

# African Swine Fever Virus (ASFV) Antigen Rapid Test

**REF** KINER5033

Ver 1.0

**IVT** For In-Vitro Test Only

**Σ** 1 x 40 tests

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### **Introduction:**

African Swine Fever (ASF) is a highly contagious viral disease of domestic and wild pigs caused by African Swine Fever Virus (ASFV), a large DNA virus in the Asfarviridae family. The disease primarily affects the hematopoietic system, leading to high fever, hemorrhages, internal organ damage, and high mortality, particularly in domestic pigs. ASF poses a severe economic threat to the swine industry due to mass mortality, trade restrictions, and control measures, as there is currently no effective vaccine widely available.

Clinical signs of ASF can vary from acute, peracute, subacute, to chronic forms, making early and accurate diagnosis critical for disease control and outbreak prevention.

### **Intended Use:**

The African Swine Fever Virus (ASFV) Antigen Rapid Test is used for the qualitative detection of ASFV antigen in clinical samples, including whole blood, serum, plasma, tonsil or nasal swabs.

### **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 2°C to 8°C 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 (18-25°C). 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:**

**Whole Blood Samples:** Clean the site with Alcohol Prep Pad. Collect the blood from vein. Using Disposable Pipette, collect blood from the puncture site. Alternatively - draw blood following laboratory procedure for obtaining venous blood. Do not test whole blood samples if older than 3 days.

**Serum/Plasma samples:** Fresh serum or plasma samples can be used for ASFV antigen testing. For serum, ensure the blood is fully clotted before separating, and for plasma, collect into tubes containing an anticoagulant. Remove any visible particulate matter by centrifugation or filtration. Avoid using highly hemolytic, turbid, or microorganism-contaminated samples. Samples may be stored at 2–8°C for up to 3 days if testing is not immediate, or frozen at –20°C or lower for longer-term storage. Repeated freeze–thaw cycles should be avoided.

**Plasma:** Collect whole blood into a collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture. Separate the plasma by centrifugation.

**Serum:** Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture. Allow the blood to clot. Separate by centrifugation.

**Nasal Swab:** Gently collect nasal secretions from each nostril using a sterile swab and place it into a specimen tube containing 1ml sample diluent. Mix the swab thoroughly with the diluent to extract the virus, then remove and safely discard the swab. The extracted sample can be used immediately for testing. If testing is delayed, samples may be stored at 2–8°C for up to 3 days or frozen at –20°C or lower for long-term storage. Repeated freeze–thaw cycles should be avoided.

**Tonsil Swab:** Collect material from the tonsillar area using a sterile swab and insert it into a specimen tube containing 1ml sample diluent. Mix the swab thoroughly with the diluent to extract the virus, then remove and safely discard the swab. The extracted sample can then be used for testing. Samples should be tested as soon as possible. . If testing is delayed, samples may be stored at 2–8°C for up to 3 days or frozen at –20°C or lower for long-term storage. Repeated freeze–thaw cycles should be avoided.

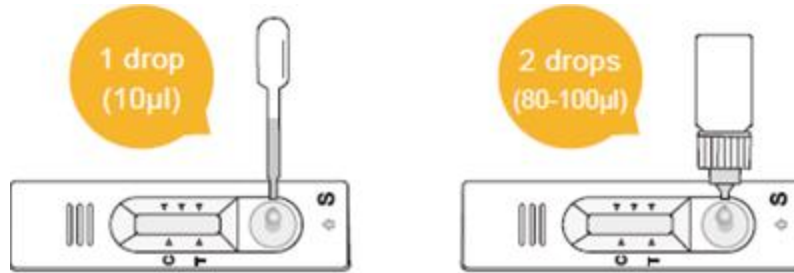
### **Preparation Before Use:**

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20°C - 30°C) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (humidity ≤ 60%, temp: 20°C - 30°C). Please use immediately when the humidity >60%.

### **Assay Procedure:**

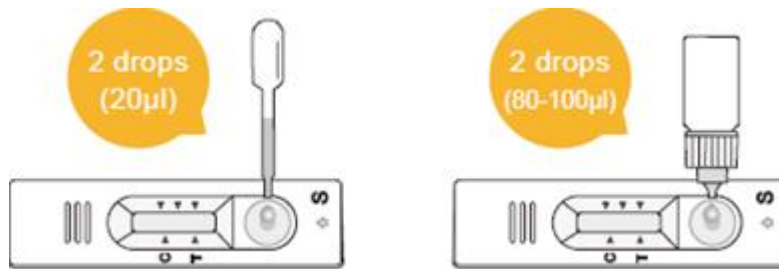
#### **For Serum / Plasma / Nasal / Tonsil**

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 serum / plasma / Nasal / Tonsil 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.



**For Whole Blood**

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add two (2) full drops of whole blood (20 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.

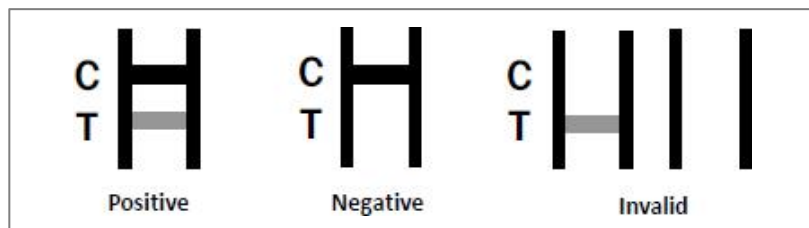


**Interpretation of Results:**

**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:  $\geq 97\%$ , Positive coincident rate with Molecular testing:  $\geq 75\%$ .

### 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



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