

One Step Porcine Epidemic Diarrhea Virus Antigen and Rotavirus Antigen Test

Anigen Rapid PED/ROTA Ag Test Kit

■ Principles

The Anigen Rapid PED/ROTA Ag Test Kit is a chromatographic immunoassay for the qualitative detection of Porcine Epidemic Diarrhea Virus antigen and Rotavirus antigen in porcine feces.

The Anigen Rapid PED Ag and ROTA Ag Test Kit has 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 always appear 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 PED antigen and/or ROTA antigen in the specimen.

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

■ Materials provided (10 tests/kit)

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

■ Precautions

- 1) For veterinary diagnostic use only.
- 2) For best results, strict adherence to the instructions is required.
- 3) All specimens should be handled as being potentially infectious.
- 4) Do not open or remove test kits from their individually sealed pouches until immediately before their use.
- 5) Do not use the test kit if the pouch is damaged or the seal is broken.
- 6) Do not reuse test kits.
- 7) All reagents must be at room temperature before running the assay.
- 8) Do not use reagents beyond the stated expiration date marked on the label.
- 9) 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°C) or refrigerated. 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.

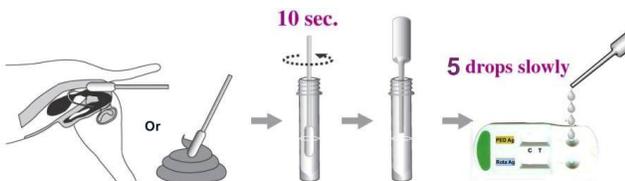
■ Specimen Collection and Preparation

- 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.

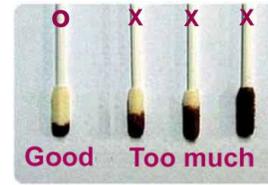
■ Procedure of the test

- 1) Collect the sample from one swine feces using the swab.
- 2) Insert one swab into a specimen tube containing 1ml of assay diluent
- 3) Mix the swab sample with the assay diluent vigorously to extract the viruses.
- 4) Remove a test device from an aluminum foil pouch, and place it on a flat and dry surface.
- 5) Using the disposable dropper provided in the aluminum foil pouch, take an aliquot from the extracted and mixed sample in the tube.
- 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 sample hole of PED Ag and the sample hole of ROTA Ag Testing using the disposable dropper. The assay diluent should be added **exactly, slowly drop by drop.**
- 8) As the test begins to work, you will see a purple color move across the result window in the center of the test device. If the migration has not appeared 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 decide after 20 minutes.

[Figure for test procedures]



[Feces specimens amount collected for best test result]

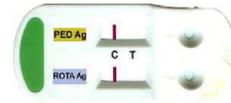


■ Interpretation of the test

A color band will appear in the left section of the result window to show that each test is working properly. This band is the control band. The right section of the result window indicates the test results. If another color band appears in the right section of the result window. This band is the test band.

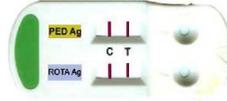
1) PED Ag and ROTA Ag Negative result

The presence of only one band within the result window on both of the PED Ag and ROTA Ag test areas indicates a negative result.



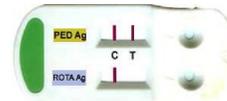
2) Simultaneous PED Ag and ROTA Ag Positive result

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



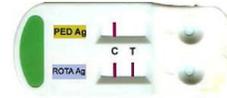
3) PED Ag Positive result

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 ROTA Ag test area, no matter which band appears first, indicates a positive result of PED.



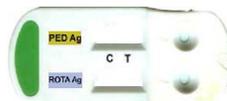
4) ROTA Ag Positive result

The presence of two color bands ("T" and "C") within the result window on the ROTA 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, indicates a positive result of ROTA.



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 that the specimen be re-tested.



■ Limitations of the test

Although the Anigen Rapid PED/ROTA Ag test kit is very accurate in detecting PED antigen and ROTA antigen, a low incidence of false results can occur. 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 PED antigen detection of this kit is approximately $10^{4.0}$ TCID₅₀/0.1ml. The limit of ROTA antigen detection is approximately $10^{4.0}$ TCID₅₀/0.1ml.

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