

REF

AKIT-PR-AB-01

PRV (Pseudorabies Virus) Ab - Instructions For Use (IFU)

For in vitro diagnostic use only.



Sample Collection Method

Intended Use

The PRV Ab RDT is a rapid, one-step immunochromatographic assay for the qualitative or machine read quantitative detection of pseudorabies virus (PRV) antibodies in blood or serum of pigs primarily, but it is also possible it could be used on other mammals. The test is intended for use by veterinarians and swine producers.

Pseudorabies virus (PRV), also known as Aujeszky's disease, is a highly contagious viral disease that affects swine and other mammals. It is caused by a herpesvirus, which is a type of virus that can establish latency in the host. PRV is not related to rabies, but it was named pseudorabies because some of the clinical signs can resemble rabies.

PRV is most common in pigs, but it can also infect other animals. The virus is transmitted through direct contact with infected animals, their saliva, or their bodily fluids. It can also be transmitted through contaminated feed, water, or bedding. The most common clinical signs of PRV include nervous system, respiratory, reproductive abnormalities. In other animals, the clinical signs of PRV are similar, but they may also include fever, depression, and loss of appetite. PRV is often fatal in animals other than pigs. PRV is a zoonotic disease, meaning that it can be transmitted from animals to humans. However, the risk of human infection is very low.

There are a number of different vaccines available for PRV. The best vaccine for your pigs will depend on a number of factors, such as the age of the pigs, the level of risk of exposure to the virus, and the local regulations. If you are concerned about PRV, you should talk to your veterinarian. They can help you to develop a prevention and control plan for your farm.

The test is based on a lateral flow immunoassay, which uses dye-labeled particles to bind to PRV antibodies in the sample. If PRV antibodies are present in the sample, a colored line will appear on the test strip. PRV contains a membrane strip, which is pre-coated with PRV-specific recombinant antigens in the test line (T). The another PRV 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 Pseudorabies Virus is a valuable tool for veterinarians and swine producers to help identify infected animals and control the spread of PRV.

Materials

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

The following materials are provided with the RDT for Antibodies for Pseudorabies Virus:

- 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.

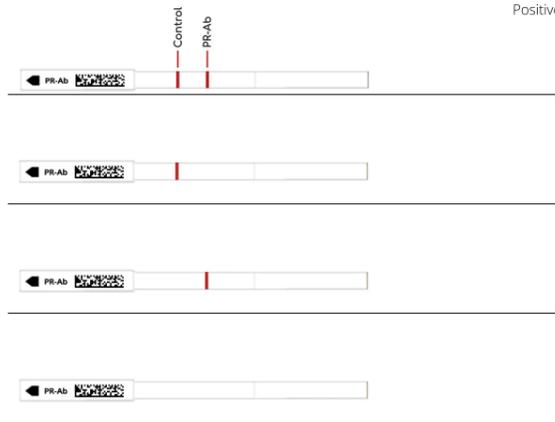
Whole blood specimens should be tested as soon as possible after collection in standard laboratory. To collect serum, use the same method for whole blood collection. Allow the blood to clot and then centrifuge to separate the serum. Transfer the serum to a clean tube. Specimen could be stored at 2-8°C 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

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Stand up the Spacket, and tear it open. Be careful not to spill the liquid reagent inside. Sample 30 uL of blood into the Spacket.

Result Interpretation



Positive Results

At 10 minutes, the appearance of the Control Line and Test Line on the Test Indicator result for the presence of antibodies for PRV. Positive test results only mean antibody the specimen

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

Negative Results

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

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 test strip and a new Test Indicator.

Internal Controls

Two internal procedural controls are needed to confirm correct assay procedure and validity of the test. One of two is a line appearing in the "Control Line" area in every run 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 result. If the background 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 how to use the test indicator into the iaX-2101, with the barcode pointing in.

- A Green (-) indicates a negative result for the presence of antibodies for PRV level is below the detection limit.
- A Yellow (!) indicates that the test is invalid and a new test must be performed with a new specimen sample.
- A Red (+) indicates a positive result for the presence of antibodies for PRV.



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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 assay timer 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 PRV only.
4. Other animals can also be infected with Pseudorabies virus, but they are much less susceptible than pigs. These animals include cattle, sheep, goats, horses, dogs, and wild animals such as raccoons and skunks. 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 Pseudorabies Virus typically show mild or no symptoms. However, they can still transmit the virus to pigs.
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 PRV Antibody Test for Pseudorabies Virus.
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. PRV 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 PRV 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 PRV or have seroconverted after a natural infection with PRV and developed antibodies to PRV.

Product Limitations

1. The contents of this kit are to be used for the qualitative detection of antibodies for PRV. 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 PRV 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 Pseudorabies Virus has been evaluated for sensitivity and specificity using a panel of known PRV-positive and PRV-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 Prevention. Archived from the original on 26 February 2020. Retrieved 9 April 2020.
2. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of 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-PR-AB-01
50 pcs per box (Carton of 50 test kits)

Symbol Legend

Catalog Number	Consult Package Insert	Do not expose to water
Batch Code	Manufacturer	Contains sufficient
In Vitro Diagnostic Medical Device	Temperature Limit	Hurt
No Direct Sunlight	Expiration Date	Do not use after
	Warning	Cl

Manufacturers

IVD

Assaya Pvt. Ltd. Singapore
160 Robinson Road, #14-04 Singapore Business Federation Centre
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
Web: nordicdx.com (https://assaya.com/nordicdx.no)