VECHEK™

ASFV Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma/Tissue) Package Insert

REF VIASFG-402	English

INTENDED USE

The ASFV Antigen Rapid Test Cassette (Whole Blood/Serum/ Plasma/Tissue) is a rapid chromatographic immunoassay for the qualitative detection of African swine fever virus (ASFV) antigen in whole blood, serum, plasma or tissue specimen.
For veterinary use only.

PRINCIPLE

The ASFV Antigen Rapid Test Cassette (Whole Blood/Serum/ Plasma/Tissue) is based on double antibody sandwich format for the qualitative detection of African Swine Fever Virus Antigen in whole blood, serum, plasma or tissue. The test cassette has a testing window with a T (test) region and C (control) region. The membrane is pre-coated with ASFV antibody. During testing, antigen to ASFV, if present in whole blood, serum, plasma or tissue specimen, will react with ASFV antibody coated colloidal gold particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with ASFV antibody on the membrane in the test line region. If the specimen contains antigen to African Swine Fever Virus, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain African Swine Fever Virus antigen, a colored line will not appear in the test line region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

PRECAUTIONS

- Do not use after the expiration date.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- Do not remove test cassette from its pouch until immediately before use.
- Do not reuse the test kit.
- Do not mix components from different lots and different products.

MATERIALS

Materials Provided

- Test cassettes
- Droppers
- Package insert
- Buffer
- Tubes and tips (for tissue specimen)

Materials Required But Not Provided

- Centrifuge
- Timer
- Weighing scale
- Mixer

DIRECTIONS FOR USE

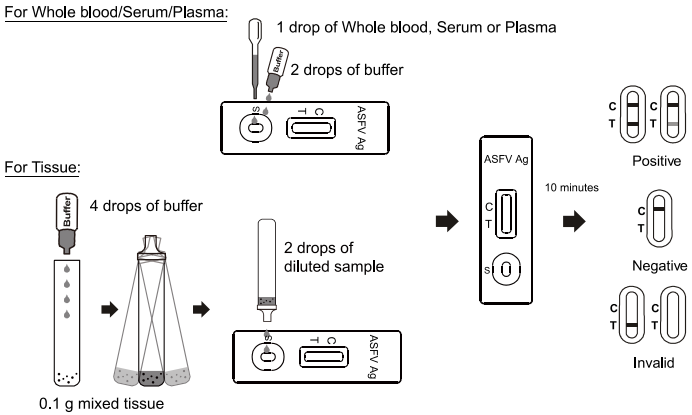
Allow the test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

Specimen Handling:

1. **For whole blood, serum and plasma**: Collect fresh whole blood, or separate serum or plasma from whole blood as soon as possible to avoid hemolysis. Only use clear, non-hemolyzed specimens. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood samples are available on the spot and cannot be frozen.
   For Tissue: Take a certain amount (rice grain size) of lymphoid tissue samples and mix them evenly with a mixer.

Test Reaction:

2. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test cassette on a clean and level surface.
   - **For whole blood, serum and plasma:**
     Hold the dropper vertically and **transfer 1 drop of whole blood/serum/plasma** (approximately 25 µL) to the specimen well (S) of the test cassette, then quickly **add 2 drops of buffer** and start the timer. See illustration below.
   - **For Tissue: (lymphoid tissue)**
     Weigh **0.1 g of the mixed tissue specimens**, put them in a specimen collection tube, add **4 drops of buffer**, fix the specimen collection tube tip and shake evenly for approximately **10 seconds**, and then slowly **add 2 drops of diluted sample** into the specimen well (S) and start the timer. See illustration below.
4. **Read the results at 10 minutes**. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS

Positive: The presence of both C line and T line, regardless of T line being strong or faint.
Negative: Only clear C line appears.
Invalid: No colored line appears in C zone, regardless of T line's appearance.

ACCURACY

The ASFV Antigen Rapid Test Cassette has been evaluated with specimens obtained from pig farm. Commercial control test is used as the reference method for the ASFV Ag Test. Specimens were considered positive if commercial control test indicated a positive result.

ASFV Ag Test	Commercial control test		Total
	Positive	Negative	
Test Positive	129	2	131
Test Negative	2	97	99
Total	131	99	230

Relative Sensitivity: 98.47% (95%CI*: 94.59%-99.81%)
Relative Specificity: 97.98% (95%CI*: 92.89%-99.75%)
Accuracy: 98.26% (95%CI*: 95.61%-99.52%)
*Confidence Interval

CROSS-REACTIVITY

The ASFV Antigen Rapid Test Cassette has been tested by PRRSV, CSFV, PDNS, ERY, SALM and PRV-gB positive specimens. The results showed no cross-reactivity.

LIMITATION

1. The ASFV Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma/Tissue) is for veterinary diagnostic use only. This test should be used for the detection of antigen to ASFV in whole blood, serum, plasma or tissue. Neither the quantitative value nor the rate of increase in ASFV antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of antigen to ASFV in the specimen and should not be used as the sole criterion for the diagnosis of ASFV infection or immune state.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA or PCR analysis.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. If the test result is negative and clinical symptoms persist, additional follow up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of ASFV infection or immune state.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	2°C 30°C	Temperature limit
	Manufacturer	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use

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