Bovine Foot-and-Mouth Disease NSP Antibody Rapid Test

Anigen Rapid FMD NSP Ab Test Kit

1. Explanation of the Test

Foot and mouth disease (FMD) caused by foot and mouth disease virus (FMDV), is a highly contagious viral disease of cloven-hoofed animals. As this disease has a considerable socio-economic impact on the countries affected, many governments have surveillance programs to prevent the disease.

The Anigen Rapid FMD Ab Test Kit is an immunochromatographic assay for the qualitative detection of FMDV antibody in whole blood, plasma and serum from bovine, ovine and porcine animals. The Anigen Rapid FMD NSP Ab Test Kit can be used for identification of FMD field infection in cattle, pigs, goats and sheep. The specially selected recombinant nonstructural protein (NSP) antigens are used as capture material in the test, which enable the Anigen Rapid FMD NSP Ab Test Kit to identify FMDV antibodies in specimens with a high degree of accuracy, and to differentiate infected animals from those that have been vaccinated.

The Anigen Rapid FMD NSP Ab Test Kit has a letter of "T" and "C" as the test line and control line on the surface of the device. Both the test line and control line in the result window are not visible before applying any samples. The Control line (C) is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working. A purple test line (T) will be visible in the result window if there is enough FMD virus antibodies in the specimen.

2. Materials Provided

Anigen Rapid FMD NSP Ab Test Kit contains following items to perform the assay.

1) Ten (10) Anigen Rapid FMD NSP Ab Test Kits
2) One (1) racks with 16 wells.
3) Ten (10) disposable droppers for whole blood dispensing
4) Ten (10) Capillary tubes
5) One (1) Developing buffer
6) One (1) Whole Blood Diluent
7) Instructions for use

3. Stability and Storage

The Anigen Rapid FMD NPS Ab Test Kit should be stored at room temperature (2~30℃). The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

4. Specimen Collection and Storage

1) [Whole blood] Collect the whole blood using a suitable anti-coagulant. Use the whole blood within 1 day after collection. Do not use hemolysed blood.
2) [Serum or plasma] Centrifuge whole blood to get plasma or serum specimen.
3) If specimens are not immediately tested they should be refrigerated at 2 ~ 8℃. For storage periods greater than three days, freeze the specimen at – 20℃ or below. They should be brought to room temperature prior to use.
4) Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

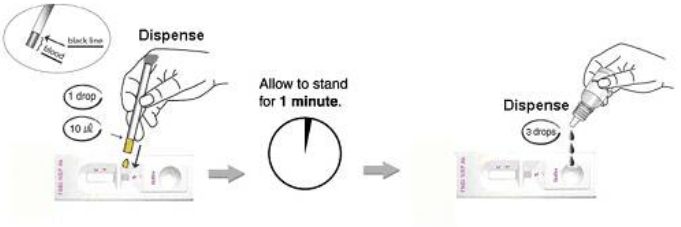
5. Precautions

1) For *in-vitro* diagnostic use only.
2) Do not eat or smoke while handling specimens.
3) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4) Avoid splashing or aerosol formation.
5) Clean up spills thoroughly using an appropriate disinfectant.
6) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7) Do not use the test kit if the pouch is damaged or the seal is broken.

6. Procedure of the Test

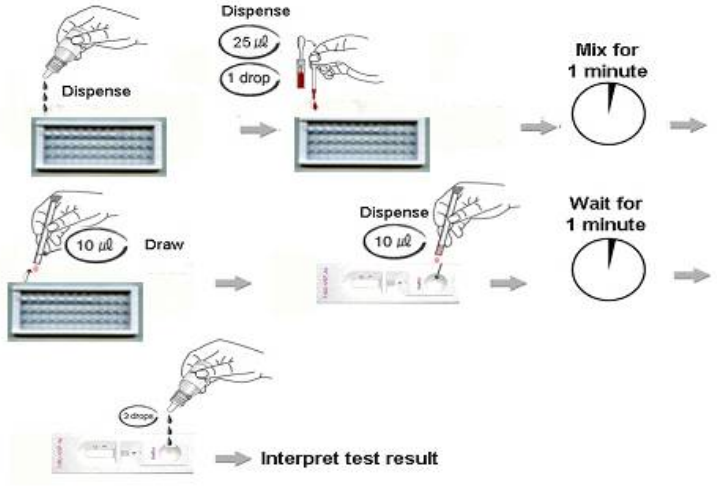
[Serum & Plasma specimen]

1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
2) Add 10ul of serum, or plasma to the sample hole marked "S" on the test device with a capillary tube and wait for 1 minute, then add 3 drops of the developing buffer into the developing hole.
3) For the test result, you will see the purple band in the result window of the kit.
Interpret test results at 15 minutes. Do not interpret after 30 minutes.



[Whole blood specimen]

1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
2) Dispense 3 drops of the whole blood diluent into the well on the rack.
Add 1 drop (25ul) of a whole blood sample with a disposable dropper and mix them for 1 minute.
3) Add 10ul of the mixed sample to the sample hole (S) with a capillary tube and wait for 1 minute.
4) Dispense 3 drops of the developing buffer into the developing hole.
5) For the test result, you will see the purple band in the result window of the kit.
Interpret test results at 15minutes. Do not interpret after 30 minutes.



Caution: The above result interpreting time is based on reading test results at room temperature of 15 ~ 30℃. If your room temperature is not significantly more than 15℃, the result interpreting time should be properly increased.

7. Interpretation of the Test Results

1) A color band will appear in the left section of the result window to show that the test is working properly. This band is the Control line **(C)**.
2) The right section of the result window indicates the test result. If another color band appears in the right section of the result window, this band is the Test line **(T)**.

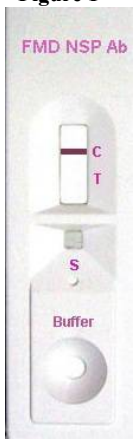
Negative or Vaccinated: The presence of only one purple color band (C) in the result window indicates vaccinated or negative result. **(Figure 1)**

Infected (Strong Positive): The presence of two color bands ("T" band and "C" band) within the result window, no matter which band appears first, indicates a positive result. **(Figure 2)**

Infected (Weak Positive): The presence of two color bands ("T" band and "C" band) within the result window, no matter which band appears first, indicates a positive result. **(Figure 3)**

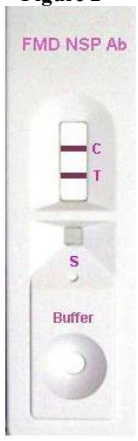
Invalid : If the Control line (purple color band) is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested. **(Figure 4, 5)**

Figure 1



Negative or Vaccinated

Figure 2



Infected Strong Positive

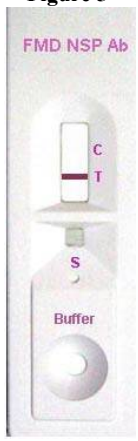
Figure 3

Infected Weak Positive

Figure 4

Invalid

Figure 5



Invalid

8. Limitations of the Test

1) The Anigen Rapid FMD NSP Ab Test Kit will only indicate the antibody presence against field infected FMD virus in the specimen.
2) As with all diagnostic tests, all results must be interpreted together with other clinical information available to the veterinarian.
3) If the test result is negative and clinical symptom is persisting, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of FMD.

9. Performance characteristics

Bovine serum from outbreak area

SN titer		Reference ELISA		AniGen	
POS	NEG	POS	NEG	POS	NEG
26	26	41	11	42	10

Bovine serum from FMD free area

SN titer		AniGen	
POS	NEG	POS	NEG
0	512	5	507

Swine serum from outbreak area

SN titer		Reference ELISA		AniGen	
POS	NEG	POS	NEG	POS	NEG
8	141	22	127	15	134

Swine serum from FMD free afrea

SN titer		AniGen	
POS	NEG	POS	NEG
0	575	9	566

10. Bibliography of suggested reading

1) Cowan,K.M. and Graves J.H. (1966) A third antigenic component associated with foot-and-mouth disease infection. Virol.,30,528
2) Chhabra R, Sharma R, Kakker NK. Comparative immunogenecity of foot and mouth disease virus antigens in FMD-haemorrhagic septicaemia combined vaccine and FMD vaccine alone in buffalo calves. Indian J Exp Biol. 2004 Mar;42(3):259-64.
3) Kweon CH, Ko YJ, Kim WI, Lee SY, Nah JJ, Lee KN, Sohn HJ, Choi KS, Hyun BH, Kang SW, Joo YS, Lubroth J. Development of a foot-and-mouth disease NSP ELISA and its comparison with differential diagnostic methods. Vaccine. 2003 Mar 28;21(13-14):1409-14.
4) Moonen P, van der Linde E, Chenard G, Dekker A.Comparable sensitivity and specificity in three commercially available ELISAs to differentiate between cattle infected with or vaccinated against foot-and-mouth disease virus. Vet Microbiol. 2004 Apr 5;99(2):93-101.

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