REF

AKIT-ASF-AG-01

ASF (African Swine Fever) Ag - Instructions For Use (IFU)

For in vitro diagnostic use only.

Sample Collection Method

Intended Use

The Rapid Antigen Test for African Swine Fever (ASF) is a chromatographic immunoassay intended for the visual qualitative detection or machine read quantitative detection of antigens to African swine fever virus (ASFV) in pig oral samples. ASF is a highly contagious viral disease of domestic and wild pigs including domesticated swine (pigs), wild boars, feral swine, warthogs, bush pigs, and giant forest hogs. It is caused by the ASFV, a large DNA virus of the Asfarviridae family. ASF is a notifiable disease to the World Organisation for Animal Health (OIE). ASF poses a significant threat to the global swine industry. Timely and accurate detection of ASF is essential for effective disease management and containment.

ASF is characterized by a range of clinical symptoms, including high fever, loss of appetite, hemorrhages, and high mortality rates. ASF can be transmitted between pigs through direct contact with infected pigs or their bodily fluids, or through indirect contact with contaminated objects. The virus can also be transmitted by ticks. Currently, there is no specific treatment or vaccine available for ASF. Infected pigs must be culled to prevent the spread of the virus. Preventative measures include biosecurity to prevent the introduction of the virus into a herd, and surveillance measures to detect the virus early. ASF is not a zoonotic disease, meaning that it cannot be transmitted from pigs to humans.

This user-friendly and reliable ASF Rapid Antigen Test has been designed to assist veterinarians, animal health professionals, and farmers in quickly identifying ASF-infected pigs, allowing for prompt action to limit the spread of the virus and minimize its economic impact.

This test utilizes a lateral flow immunoassay, employing dye-labeled particles that bind to ASF antigens in the sample. A nitrocellulose membrane is immobilized with a monoclonal antibody against the ASF antigen. Another anti-ASF Ag monoclonal antibody is conjugated to colloidal gold particles. This conjugate is placed on a polyester pad as a conjugate pad. When the test is in assay buffer containing specimens, the solubilized conjugated migrates with the sample by passive diffusion and both the conjugate and sample come into contact with the anti-ASF antibody that it absorbed onto the nitrocellulose. The appearance of a colored line on the test strip indicates the presence of ASFV antigens.

Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results should be considered in the context of recent exposures, history and the presence of clinical signs and symptoms. The Rapid Antigen Test for ASF is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel.

Materials

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

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

- LEIQA Test strips with desiccant (50 kits)
- Buffer solution (50 Spackets)
- 1 SWAC (Sterile Wood Abrasive Collector)
- 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 2-30°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.

The SWAC (Sterile Wood Abrasive Collector) is used to collect an oral fluid sample. This is a non-invasive method that collects a sample of saliva from the animal's mouth using the SWAC. Oral fluid samples are easy to collect and can be used on animals of all ages.

When collecting samples, it is important to use sterile equipment and to avoid contaminating the sample. Samples should be labeled with the animal's identification number and the date and time of collection. Samples should be transported to the laboratory as soon as possible for testing. Appropriate PPE should be worn when collecting samples from animals, and caution should be used if an animal is sick or aggressive.

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.

1.

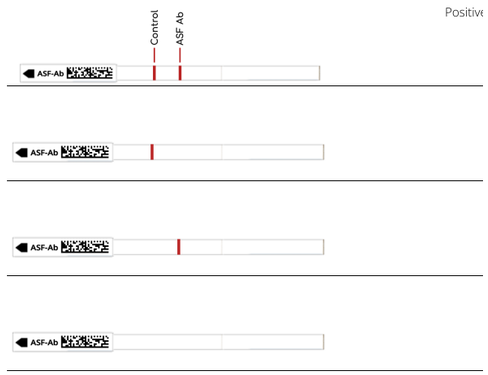
Obtain the sterile SWAC. Make sure the SWAC head does not touch anything until sample collection.

2.

Insert the SWAC into the mouth of the animal being tested. Keep the SWAC near the cheek in the mouth. Rotate the SWAC 5 times to collect saliva.

Assay Procedure

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 antigens for ASFV. Positive test results only mean antigens specimen

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

Negative Results

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

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 t new Test Indicator.

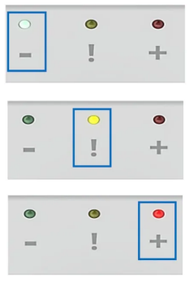
Internal Controls

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 antigens for ASFV, 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 presence of antigens for ASFV.



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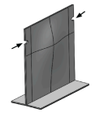
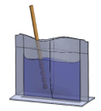
1.



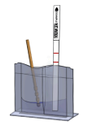
Stand up the Spacket, and tear it open. Be careful not to spill the liquid reagent inside.

2.



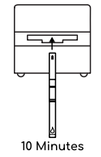
Put the SWAC into the Spacket. Roll the swab 5 times. Leave the SWAC in the Spacket for 1 minute before inserting the test indicator.

3.



While the SWAC remains in the Spacket, place the test indicator into the Spacket with 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.

4.



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 oral sample only.
3. This test has been authorized for the detection of antigens for ASFV only.
4. Other animals can also be infected with ASF, but they are much less susceptible than pigs. These animals include boars, ticks, and other wild animals. 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. To obtain accurate results, you must follow the Package Insert.
6. 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.
7. Do not interchange or mix different lots of assaya Rapid Antigen Test for ASF.
8. Do not reuse kit components.
9. Use of protective tools is recommended when collecting, handling, storing, and disposing of the components within process.
10. Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
11. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
12. Disregard test results beyond the specified time (20 min).
13. Test results must be interpreted together with other clinical information available to the physician.
14. 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.

Product Limitations

1. The contents of this kit are to be used for the qualitative detection of antigens for ASFV. 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 antigens in the specimen may decrease or increase as the duration of illness increases.
3. Test result must be combined with clinical observations, clinical history, and epidemiology to make an overall judgment.
4. Positive test results only mean antigens for ASFV exist in the specimen. Negative test result may occur if the level of antigens in a specimen is below the detection limit of the test.

Clinical Performance

The RDT for ASF has been evaluated for sensitivity and specificity using a panel of known ASF-positive and ASF-negative pig oral 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-ASF-AG-01
50 pcs per box (Carton of 50 test kits)

Symbol Legend

Manufacturers

IVD

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

Spacket

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