Foot and Mouth Disease (FMD) Antigen Rapid Test

REF KINER5081

Ver 1.0

IVT For In-Vitro Test Only

Σ 40 test/kit

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Introduction:

Foot and Mouth Disease (FMD) is a highly contagious viral disease of cloven-hoofed animals caused by the Foot-and-Mouth Disease Virus (FMDV). It affects cattle, buffalo, sheep, goats, pigs, and other susceptible livestock, and is characterized by fever and the formation of painful vesicular lesions in the mouth, on the tongue, lips, gums, teats, and feet, leading to lameness, reduced feed intake, and significant production losses. FMD spreads rapidly through direct contact, aerosols, and contaminated materials, posing a serious threat to animal health, food security, and international trade. Early and accurate detection of FMD is essential for prompt outbreak control, effective surveillance, and implementation of biosecurity and disease management measures.

Intended Use:

The Foot and Mouth Disease (FMD) Antigen Rapid Test is used for qualitative detection of Foot-and-Mouth Disease Virus antigen in clinical samples such as vesicular fluid, epithelial tissue, oral or nasal swabs, or tissue homogenates from susceptible 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: Vesicular fluid should be collected aseptically from fresh or recently ruptured vesicles on the mouth, tongue, lips, teats, or feet of affected animals using sterile syringes or swabs. The collected fluid should be transferred immediately into the provided sample extraction buffer or a sterile container and mixed gently before testing. Samples should be tested as soon as possible after collection. If testing is delayed, vesicular fluid may be stored at 2–8ºC for up to 24–48 hours. For longer storage, samples can be frozen at −20ºC or below, avoiding repeated freeze–thaw cycles.

Epithelial Tissue: Epithelial tissue samples should be collected aseptically from the margins of fresh vesicular lesions. The tissue should be placed in a sterile container and homogenized in an appropriate volume of sample extraction buffer or phosphate-buffered saline to obtain a uniform suspension. Prepared homogenates should be tested immediately after preparation. If immediate testing is not feasible, samples may be stored at 2–8ºC for up to 48 hours or frozen at −20ºC or below for extended storage, avoiding repeated freeze–thaw cycles.

Oral or Nasal Swabs: Oral or nasal swabs should be collected using sterile swabs from the oral cavity or nasal passages of suspected animals. Swabs should be placed immediately into the sample extraction buffer and mixed thoroughly to release viral antigen. Prepared samples should be tested promptly. If testing is delayed, swab samples may be stored at 2–8ºC for up to 24–48 hours. For longer storage, samples can be frozen at −20ºC or below, avoiding repeated freeze–thaw cycles.

Tissue Homogenates: Tissue samples such as tongue epithelium, foot lesions, or lymph nodes should be collected aseptically from freshly affected or deceased animals. The tissues should be homogenized in the provided sample extraction buffer to prepare a uniform suspension. Clarified homogenates should be used for testing as soon as possible. If storage is required, homogenates may be kept at 2–8ºC for up to 48 hours or frozen at −20ºC or below for long-term storage, avoiding repeated freeze–thaw cycles.

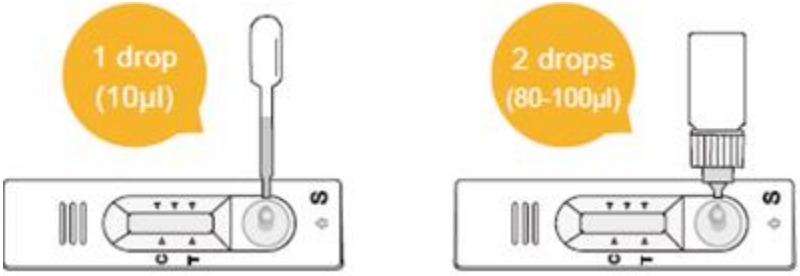
Preparation Before Use:

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 / Epithelial Tissue / Oral or Nasal Swabs or Tissue Homogenates

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.

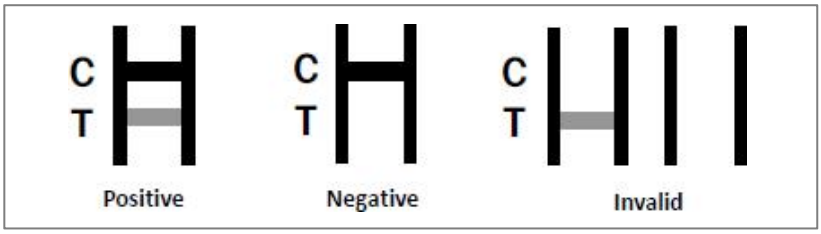


Interpretation of Results:

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

LIMITED WARRANTY

KINETIC BIOTECH FZCO does not warrant against damages or defects arising in shipping or handling, or out of accident or improper or abnormal use of the product; against defects in products or components not manufactured by KINETIC BIOTECH FZCO, or against damages resulting from such non-KINETIC BIOTECH FZCO made products or components. KINETIC BIOTECH FZCO passes on to customer the warranty it received (if any) from the maker thereof of such non-KINETIC BIOTECH FZCO made products or components. This warranty also does not apply to product to which changes or modifications have been made or attempted by persons other than pursuant to written authorization by KINETIC BIOTECH FZCO.

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