

Porcine Circovirus (PCV2) Antigen Rapid Test



KINER5047

Ver 1.0



For In-Vitro Test Only



1 x 40 tests

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Introduction:

Porcine circovirus type 2 (PCV2) belongs to the viral family Circoviridae and to the genus Circovirus. Porcine Circovirus type 2 (PCV2) is a small single-stranded, nonenveloped DNA viruses that have an unsegmented circular genome. PCV2 is the primary causative agent of several syndromes collectively known as porcine circovirus-associated disease (PCVAD), which include Postweaning Multisystemic Wasting Syndrome (PMWS), respiratory disease, reproductive failure, and porcine dermatitis and nephropathy syndrome (PDNS).

PCV2 infection leads to immunosuppression in affected pigs, increasing susceptibility to secondary infections and co-infections with other pathogens such as PRRSV and swine influenza virus, thereby exacerbating disease severity.

Intended Use:

The Porcine Circovirus (PCV2) Antigen Rapid Test is used for the qualitative detection of Porcine Circovirus type 2 (PCV2) antigen in serum, plasma and whole blood.

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:

Whole Blood Samples: Clean the site with Alcohol Prep Pad. Collect the blood from vein. Using Disposable Pipette, collect blood from the puncture site. Alternatively - draw blood following laboratory procedure for obtaining venous blood. Do not test whole blood samples if older than 3 days.

Serum/Plasma samples: Fresh serum or plasma samples can be used. For serum, ensure the blood is fully clotted before separating, and for plasma, collect into tubes containing an anticoagulant. Remove any visible particulate matter by centrifugation or filtration. Avoid using highly hemolytic, turbid, or microorganism-contaminated samples.

Samples may be stored at 2–8°C for up to 3 days if testing is not immediate, or frozen at –20°C or lower for longer-term storage. Repeated freeze–thaw cycles should be avoided.

Plasma: Collect whole blood into a collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture. Separate the plasma by centrifugation.

Serum: Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture. Allow the blood to clot. Separate by centrifugation.

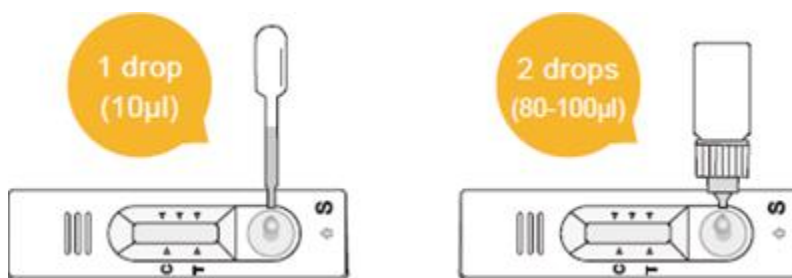
Preparation Before Use:

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:

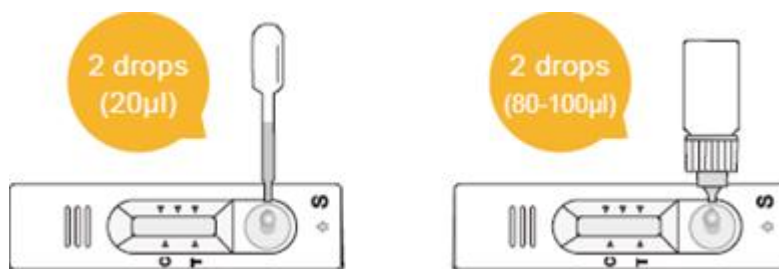
For Serum / Plasma

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 serum or plasma (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.



For Whole Blood

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add two (2) full drops of whole blood (20 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.

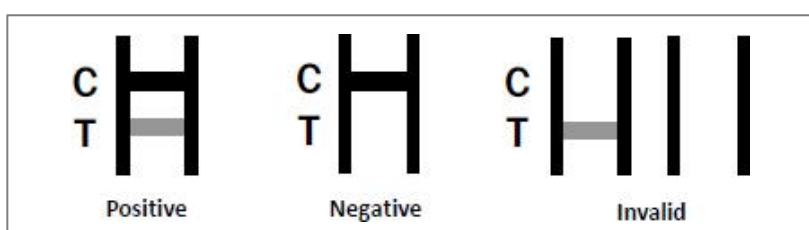


Interpretation of Results:

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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