Foot and Mouth Disease (Type O) Antigen Rapid Test

REF KINER5013

Ver 1.0

IVT For In-Vitro Test Only

Σ 1 x 40 tests

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Introduction:

Foot and Mouth Disease (FMD) Type O is a highly contagious viral disease of cloven-hoofed animals caused by Foot and Mouth Disease Virus (FMDV) serotype O, a member of the Aphthovirus genus within the Picornaviridae family. It is characterized by fever and the formation of vesicles on the mouth, feet, and teats, leading to severe production losses. FMD Type O is the most prevalent serotype worldwide and poses a major threat to livestock health, food security, and international trade.

Intended Use:

The Foot and Mouth Disease (Type O) Antigen Rapid Test is used for qualitative detection of Foot and Mouth Disease Virus (FMDV) serotype O antigen in clinical samples from cloven-hoofed animals.

Principle:

This Rapid Test is an immuno-chromatographic test, using colloidal gold immunoassay method to detect the indicated antigen/antibody. After the addition of the sample, as per the instruction for use (IFU), the sample moves along with the colloidal gold labeling protein. If the relevant protein is present, it will develop a reddish color line near the space marked as “T”. This indicates the sample is Positive and if a line is not developed or seen, it indicates the sample is Negative for the tested antigen/antibody.

Materials Provided:

1. Cassette: with a pad in the device.
2. Sample Diluent - 3 ml

Materials to be provided by the End-User:

1. Adjustable pipettes and multichannel pipettor to measure volumes ranging from 25 ul to 1000ul
2. Alcohol prep-pad
3. Clock or timer
4. Specimen collection container
5. Centrifuge
6. Biohazard waste container
7. Sterile gauze or cotton

Handling / Storage:

1. All reagents should be stored at 2ºC to 8ºC for stability.
2. All the reagents and wash solutions should be used within 12 months from manufacturing date.
3. Before using, bring all components to room temperature (18-25ºC). Upon assay completion ensure all components of the kit are returned to appropriate storage conditions.

Health Hazard Warnings:

1. Reagents that contain preservatives may be harmful if ingested, inhaled or absorbed through the skin.
2. For Research Use Only.

Sample Preparation and Storage:

Vesicular fluid: Collect vesicular fluid from an intact blister using a sterile syringe. If the blister has ruptured, collect the lesion fluid using a sterile disposable swab. For an intact blister, add 250 µL sample dilution buffer to the tube, then add 250 µL vesicular fluid and mix gently. For a ruptured blister**,** add 500 µL sample dilution buffer to the tube, immerse and swirl the sample-soaked swab, press against the tube wall to extract the sample, and discard the swab.

Saliva: Collect saliva from the bovine tongue using a sterile swab, free from visible impurities. Centrifuge at 6,000 rpm for 10 minutes and collect the supernatant. Add 500 µl sample dilution buffer to the sample tube. Soak a swab in the supernatant, immerse it in the dilution buffer, swirl gently, press against the tube wall to extract the sample, and discard the swab.

Samples should be stored frozen (-20ºC or lower). Avoid sample deterioration by multiple freeze-thaw cycles.

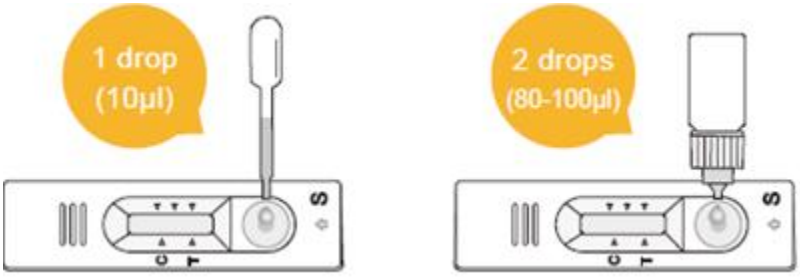
Preparation Before Use:

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20ºC - 30ºC) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (humidity ≤ 60%, temp: 20ºC - 30ºC). Please use immediately when the humidity＞60%.

Assay Procedure:

For vesicular fluid or saliva

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add one (1) full drop of prepared sample (10 ul) vertically into the sample well.
3. Add two (2) drops (80-100 ul) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.

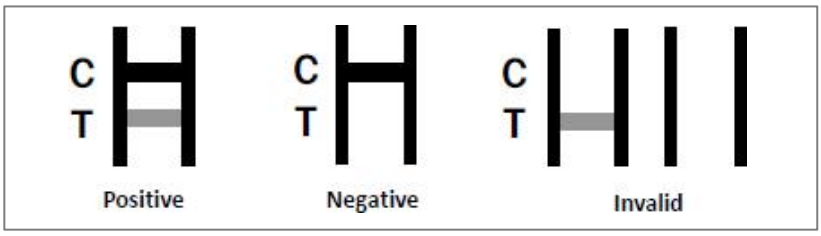


Interpretation of Results:

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



Quality Control:

It is recommended that for each laboratory assay appropriate quality control samples in each run to be used to ensure that all reagents and procedures are correct.

Performance Characteristics of the Kit:

Sensitivity:
Negative coincident rate with Molecular testing: ≥ 97%, Positive coincident rate with Molecular testing: ≥ 75%.

Limitations of Method

Any diagnosis should not be based on the results of in vitro methods alone. Veterinarians are suggested to consider all clinical and laboratory findings possible to state a diagnosis. This reagent is designed for the qualitative screening test.

Safety Precautions:

- Follow the working instructions carefully.
- The expiration dates stated on the kit are to be observed. The same relates to the stability stated for reagents.
- Do not use or mix reagents from different lots.
- Do not use reagents from other manufacturers.
- Avoid time shift during pipetting of reagents.
- All reagents should be kept in the original shipping container.
- Some of the reagents contain small amount of sodium azide (< 0.1 % w/w) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Since the kit contains potentially hazardous materials, the following precautions should be observed
  - Do not smoke, eat or drink while handling kit material.
  - Always use protective gloves.
  - Never pipette material by mouth.
  - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.

Symbols


Use by

Lot/Batch

Catalog number


Temperature limitation


Caution, consult accompanying documents


Manufacturer

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