REF

AKIT-CSF-AB-01

CSF (Classical Swine Fever) Ab - Instructions For Use (IFU)

For in vitro diagnostic use only.

Sample Collection Method

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Intended Use

The RDT for Antibodies for Classical Swine Fever is a immunochromatographic test intended for the visual qualitative detection or machine read quantitative detection of antibodies to CSFV in pig blood or serum. The test is intended for use by veterinarians and swine producers.
Classical swine fever (CSF) is a highly contagious viral disease of pigs, including wild boar. It is caused by the classical swine fever virus (CSFV), a member of the family Flaviviridae. CSF is characterized by a variety of clinical signs, including fever, lethargy, loss of appetite, difficulty breathing, and diarrhea. The disease can be fatal, and there is no treatment available.
Vaccination is one frequently recommended option to control CSF. However, it is important to be able to identify infected animals so that they can be isolated and prevented from spreading the virus to other pigs.
The RDT for Antibodies for Classical Swine Fever is a rapid and easy-to-use test for detecting antibodies to CSFV in pig whole blood or serum. The test is based on a lateral flow immunoassay, which uses dye-labeled particles to bind to CSFV antibodies in the sample. If CSFV antibodies are present in the sample, a colored line will appear on the test strip. The test contains a membrane strip, which is pre-coated with CSF-specific recombinant antigens in the test line (T). The another CSF antigen-conjugated gold particles and specimen moves along the membrane chromatographically to the test region (T) and forms a visible line coming from the antigen-antibody-antigen colloid gold particle complex with high degree of sensitivity and specificity.
This RDT for Antibodies for Classical Swine Fever can detect both natural or vaccinal antibodies, and is a valuable tool for veterinarians and swine producers to help identify infected animals and control the spread of CSF.

Materials

Each box contains 50 test kits. Each test kit contains:

The following materials are provided with the RDT for Antibodies for Classical Swine Fever:

- LEIQA Test strips with desiccant (50 kits)
- Buffer solution (50 Spackets)
- UTID.ORG DataMatrix label for reading

Materials Required but not Provided:

- Timer – you may use a smartphone to read the QR code of the Spacket
- Gloves and Cleaning disinfectant
- Blood or serum collection and transfer devices

Storage And Disposal

The product should be stored at 4-30°C. Do not freeze or overheat the test kit or kit reagents. Kit contents are stable until the expiration date printed on each test kit. The indicators must be kept in the foil pouch until use. Dispose of used contents in accordance with federal, state, and local requirements.

Sample Preparation

Before use, check the expiration date of the packaging. If the kit is past its expiration date, do not use. Confirm that all components needed are in the kit.
Whole blood is collected in anticoagulant tubes by syringe via ear prick collection. Clean the pig's ear with a disinfectant. Apply the tourniquet to the pig's ear above the vein where you will be collecting blood. Insert the needle into the vein and draw blood into the syringe. Release the tourniquet and remove the needle. Apply pressure to the puncture site with a gauze pad until the bleeding stops.
Whole blood specimens should be tested as soon as possible after collection in standard laboratory. To collect serum, use the same method for whole blood collection. Allow the blood to clot and then centrifuge to separate the serum. Transfer the serum to a clean tube. Specimen could be stored at 2-8°C for up to 72 hours, or could also be stored below -20°C for long-term until before used. Specimens should be avoided to repeat freezing and thawing. The frozen specimen should be thawed to 15-30°C and mixed well before testing. In addition, inadequate or inappropriate sample collection, storage, and transport may yield false test results. The training in specimen collection is highly recommended because of the importance of specimen quality.

Assay Procedure

1.

Stand up the Spacket, and tear it open. Be careful not to spill the liquid reagent inside.

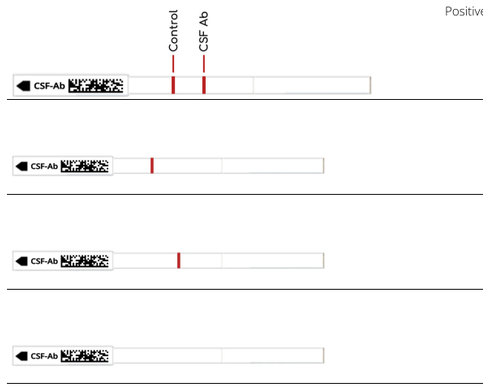
2.

Sample 30 uL of blood into the Spacket.

3.

4.

Result Interpretation



Positive Results

At 10 minutes, the appearance of the Control Line and Test Line on the Test Indicat result for the presence of antibodies for CSFV. Positive test results only mean antibo the specimen

- The appearance of a Control Line and Test Line, indicates a positive result for t antibodies for CSFV. The intensity of the test line may vary depending on the a present in the sample.

Negative Results

At 10 minutes, the appearance of only Control Line indicates a negative result for th antibodies for CSFV.

Invalid Results

If at 10 minutes, the Control Line does not appear, even if a Test Line appears in the considered invalid. If the test is invalid, a new test should be performed with a new new Test Indicator.

Internal Controls

Two internal procedural controls are needed to confirm correct assay procedure an components. One of two is a line appearing in the "Control Line" area in every run o validity of the test. Another one is a clear background serving as an internal negative background color should be white and not interfere with the reading of the test resu color interferes with the reading, it is recommended to repeat the test.

Result Interpretation with the iaX-2101

Please refer to the full iaX-2101 Instructions for Use for complete instructions on ho Place the test indicator into the iaX-2101, with the barcode pointing in.

- A Green (–) indicates a negative result for the presences of antibodies for CSF level is below the detection limit.
- A Yellow (!) indicates that the test is invalid and a new test must be performec collected specimen sample.
- A Red (+) indicates a positive result for the presences of antibodies for CSFV.

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10 Minutes

Place the test indicator in the Spacket with the sample pad going down. Leave the test indicator in the Spacket for 10 minutes. Use the assaya timerDx to keep track of the test time.

Take out the test indicator and read the result at 10 minutes. Do not read the result after 20 minutes. The test indicator may also be read by the intelligent analyzer eXpress (iaX-2101) after 10 minutes.

Warnings & Precautions

1. For in vitro diagnostic use only.
2. The test is intended for use with pig blood or serum only.
3. This test has been authorized for the detection of antibodies against CSFV only.
4. Other animals can also be infected with African and Classical Swine Fever, but they are much less susceptible than pigs. These animals include cattle, sheep, goats, horses, and dogs. While this RDT has not been validated for other animals, it is not recommended for use with other animal species or with other body fluids, such as saliva or milk.
5. Animals that are infected with African and Classical Swine Fever typically show mild or no symptoms. However, they can still transmit the virus to pigs. Classical Swine Fever is not at the present time known to be transmissible to humans.
6. To obtain accurate results, you must follow the Package Insert.
7. Check if the device package is complete; test indicator must be sealed in foil pouch and the expiration date of the device must be shown. Do not use if any of the test materials is broken or beyond the labelled expiration date.
8. Do not interchange or mix different lots of assaya CSF Antibody Test for Classical Swine Fever.
9. Do not reuse kit components.
10. Use of protective tools is recommended when collecting, handling, storing, and disposing of the components within process.
11. Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
12. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
13. Disregard test results beyond the specified time (20 min).
14. Test results must be interpreted together with other clinical information available to the physician.
15. Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. When contacted acidic substances, it may produce highly toxic gases. In case of accidental contact with the skin, please wash immediately with plenty of water.
16. CSFV antibodies are usually found in blood-related samples in the middle and late stages of infection or after infection recovery.
17. The test should not be used to diagnose CSF or test for antigens as part of an acute infection, but rather be used to test for antibodies in pigs that have been vaccinated against CSFV or have seroconverted after a natural infection with CSF and developed antibodies to CSFV

Product Limitations

1. The contents of this kit are to be used for the qualitative detection of antibodies for CSFV. For quantitative detection of the assay, use the iaX-2101. Please refer to the iaX-2101 IFU for full instructions on using the iaX-2101.
2. The amounts of antibodies in the specimen may decrease or increase as the duration of illness increases.
3. Test result must be combined with clinical observations, patient history and epidemiology to make an overall judgment.
4. Positive test results only mean antibodies for CSFV exist in the specimen. Negative test result may occur if the level of antibodies in a specimen is below the detection limit of the test.
5. As the production of antibodies in the immune response varies among individuals, the device may fail to detect, or detect with less sensitivity.

Clinical Performance

The RDT for Antibodies for Classical Swine Fever has been evaluated for sensitivity and specificity using a panel of known CSFV-positive and CSFV-negative pig serum samples. The test was found to have a sensitivity of 99% and a specificity of 98%.

References

1. "How to Protect Yourself & Others". Centers for Disease Control and Preventio Archived from the original on 26 February 2020. Retrieved 9 April 2020.
2. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Dep Human Services, CDC, NIH, Washington, DC (2007).
3. Henretig F.M. MD, King C. MD, Textbook of Pediatric Procedures, Chapter 123 - Specimens Williams and Williams (April 1997).

Technical Support

Email: support@assaya.com (mailto:support@assaya.com)

Adverse Events Reporting

Use this link to report any adverse events: assaya.com/ae (https://assaya.com/ae)

Ordering Information

Catalog Number (REF): AKIT-CSF-AB-01
50 pcs per box (Carton of 50 test kits)

Symbol Legend

Catalog Number	Consult Package Insert	Dc
Batch Code	Manufacturer	Contains suf
In Vitro Diagnostic Medical Device	Temperature Limit	Hur
No Direct Sunlight	Expiration Date	Do not r c
Do not expose to water	Warning	CI

Manufacturers

IVD

Assaya Pvt. Ltd. Singapore
160 Robinson Road, #14-04 Singapore Business Federation Ce 068914
Web: assaya.com/ (https://assaya.com/)

Spacket

Taiwan Swabs Technology Company Inc.
No.329-1, Sucuo, Anding Dist.,
Tainan City 745, Taiwan
Web: yt-swabs.com.tw/eng (http://www.yt-swabs.com.tw/eng)

Distributor

NordicDx
Måltidets hus,
Richard Johnsens Gate 4
4021 Stavanger, Norway
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