ONE STEP Foot and Mouth Disease NSP Antibody TEST

For veterinary diagnostic use only

Anigen Rapid FMD NSP Ab Test Kit

■ Principles

The Anigen Rapid FMD NSP Ab Test Kit is an immunochromatographic assay for the qualitative detection of FMDV antibody in whole blood, plasma or serum from cattle, pigs, goats and sheep.

The Anigen Rapid FMD NSP Ab Test Kit has two letters which are test line(T) and control line(C) on the surface of device. Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line has to appear every time when the test

has performed. A purple test line would appear in the result window if the FMD NSP antibodies in the sample.

The highly selective recombinant nonstructural protein(NSP) antigens are used as a capture material in the assay. These are capable of detecting FMDV antibodies with high accuracy, and to differentiate infected animals from those that have been vaccinated.

■ Materials provided

Materials	10 Tests/Kit
Anigen Rapid FMD NSP Ab Test Device (See figure 1)	10
Disposable capillary tube (See figure 2)	10
Developing buffer bottle	1
Whole blood diluent bottle	1
Test tube	10
Anticoagulant tube	10
Disposable dropper	10
Paper rack for test tube	1
Instructions for use	1

Figure 1. Test Device

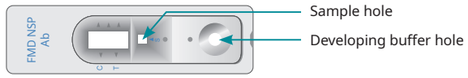
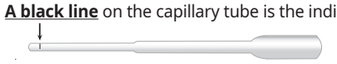


Figure 2. **A black line** on the capillary tube is the indicator line for 10μl.



■ Materials required, but not provided

1) Timer

■ Precautions

1) The test kit is for cattle, pig, goat and sheep use only. Do not use for other animals.
2) The test device is sensitive to humidity as well as heat. Perform the test immediately after removing the test device from the foil pouch.
3) Do not reuse test components.
4) Apply the sample and assay diluent vertically.
5) Do not touch the membrane in the result window of test device.
6) Do not use the test kit beyond the stated expiration date marked on the package label.
7) Do not use the test kit if the pouch is damaged or the seal is broken.
8) Do not mix components from different lot numbers because the components in this kit have been qualitycontrol tested as standard batch unit.
9) All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
10) Decontaminate and dispose of all samples, reaction kits and potentially contaminated materials safely in accordance with national and local regulations.
11) In case of using whole blood specimen, it may cause false negative result compared to serum and plasma specimens because whole blood specimen is diluted. Use of serum or plasma specimen is recommended for more accurate results excluding emergency situation.

■ Storage and stability

1) Store the test kit at 2~30°C. **DO NOT FREEZE.**
2) Do not store the test kit in the direct sunlight.
3) The test kit is stable within the expiration date that marked on the package label.

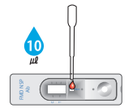
■ Collection and Preparation of Sample

1) Whole blood, serum or plasma should be used as a sample for this test.
   [Whole blood] Collect the whole blood into the anticoagulant tube(Max.
   vol.1.5ml) provided. If anticoagulated whole blood is not immediately tested, they should be refrigerated at 2~8°C and used within 24 hours.
   [Serum] Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate), leave to settle for 30 minutes for blood coagulation and then centrifuge to get serum supernatant.
   [Plasma] Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) and then centrifuge to get plasma.
2) If serum or plasma samples are not tested immediately, they should be refrigerated at 2~8°C. For longer storage, freezing is recommended. Frozen samples should be brought to room temperature (15~30°C) prior to use.
3) Samples containing precipitate may yield inconsistent test results. Such samples must be clarified prior to assaying.
4) The use of hemolytic or bacterially contaminated samples should be avoided. Erroneous result may occur.

■ Procedure of the Test

[Serum & Plasma sample]

1) All reagents and samples must be at room temperature(15~30°C) before use.
2) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
3) Using the disposable capillary tube, add 10μl of serum or plasma to the sample hole(marked "S" on the test device) and wait for 1 minute.

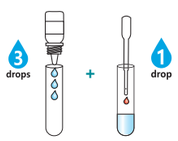


4) Add 3 drops of the developing buffer in dropping bottle into the developing buffer hole vertically.
5) Start the timer. The sample will flow across the result window. If it does not appear after 1minute, add one more drop of developing buffer to the developing buffer hole.

6) Interpret test results at 15 minutes. Do not interpret after 25 minutes

[Whole blood sample]

1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
2) Add 3 drops of the whole blood diluent into the test tube.
3) Add 1 drop (30μl) of a whole blood sample using the disposable dropper and mix them for 1 minute.



4) Add 10μl of the mixed sample using a capillary tube to the sample hole (marked "S" on the test device) and wait for 1 minute.

5) Add 3 drops of the developing buffer into the developing buffer hole.
6) Start the timer. The sample will flow across the result window. If it does not appear after 1minute, add one more drop of developing buffer to the developing buffer hole.

7) Interpret test results at 15 minutes. Do not interpret after 25 minutes

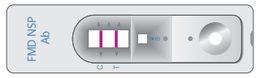
■ Interpretation of the Test Results

1) Negative result

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

2) Infected (Strong Positive)

Control ("C") line and dark test ("T") line within the result window indicate the presence of FMD NSP antibodies.



3) Infected (Weak Positive)

Control ("C") line and weak test ("T") line within the result window indicate the presence of FMD NSP antibodies.

4) Invalid

If the control ("C") line does not appear , the result might be considered invalid. The sample should be retested.

■ Limitation of the Test

1) The Anigen Rapid FMD NSP Ab Test Kit will only indicate the antibody presence against field infected FMD virus.
   Although the test kit is very accurate in detecting FMD NSP antibodies, a low incidence of false results can occur. Other clinical and/or laboratory tests might be required if questionable results are obtained. As other diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be diagnosed by veterinarian after all clinical and laboratory findings have been evaluated.
2) The reading window may show a light pink background coloration; this will not affect the accuracy of the results.
3) BioNote and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.

■ Performance Characteristics

Bovine serum from outbreak area

SN titer		Reference ELISA		Anigen	
Positive	Negative	Positive	Negative	Positive	Negative
26	26	41	11	42	10

Bovine serum from FMD free area

SN titer		Anigen	
Positive	Negative	Positive	Negative
0	512	5	507

Swine serum from outbreak area

SN titer		Reference ELISA		Anigen	
Positive	Negative	Positive	Negative	Positive	Negative
8	141	22	127	15	134

Swine serum from FMD free area

SN titer		Anigen	
Positive	Negative	Positive	Negative
0	575	9	566

■ 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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口蹄疫NSP抗体快速检测试剂盒

兽医诊断使用

Anigen Rapid FMD NSP Ab Test Kit

安捷口蹄疫NSP抗体快速检测试剂盒

■ 原理

口蹄疫NSP抗体速测试剂盒是一种免疫层析法检测技术，检测猪、牛、绵羊、山羊的血液样本。该试剂盒可以区分动物是否感染了口蹄疫野毒。该试剂盒专门采用复合的非结构蛋白（NSP）作为捕获材料，对检测样品中是否存在口蹄疫病毒抗体，并且区分出野毒感染抗体有很高的准确性。

韩国安捷公司**口蹄疫NSP抗体快速检测试剂盒**的试剂板表面有两个字母，一个是“T”，代表检测线，另一个是“C”，代表对照线。在加入样品之前，两条线是看不见的。对照线用于操作的对照作用。如果试验操作正确，并且对照线中的试剂还有效，对照线应该出现。如果样品中含有足够量的口蹄疫病毒抗原，检测结果为出现紫色的检测线。

■ 提供的材料

提供的材料	10 份试纸
口蹄疫（FMD）NSP抗体检测卡	10
毛细管	10
缓冲液	1
全血样品提取液	1
试管	10
抗凝管	10
一次性滴管	10
纸质试管架	1
使用说明	1

图1. 测试板

图2. 黑色线刻度为 10μl.

■ 需要但未提供的

1) 计时器

■ 注意事项

1) 仅用于检测猪、牛、绵羊、山羊、不用于其他动物。
2) 测试板对湿度和温度敏感、请随用随拆。
3) 不要重复使用试纸。
4) 请垂直滴加样品或稀释液。
5) 不要触碰测试窗口的膜。
6) 不要使用过期产品。
7) 如果包装损坏请不要使用。
8) 不要混用不同批次的产品因为每批产品都经过自身的质控标准。
9) 样品要作为有传染性来处理。请戴手套，操作后请洗手。
10) 请适当处理废弃物，不要污染环境。
11) 使用全血检测时，由于检测样本浓度相对较低，可能会引起部分假阴性的结果。为了获得准确的检测结果，建议您使用血清或血浆进行检测。

■ 保存和稳定性

1) 试纸可以保存于室温(2~30°C)或者冷藏保存。不要冷冻。
2) 在有效期内的试纸是稳定的。
3) 不要将试纸放置于太阳直射处。

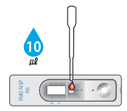
■ 采样和准备

1) 测试需要血清、血浆或全血。
[全血] 请使用含有抗凝剂的最大容量为1.5ml全血的采集管收集血液比如肝素、枸橼酸钠或EDTA,如果血液不是马上使用，请放于冰箱2-8度可冷藏24小时。
[血清] 请使用不含有抗凝剂的采集管收集血液，静置30分钟后离心,采集上清液。
[血浆] 请使用含有抗凝剂的采集管收集血液，离心后采集上清液。
2) 血清或血浆要立刻使用。若不马上使用时，请置于2-8°C冷藏保管。如需更长时间保管时，请置于低于-20°C或以下进行冷冻。冷冻的样品在使用前应恢复至室温(15~30°C)。
3) 样品包含的沉淀物必须静止沉淀后使用。
4) 溶血、脂血、黄疸或菌血要避免使用，会产生错误结果。

■ 检测步骤

[血清和血浆样本]

1) 所有反应物要到达室温。
2) 取出试纸，将它平放于宽敞和干燥的表面。
3) 用毛细管吸取1滴（10μl）血清或血浆样本，于样品孔（标有“S”）中滴 加1滴样本，等待1分钟。

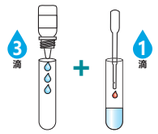


4) 然后在扩展孔中滴加3滴扩展液。
5) 开始时，你可以看到有一条紫色的条带在移动。如果1分钟后仍然没有移动，再往样品孔中滴加一滴缓冲稀释液。

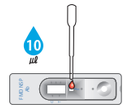
6) 15分钟判读结果，不要超过25分钟。

[全血样本]

1) 所有反应物要到达室温。
2) 取出试纸，将它平放于宽敞和干燥的表面。
3) 加3滴稀释液到试管中以稀释全血。
4) 利用滴管取1滴（30μl）全血加入其中，混合1分钟。



5) 用毛细管吸取1滴（10μl）全血样本，于样品孔（标有“S”）中滴 加1滴样本，等待1分钟。



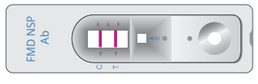
6) 然后在扩展孔中滴加3滴扩展液。
7) 开始时，你可以看到有一条紫色的条带在移动。如果1分钟后仍然没有移动，再往样品孔中滴加一滴缓冲稀释液。

8) 15分钟判读结果，不要超过25分钟。

■ 结果的解释

1) 阴性或免疫
只显示1条线，“C”线。

2) 感染（强阳性）
显示2条线，“C”线和“T”线。



3) 感染（弱阳性）
显示2条线，“C”线和“T”线。

4) 无效
如果试验操作完成后，未出现对照紫色线(C)，说明结果无效。可能操作不当造成，建议重新检测。

■ 解释

1) 安捷公司的口蹄疫NSP抗体快速检测试剂盒只能检测样品中口蹄疫野毒抗体。与其它诊断试剂一样，所有的检测结果必须与该动物的临床症状相结合。如果对检测结果持怀疑的态度，请利用更精准的检测进行验证。
2) 阅读窗口可能会显示粉红色的背景，这不会影响结果的准确性。
3) 安捷公司和代理商不会对试纸的勿使用或误判断负责。

■ 试剂盒的特点

来自疫区的牛血清

中和抗体实验		ELISA实验		安捷的金标卡	
阳性	阴性	阳性	阴性	阳性	阴性
26	26	41	11	42	10

来自无疫区的牛血清

中和抗体实验		安捷的金标卡	
阳性	阴性	阳性	阴性
0	512	5	507

来自疫区的猪血清

中和抗体实验		ELISA实验		安捷的金标卡	
阳性	阴性	阳性	阴性	阳性	阴性
8	141	22	127	15	134

来自无疫区的猪血清

中和抗体实验		安捷的金标卡	
阳性	阴性	阳性	阴性
0	575	9	566

■ 相关文献

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.
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