

Anigen Rapid TGE/PED Ag Test Kit

Principles

The Anigen Rapid TGE/PED Ag Test Kit is a chromatographic immunoassay for the qualitative detection of Porcine Transmissible Gastroenteritis (TGE) Virus antigen and Porcine Epidemic Diarrhea Virus antigen in porcine feces.

The Anigen Rapid TGE Ag and PED Ag Test Kit the letters "T" and "C" as the Test line and Control line on the surface of the device. Both the test line and control line in the result window are not visible before applying any samples. The control line is used for procedural control, and should be always appeared if the test procedure is performed properly and the test reagents of the control line are working. A purple test line will be visible in the result window if there is enough TGE antigen and/or PED antigen in the specimen.

The specially selected Porcine Transmissible Gastroenteritis (TGE) Virus antibodies and Porcine Epidemic Diarrhea Virus antibodies are used in the test band as both capture and detector materials. These enable the Anigen Rapid TGE/PED Ag Test Kit to identify Porcine Transmissible Gastroenteritis (TGE) Virus antigen and Porcine Epidemic Diarrhea Virus antigen in swine feces with a high degree of accuracy.

Materials provided (10 tests/kit)

- 1) Ten(10) Anigen Rapid TGE/PED Ag Test Kits
- 2) Ten(10) Specimen tubes containing assay diluent buffer for TGE Ag
- 3) Ten(10) Specimen tubes containing assay diluent buffer for PED Ag
- 4) Twenty(20) Sample collection swabs
- 5) Twenty (20) Disposable droppers (2 droppers are included into an aluminum pouch)
- 6) One(1) Instructions for use

Precautions

- 1) For veterinary diagnostic use only.
- 2) The composition of the assay diluent buffers of TGE Ag and PED Ag is so different. These assay diluent should not be changed and mingled. It must be distinguished.
- 3) For the best results, strict adherence to the instructions is required.
- 4) All specimens should be handled as being potentially infectious.
- 5) Do not open or remove test kits from their individually sealed pouches until immediately before their use.
- 6) Do not use the test kit if the pouch is damaged or the seal is broken.
- 7) Do not reuse test kits.
- 8) All reagents must be stored at room temperature before running the assay.
- 9) Do not use reagents beyond the stated expiration date marked on the label.
- 10) The components in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.

Storage and Stability

The kit can be stored at room temperature (2~30℃) or in the refrigerator. The test kit is stable through the expiration date marked on the package label. **DO NOT FREEZE.** Do not store the test kit in direct sunlight.

Specimen Collection and Preparation

- 1) Samples from swine feces should be used for this test.
- 2) Each sample should be collected by each sample collection swab.
- 3) The specimens should be tested immediately after collection.

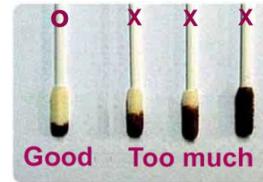
Procedure of the test

- 1) Collect two samples from one swine feces using two swabs.
- 2) Insert one swab into a specimen tube containing 1ml of assay diluent for TGE Ag
- 3) Insert another swab into a specimen tube containing 1ml of assay diluent for PED Ag.
- 3) Mix the each swab sample with the each assay diluent vigorously to extract the viruses.
- 4) Remove a test device from an aluminum foil pouch, and place it on the flat and dry surface.
- 5) Use two disposable droppers provided in the aluminum foil pouch and take two aliquot from the two extracted and mixed samples in the tubes respectively.
- 6) If the feces particles are large, wait for 1 minute until the large particles are settled, and then take the supernatant of the sample in the each tubes respectively.
- 7) Add five (5) drops into the each sample holes of TGE Ag and PED Ag Testing device by using the disposable dropper respectively. The each assay diluent should be added **exactly and slowly drop by drop.**
- 8) As the test begins to work, you will see purple color moving across the result window in the center of the test device. If the migration dose not appear after 1 minute, add one more drop of the mixed assay diluent to the sample well.
- 9) Interpret test results at 5 ~ 10 minutes. Do not read after 20 minutes.

[Figure for test procedures]



[Feces specimens amount collected for the best test result]

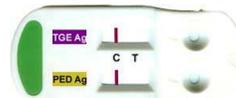


Interpretation of the test

A color band which would be appeared in the left section of the result window shows that the each test works properly. And it is called control band. The right section of the result window called test band indicates the test results. If another color band appears on the test band.

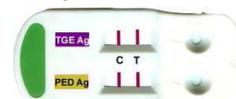
1) TGE Ag and, PED Ag Negative result

The presence of only one band within the result window on both of the TGE Ag and PED Ag test areas means negative result.



2) Simultaneous TGE Ag and PED Ag Positive result

The presence of two color bands ("T" and "C") within the result window on both of the TGE Ag and PED Ag test areas respectively, no matter which band appears first, means positive result of TGE and PED simultaneously.



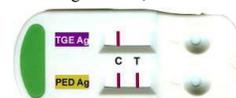
3) TGE Ag Positive result

The presence of two color bands ("T" and "C") within the result window on the TGE Ag test area, and the presence of only one band ("C") within the result window on the PED Ag test area, no matter which band appears first, means positive result of TGE.



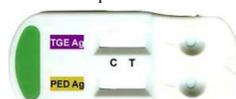
4) PED Ag Positive result

The presence of two color bands ("T" and "C") within the result window on the PED Ag test area, and the presence of only one band ("C") within the result window on the TGE Ag test area, no matter which band appears first, means positive result of PED.



3) Invalid Result

If the purple color band is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended to take the test again with same specimen.



Limitations of the test

Although the Anigen Rapid TGE/PED Ag test kit is very accurate in detecting TGE antigen and PED antigen, a low incidence of false results can be occurred. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the veterinarian after all clinical and laboratory findings have been evaluated. The limit of TGE antigen detection of this kit is approximately $10^{4.0}$ TCID₅₀/0.1ml. The limit of PED antigen detection is approximately $10^{4.0}$ TCID₅₀/0.1ml.