SaberVet

Classical Swine Fever Virus Antibody Rapid Test (CSFV Ab)

Intended Use

Classical Swine Fever Virus Antibody Rapid Test is a lateral flow immunoassay intended for the qualitative detection of specific antibody from Classical Swine Fever Virus (CSFV) in porcine serum, plasma.

Reagent and materials provided

· Test devices ·Dropper
·Package insert

Materials required but not provided

Timer

Storage and Stability

The test device is sealed and should be stored away from light at a room temperature (4–30℃). Do not freeze.
The test device should be used before the expiration date marked on the package label.

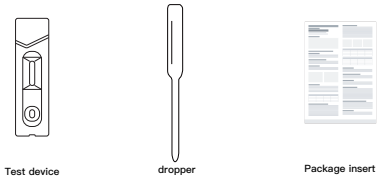
Warnings, Precautions and Safety Information

1. The test device is used for porcine only.
2. The results may be influenced by Humidity and Temperature.
3. Make sure that the foil pouch containing the test is not damaged before open. Perform the test immediately when the pouch package is opened.
4. Do not reuse the test components.
5. Do not use after the expiry date.
6. Do not mix product components in different lot numbers
7. As all samples are potentially infectious. Operators should wear protective gloves while handling samples and wash hands thoroughly afterwards.
8. Decontaminate and dispose of all samples, used kits and potentially contaminated materials safely in accordance with national and local regulations.

Specimen Collection,handling, and Transport

1.Whole blood, serum or plasma should be used with this test.
Whole blood: Collect the whole blood. If whole blood samples are 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), and then centrifuge whole blood to get serum.
Plasma: Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) and then centrifuge whole blood to get plasma.
2.Samples should be stored at 2~8°C. Please freeze the samples at -20°C or below for longer storage and avoid repeated freezing and thawing.
3. Samples containing precipitate may yield inconsis–tent test results. They must be clarified prior to assaying.
4. Hemolyzed or contaminated samples may lead to erroneous results.

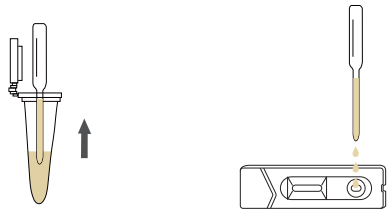
STEP 1 CHECK THE KIT CONTENTS BEFORE USE



Test device dropper Package insert

Check the product contents and make sure the test operation is under the room temperature (15—30 ℃) before testing.

STEP 2 TEST PROCEDURE



Take the test device out of the aluminum foil bag, and place it on a clean, flat table.Add three drops (about 90 μl) of serum or plasma specimens vertically into the specimen well (S) of the test device.

STEP 3 INTERPRETATION OF TEST RESULT

Read the result at 5–10 minutes.
The result is invalid after 15 minutes.

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 region, regardless of T line's appearance.

Limitations

Although the Classical Swine Fever Virus Antibody Rapid Test is very accurate in detecting Classical Swine Fever Virus antibody, a low incidence of false results may be occurred. Other clinically 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 the veterinarian after all clinical and laboratory findings have been evaluated.

Performance Characteristics

Method		Elisa		Total
		Positive	Negative	
CSFV Ab	Positive	165	3	168
	Negative	5	177	182
Total		170	180	350

Diagnostic Sensitivity of CSFV Ab: 165/170=97.50% (95%CI* (93.53%–99.24%))
Diagnostic Specificity of CSFV Ab: 177/180=98.33% (95%CI* (94.99%–99.66%))
Total Agreement of CSFV Ab:342/350=97.94% (95%CI* (95.73%–99.09%))

LOT batch code
use by
manufacturer
contains sufficient for <n> tests
IVD in vitro diagnotic medical device
temperature limitation
Do not reuse
consult instructions for use

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