For veterinary diagnostic use only

* Anigen Rapid ASFV Ag Test Kit

Principles

The **Anigen Rapid ASFV Ag Test Kit** is a chromatographic immunoassay for the qualitative detection of African Swine Fever Virus antigen in swine serum, plasma or whole blood.

The Anigen Rapid ASFV Ag Test Kit has the letter "1", "2" and "C" as the test line and control line on the surface of the device. Two test lines are coated on the membrane for high sensitivity to African Swine Fever Virus Antigen. The first line ("1") and second line ("2") can detect the p72, p32 (also known as p30) respectively. Both p72 and p32 are major protein of African Swine Fever virus, and related to structure and immunoreaction of virus [1][2][3]. All of the the test lines in the result window are not visible before applying samples. The purplet test line will be visible in the result window if there are enough African Swine Fever Vrius antigens in the specimen. The control line 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 well.

The highly selective antibodies to African Swine Fever Virus antigens are used as each capture and detector in the assay. These are capable of detecting African Swine Fever Virus antigens in sample with high accuracy.

■ Materials provided

Materials	10 Tests/Kit
Anigen Rapid ASFV Ag Test device	10
Disposable dropper	10
Assay diluent bottle	1
Anticoagulant tube	10
Waste bag	10
Instructions for use	1

■ Materials required, but not provided

1) Timer

■ Precautions

- 1) The test kit is for use only in swine. 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 vertically.
- 5) Do not disassemble or reassemble the 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 each kit have been quality control 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, used kits and potentially contaminated materials safely in accordance with national and local regulations.

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 for this test.

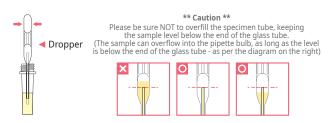
[Whole blood] Collect the whole blood into the anticoagulant tube (Max. vol.1.5ml) provided. If anticoagulated whole blood is not immediately tested, they should be refrigerated at 2~8°C and used within 24 hours.

[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 blood to get supernatant.

- **[Plasma]** Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) and then centrifuge blood to get plasma.
- 2) Serum, plasma samples should be stored at 2–8°C. For longer storage, freeze the samples at -20°C or below. Avoid repeated freezing and thawing.
- 3) Samples containing precipitate may yield inconsistent test results. They must be clarified prior to assaying.
- 4) Hemolyzed or contaminated samples may give erroneous results.

■ Procedure of the Test

- 1) All reagents and samples must be at room temperature(15~30°C) before use.
- 2) Remove the test device from the foil pouch, and place it on a flat and dry surface.
- 3) Using a disposable dropper, apply 100 μℓ of sample into the sample hole. If the sample is whole blood, apply 1 drop of the assay diluent additionally after 1 minute from sample application.
- 4) Start the timer. The sample will flow across the result window. If it does not appear after 1 minute, add one more drop of assay diluent to the sample hole.
- 5) Interpret test results at **20 minutes**. Do not read before 20 minutes or after 30 minutes.
- After the test is done, discard used test materials into the waste bag.



Please be sure to squeeze the bulb of pipette with 3/4 pressure, then collect the sample and completely fill the glass tube.

Whole blood



Serum/plasma



■ Interpretation of the Result

1) Negative result

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



2) Positive result

The single or all test line ("1", "2") and control line ("C") within result window indicate the presence of African Swine Fever Virus antigens.



3) Invalid Result

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





■ Limitations of the Test

- 1) Although the Anigen Rapid ASFV Ag Test kit is very accurate in detecting African Swine Fever Virus antigen, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the 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.

■ Bibliography of suggested reading

- [1] Mapping and Sequence of the Gene Coding for Protein p72, the Major Capsid Protein of African Swine Fever Virus. Virology. 1990.
- [2] The African Swine Fever Virus Proteins p54 and p30 Are Involved in Two Distinct Steps of Virus Attachment and Both Contribute to the Antibody-Mediated Protective Immune Response. Virology. 1998. 243(2):461-471.
- Neutralizing Antibodies to Different Protein of African Swine Fever Virus Inhibit both Virus Attatchment and Internalization. Journal of Virology. 1996. 70(8):5689-5694.

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