

Porcine Pseudorabies Virus Antigen Rapid Test

REF

KINER5051

Ver 1.0

IVT

For In-Vitro Test Only



1 x 40 tests

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Introduction:

Porcine Pseudorabies Virus (PRV), also known as Suid herpesvirus 1, is a highly contagious viral pathogen of porcine that causes Aujeszky's disease.

Aujeszky's disease is a highly contagious disease affecting porcine, causing severe neurological, respiratory, and reproductive issues, often leading to high mortality, especially in piglets, and significant economic losses in swine farming. It establishes lifelong latent infections in infected porcine, allowing reactivation and spread under stress, making eradication difficult. As a result, although vaccination and eradication programs have significantly reduced its prevalence in many regions, outbreaks continue to occur in endemic areas.

Intended Use:

The Porcine Pseudorabies Virus Antigen Rapid Test is used for qualitative detection of PRV antigen in nasal/oropharyngeal swab, and tissue homogenates.

Principle:

This Rapid Test is an immuno-chromatographic test, using colloidal gold immunoassay method to detect the indicated antigen/antibody. After the addition of the sample, as per the instruction for use (IFU), the sample moves along with the colloidal gold labeling protein. If the relevant protein is present, it will develop a reddish color line near the space marked as "T". This indicates the sample is Positive and if a line is not developed or seen, it indicates the sample is Negative for the tested antigen/antibody.

Materials Provided:

1. Cassette: with a pad in the device.
2. Sample Diluent - 3 ml

Materials to be provided by the End-User:

1. Adjustable pipettes and multichannel pipettor to measure volumes ranging from 25 ul to 1000ul
2. Alcohol prep-pad
3. Clock or timer
4. Specimen collection container
5. Centrifuge
6. Biohazard waste container
7. Sterile gauze or cotton

Handling / Storage:

1. All reagents should be stored at 2°C to 8°C for stability.
2. All the reagents and wash solutions should be used within 12 months from manufacturing date.
3. Before using, bring all components to room temperature (18-25°C). Upon assay completion ensure all components of the kit are returned to appropriate storage conditions.

Health Hazard Warnings:

1. Reagents that contain preservatives may be harmful if ingested, inhaled or absorbed through the skin.
2. For Research Use Only.

Sample Preparation and Storage:

Nasal/Oropharyngeal Swab Samples: Gently collect nasal/oropharyngeal secretions using a sterile swab and place it into a specimen tube containing 1ml sample diluent. Mix the swab thoroughly with the diluent to extract the virus, then remove and safely discard the swab. The extracted sample can be used immediately for testing. If testing is delayed, samples may be stored at 2–8°C for up to 3 days or frozen at –20°C or lower for long-term storage. Repeated freeze–thaw cycles should be avoided.

Tissue homogenate: Collect tissue samples aseptically and cut approximately 0.1 g (100 mg) of tissue and place it into a sterile tube containing 1.0 mL of sample diluent. Homogenize thoroughly to obtain a uniform suspension. Allow large debris to settle or clarify by brief centrifugation if necessary, and use the clear supernatant for testing. Prepared samples should be tested immediately. If testing is delayed, store at 2–8°C for up to 24 hours or at –20°C or below for long-term storage. Avoid repeated freeze–thaw cycles.

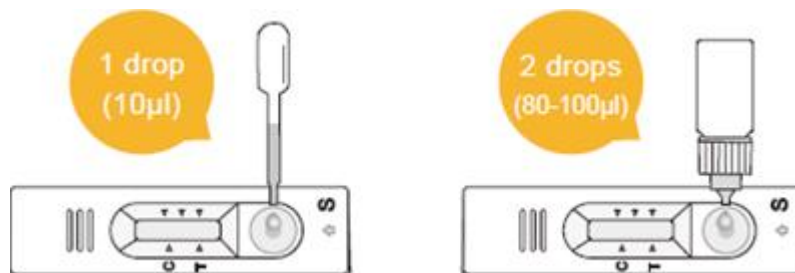
Preparation Before Use:

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20°C - 30°C) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (humidity ≤ 60%, temp: 20°C - 30°C). Please use immediately when the humidity > 60%.

Assay Procedure:

For Nasal/ Oropharyngeal/ Tissue Homogenate samples

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add one (1) full drop of prepared sample (10 ul) vertically into the sample well.
3. Add two (2) drops (80-100 ul) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.

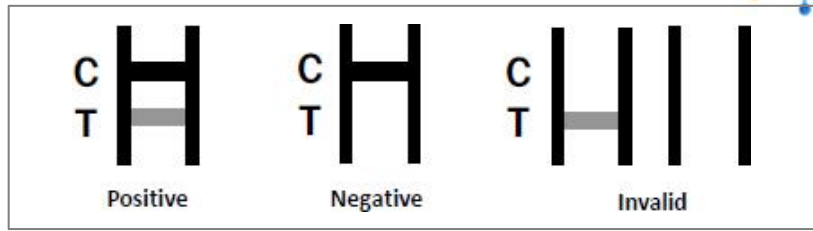


Interpretation of Results:

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region (C). No red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



Quality Control:

It is recommended that for each laboratory assay appropriate quality control samples in each run to be used to ensure that all reagents and procedures are correct.

Performance Characteristics of the Kit:

Sensitivity:

Negative coincident rate with Molecular testing: $\geq 97\%$, Positive coincident rate with Molecular testing: $\geq 75\%$.

Limitations of Method

Any diagnosis should not be based on the results of in vitro methods alone. Veterinarians are suggested to consider all clinical and laboratory findings possible to state a diagnosis. This

reagent is designed for the qualitative screening test.

Safety Precautions:

- Follow the working instructions carefully.
- The expiration dates stated on the kit are to be observed. The same relates to the stability stated for reagents
- Do not use or mix reagents from different lots.
- Do not use reagents from other manufacturers.
- Avoid time shift during pipetting of reagents.
- All reagents should be kept in the original shipping container.
- Some of the reagents contain small amount of sodium azide ($< 0.1\%$ w/w) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Since the kit contains potentially hazardous materials, the following precautions should be observed
 - Do not smoke, eat or drink while handling kit material
 - Always use protective gloves
 - Never pipette material by mouth
 - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.

Symbols



Use by



Lot/Batch



Catalog number



Temperature limitation



Caution, consult accompanying documents



Manufacturer

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