduced milk production (in dairy cows). There is no specific treatment for FMD. The disease is usually self-limiting, but affected animals may need supportive care, such as fluids and pain medication. In some cases, antibiotics may be necessary to prevent secondary infections. The best way to prevent FMD is to vaccinate animals against the virus. Vaccination is required for all livestock in many countries. Other preventive measures include biosecurity practices such as quarantine of new animals and disinfection of equipment.

This user-friendly and reliable FMD Rapid Antibody Test has been designed to assist veterinarians, animal health professionals, and farmers in quickly identifying FMD-infected animals, allowing for prompt action to limit the spread of the virus and minimize its economic impact.

This test utilizes a lateral flow immunoassay, employing dye-labeled particles that bind to FMDV antibodies in the sample. The test kit contains a test strip with nitrocellulose membrane coated with FMD virus antigens. When a blood sample is applied to the test strip, the FMD antibodies in the sample bind to the antigens and form a colored complex. The appearance of a colored line on the test strip indicates the presence of FMDV antibodies.

Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results should be considered in the context of recent exposures, history and the presence of clinical signs and symptoms. The Rapid Antibody Test for FMD is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel.

Materials

Each box contains 50 test kits. Each test kit contains:

The following materials are provided with the RDT for Foot and Mouth Disease:

- LEIQA Test strips with desiccant (50 kits)
- Buffer solution (50 Spackets)
- UTID.ORG DataMatrix label for reading

Materials Required but not Provided:

- Timer – you may use a smartphone to read the QR code of the Spacket
- Gloves and Cleaning disinfectant
- Blood or serum collection and transfer devices

Storage And Disposal

The product should be stored at 2-30°C. Do not freeze or overheat the test kit or kit reagents. Kit contents are stable until the expiration date printed on each test kit. The indicators must be kept in the foil pouch until use. Dispose of used contents in accordance with federal, state, and local requirements.

Sample Preparation

Before use, check the expiration date of the packaging. If the kit is past its expiration date, do not use. Confirm that all components needed are in the kit.

Blood samples can be collected from various sites on the animal's body, depending on the species. For bovine and ovine species, blood can be collected from the jugular vein. For caprine species, blood can be collected from the jugular vein or the saphenous vein. For porcine species, blood can be collected from the jugular vein or the anterior ear vein.

To collect blood, clean and disinfect the collection site. Apply a tourniquet to the animal's limb proximal to the collection site. Insert the needle into the vein and collect the blood into the syringe. Release the tourniquet and remove the needle. Transfer the blood to a blood collection tube and label it with the animal's identification number and the date of collection.

Whole blood specimens should be tested as soon as possible after collection in a standard laboratory. To collect serum, use the same method for whole blood collection. Allow the blood to clot and then centrifuge to separate the serum. Transfer the serum to a clean tube. Specimens could be stored at 2-8°C for up to 72 hours, or could also be stored below -20°C for long-term until before use. Specimens should be avoided to repeat freezing and thawing. The frozen specimen should be thawed to 15-30°C and mixed well before testing. In addition, inadequate or inappropriate sample collection, storage, and transport may yield false test results. The training in specimen collection is highly recommended because of the importance of specimen quality.

Assay Procedure

1.

Stand up the Spacket, and tear it open. Be careful not to spill the liquid reagent inside.

2.

Sample 30 uL of blood into the Spacket.

3.

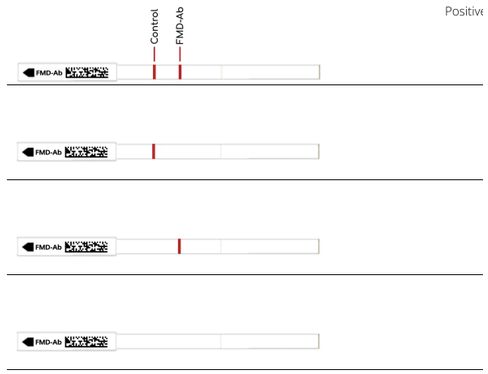
Place the test indicator in the Spacket with the sample pad going down. Leave the test indicator in the Spacket for 10 minutes. Use the assaya timerDx to keep track of the test time.

4.

10 Minutes

Take out the test indicator and read the result at 10 minutes. Do not read the result after 20 minutes. The test indicator may also be read by the intelligent analyzer eXpress (iaX-2101) after 10 minutes.

Result Interpretation



Positive Results

At 10 minutes, the appearance of the Control Line and Test Line on the Test Indicat result for the presence of antibodies for FMDV. Positive test results only mean antib in the specimen

- The appearance of a Control Line and Test Line, indicates a positive result for t antibodies for FMDV. The intensity of the test line may vary depending on the a present in the sample.

Negative Results

At 10 minutes, the appearance of only Control Line indicates a negative result for th antibodies for FMDV.

Invalid Results

If at 10 minutes, the Control Line does not appear, even if a Test Line appears in the considered invalid. If the test is invalid, a new test should be performed with a new new Test Indicator.

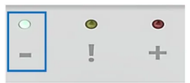
Internal Controls

Two internal procedural controls are needed to confirm correct assay procedure an components. One of two is a line appearing in the "Control Line" area in every run o validity of the test. Another one is a clear background serving as an internal negative background color should be white and not interfere with the reading of the test resu color interferes with the reading, it is recommended to repeat the test.

Result Interpretation with the iaX-2101

Please refer to the full iaX-2101 Instructions for Use for complete instructions on ho Place the test indicator into the iaX-2101, with the barcode pointing in.

- A Green (–) indicates a negative result for the presence of antibodies for FMD level is below the detection limit.
- A Yellow (!) indicates that the test is invalid and a new test must be performec collected specimen sample.
- A Red (+) indicates a positive result for the presence of antibodies for FMDV.



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Warnings & Precautions

1. For in vitro diagnostic use only.
2. The test is intended for use with blood or serum only.
3. This test has been authorized for the detection of antibodies for FMDV only.
4. This RDT is not recommended for use with other animal body fluids, such as saliva or milk.
5. To obtain accurate results, you must follow the Package Insert.
6. Check if the device package is complete; test indicator must be sealed in foil pouch and the expiration date of the device must be shown. Do not use if any of the test materials is broken or beyond the labelled expiration date.
7. Do not interchange or mix different lots of assaya Rapid Antibody Test for FMD.
8. Do not reuse kit components.
9. Use of protective tools is recommended when collecting, handling, storing, and disposing of the components within process.
10. Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
11. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
12. Disregard test results beyond the specified time (20 min).
13. Test results must be interpreted together with other clinical information available to the physician.
14. Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. When contacted acidic substances, it may produce highly toxic gases. In case of accidental contact with the skin, please wash immediately with plenty of water.
15. FMDV antibodies are usually found in blood-related samples in the middle and late stages of infection or after infection recovery.

Product Limitations

1. The contents of this kit are to be used for the qualitative detection of antibodies for FMDV. For quantitative detection of the assay, use the iaX-2101. Please refer to the iaX-2101 IFU for full instructions on using the iaX-2101.
2. The amounts of antibodies in the specimen may decrease or increase as the duration of illness increases.
3. Test result must be combined with clinical observations, clinical history, and epidemiology to make an overall judgment.
4. Positive test results only mean antibodies for FMDV exist in the specimen. Negative test result may occur if the level of antibodies in a specimen is below the detection limit of the test.

Clinical Performance

The RDT for FMD has been evaluated for sensitivity and specificity using a panel of known FMD-positive and FMD-negative animal serum samples. The test was found to have a sensitivity of 99% and a specificity of 98%.

References

1. "How to Protect Yourself & Others". Centers for Disease Control and Preventio Archived from the original on 26 February 2020. Retrieved 9 April 2020.
2. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Dep Human Services, CDC, NIH, Washington, DC (2007).
3. Henretig F.M. MD, King C. MD, Textbook of Pediatric Procedures, Chapter 123 - Specimens Williams and Williams (April 1997).

Technical Support

Email: support@assaya.com (mailto:support@assaya.com)

Adverse Events Reporting

Use this link to report any adverse events: assaya.com/ae (https://assaya.com/ae)

Ordering Information

Catalog Number (REF): AKIT-FMD-AB-01
50 pcs per box (Carton of 50 test kits)

Symbol Legend

Catalog Number	Consult Package Insert	Dc
Batch Code	Manufacturer	Contains suf
In Vitro Diagnostic Medical Device	Temperature Limit	Hur
No Direct Sunlight	Expiration Date	Do not r c
Do not expose to water	Warning	Cl

Manufacturers

IVD

Assaya Pvt. Ltd. Singapore
160 Robinson Road, #14-04 Singapore Business Federation Ce 068914
Web: assaya.com/ (https://assaya.com/)

Spacket

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Distributor

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