

*Anigen Rapid TGE Ag Test Kit

■ Principles

The **Anigen Rapid TGE Ag Test Kit** is a chromatographic immunoassay for the qualitative detection of Porcine Transmissible Gastroenteritis (TGE) Virus antigen in porcine diarrhea feces.

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

The specially selected TGE virus antibodies are used in test band as both capture and detector materials. These enable the Anigen Rapid TGE Ag Test Kit to identify TGE virus antigen in porcine diarrhea feces with a high degree of accuracy.

■ Materials provided (10 tests/kit)

- 1) Ten(10) Anigen Rapid TGE Ag Test Kits
- 2) Ten(10) Specimen tubes containing assay diluent buffer
- 3) Ten(10) Sample collection swabs
- 4) Ten(10) Disposable droppers
- 5) One(1) Instruction for use

■ Precautions

- 1) **The specimen should be fresh porcine diarrhea feces**
- 2) For veterinary diagnostic use only.
- 3) For best results, strict adherence to these instructions is required.
- 4) All specimens should be handled as being potentially infectious.
- 5) Do not open or remove test kit 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 kit.
- 8) All reagents must be 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 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 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.

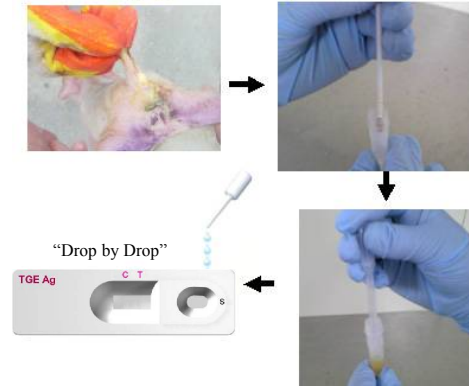
■ Specimen Collection and Preparation

- 1) The samples from porcine feces should be used for this test.
- 2) The specimens should be tested immediately as soon as collect the samples.

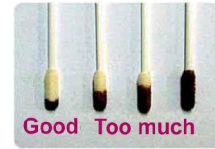
■ Procedure of the test

- 1) **Collect the samples** from **fresh porcine diarrhea feces** using the swab.
- 2) Insert the swab into the specimen tube containing 1 ml of assay diluent.
- 3) **Mix the swab samples with assay diluent** to extract well.
- 4) Remove the test device from the foil pouch, and place it on a flat and dry surface.
- 5) Using the disposable dropper provided, take the samples from extracted and mixed specimens in the tube.
- 6) **Add four (4) drops** into the sample hole using the disposable dropper slowly and drop by drop..
- 7) As the test begins to work, you will see 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.
- 8) For best result, test 5 diarrhea feces in the farm.
- 9) **Interpret test results at 5 ~ 10 minutes**. Do not decide after 20 minutes.

[Figure for test procedures]



[Sample amount collected by swab]



■ Interpretation of the test

- 1) A color band will appear in the left section of the result window.

This means that the 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, it means that the specimens have the TGEV antigens

Positive



Negative



- 2) 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 kit may have deteriorated. It is recommended that the specimen be re-tested.



■ Limitations of the test

Although the TGE Ag Test kit is very accurate in detecting TGE virus antigen, a low incidence of false results can be occurred. TGE Ag Test kit may cross react with porcine respiratory corona virus. Other clinically or laboratory 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 detection limit of this kit is about $10^{4.0}$ TCID₅₀/0.1 ml.

■ Expected Values

Anigen Rapid TGE Test Kit has been compared with a RT-PCR tests. The sensitivity is 97% and the specificity is 82%.

Doc. No. : I 1402-1E
Issued date : MAR 31, 2006



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