

VDRF® ASFV Ag Rapid kit

CAT. NO. PS-ASF-11



GENERAL DESCRIPTION

"VDRF® ASFV Ag Rapid kit" is a lateral flow chromatographic immunoassay for detection of African swine fever virus (ASFV) antigen in blood of porcine.

This is diagnostic kit to detect ASFV antigen using porcine whole blood. You can drop the specimen onto the sample hole and add dilution buffer.

If there are ASFV antigens in the porcine whole blood, these antigens bind to ASFV antibody-fluorescent particle conjugates and move on the membrane by capillary forces. And then the reaction appears on the test line when the result is read using a fluorescent reader.

This test kit is the diagnostic reagent that can detect ASFV antigens quickly and simply at **15 minutes (reaction time)** after infection of samples.

KIT COMPONENTS

| Reagents | 30 tests/kit |
|----------------------------------|--------------|
| ① ASFV Ag Rapid Test Device | 30 tests |
| ② Sample Dilution Buffer(3.5 ml) | 1 bottle |
| ③ Dropper | 30 ea |
| ④ Instruction Manual | 1 copy |

DEVICE APPEARANCE

- In a test device : The cassette assembled from a plastic ivory top and bottom plate. Inside the cassette is a white examination window with antibodies absorbed. Specimen application round hole is located at lower part of plastic cassette.
- Sample dilution container : There is a colorless or faint yellow liquid buffer in the plastic container for dilution of a sample.

COMPONENTS AND QUANTITIES

| Name | | Purpose | Material | Quantity |
|---------------------------|----------------------|--------------|----------------------------------|----------|
| ASFV Ag Rapid Test Device | Test line | Ab | ASFV MoAb | suitable |
| | Control line | Ab | anti-malaria Ab | suitable |
| | Fluorescent particle | Ab | ASFV MoAb-fluorescent particle | suitable |
| | | Ag | Malaria rAg-fluorescent particle | Suitable |
| Sample Dilution Buffer | | Buffer | Borax buffer | 50mM |
| | | Detergent | Triton X-100 | 0.50% |
| | | Preservative | Sodium Chloride | 1M |
| | | Preservative | Proclin300 | 0.05% |
| | | Preservative | Sodium azide | 0.10% |

SAMPLE PREPARATION

Before the test, be sure to read yourself with TEST PROCEDURE and PRECAUTIONS in user manual

1. Blood collection

Blood should be collected from the jugular or ear vein of the suspected or infected pigs using a sterile disposable syringe.

2. Sample preparation

- Sample's ID should be marked on the surface of the sample tube (Eppendorf tube).
- The fresh blood should be mixed with anticoagulant (EDTA) and be dropped into the eppendorf tube with 0.5~1 ml.
- Kept at 2~8°C within 48 hours.
- The person who collect blood and the person who test should be separated and do not contact directly each other.
- The test should be done at the separated, clean and flat place avoiding contact and contamination of the device, reader and smartphone with blood sample.

TEST PROCEDURE

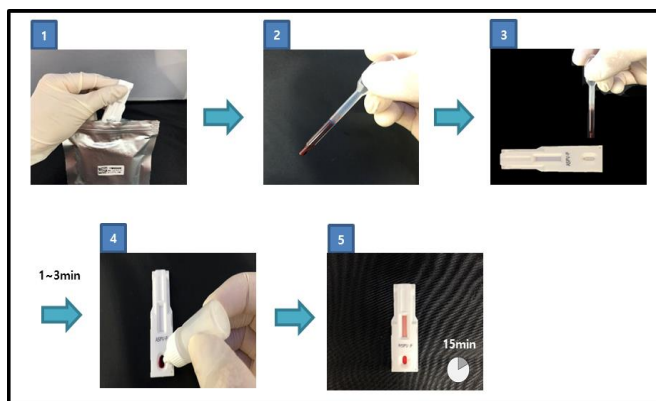
* Transfer the kit to room temperature (25~30°C) before the test and use it after about 30 minutes. (It is helpful to see the rehearsal video on our website).

- The test must be conducted at room temperature (25~30°C)
- The test must be conducted to avoid direct sunlight.

* Before the test, install the Cloud detection app(Installation : Refer to VDRF® Reader user manual) on your phone to ensure it works with the VDRF® Reader. And start the test.

* If the samples are stored, use fresh whole blood within 3 days of blood collection.

- Place the ASFV Ag Rapid Test Device on a flat surface and shades. (Do the test by avoiding direct sunlight)
- Collect whole blood sample to the scale by using dropper (40µl).
- Drop the whole blood (40µl) onto the sample hole of the device first.
- After 1-3 minutes, add 2 drops (60µl) of dilution buffer. (If the diluted blood sample does not run, add 1 drop (30µl) again.)
- The results are read after 15 minutes. (By using VDRF® Reader and refer to the manual for it.)



VDRF[®] ASFV Ag Rapid kit

CAT. NO. PS-ASF-11



INTERPRETATION OF RESULT

1. Result interpretation : Check the Reading value using VDRF[®] Reader and determine the following standard.

- 1) Negative : <16
- 2) Suspect : 16~49
- 3) Positive : ≥50

2. Precautions for interpretation result

- 1) If it is positive, re-test using a new device to verify it again. (Occasionally, if the sample is too high in viscosity or is hemolytic, the flow along the membrane may be interrupted resulting in a non-specific reaction).
- 2) This kit is intended for screening (specificity 99.2%, sensitivity 79.5%), and the verification shall be in accordance with the prescribed precision inspection results.
- 3) Recommend at least 10 pigs to test at a farm. If it is positive, completely disinfect the outside of the VDRF[®] Reader with ASFV-sensitive disinfectants (e.g., VirkonS etc). After then, seal it in a plastic bag, and transport to an appropriate sterilization facility. Be sure to sterilize the Reader by sterilizing/disinfecting it.

PRECAUTIONS

1. For in-vitro animal diagnostic use only
2. Extended exposure of this Rapid Test Device to moisture may decrease test performance. Therefore, open the device right before use (<10 minutes).
3. Make sure to use a dropper for each sample.
4. Do not touch the membrane in the device. The results may be affected.
5. Do not use test device and reagents after expiration date.
6. Be sure to check within the reaction time, and consider the subsequent response as non-specific.
7. Wear personal protective equipment (PPE) such as lab coat, goggle, and disposable gloves while performing the assay. Wash hands thoroughly afterwards.
8. After use, all wastes should be sterilized with high pressure steam at 121 degrees Celsius for ≥ 15 minutes or comparable methods.
9. This kit is a diagnostic reagent designed for primary screening purposes for the diagnosis of ASFV antigen, and results can be obtained in a simple and quick manner. But differences between inspection methods and detection sensitivity designed with more precise principles.
10. This Rapid kit is made for preliminary test only. The result should be confirmed by other laboratory tests for final diagnosis.

TEST METHOD SUMMARY

Device preparation



Collect whole blood sample to the scale by using dropper (40μl)



1~3min



Add sample dilution buffer (2 Drops)



15min



Reading the results

STORAGE AND STABILITY

1. Storage

*Short-term storage : store all reagents at 2-30°C

*Long-term storage : store all reagents at 2-8°C

2. Stability

*2~8°C : 1-year

*17~25°C : 4month

*25~32°C : 2month

MEDIAN Diagnostics Inc.

878, Sunhwan-daero, Dongnae-myeon, Chuncheon-si, Gangwon-do, 24399, Republic of Korea

Tel: +82 (0)33 244 0100

Fax: +82 (0)33 244 4634

E-mail: median@mediandx.com