

One Step Porcine Transmissible Gastroenteritis Virus and Porcine Epidemic Diarrhea Virus Antigen Test

For veterinary diagnostic use only

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/PED Ag Test Kit has two letters which are test("T") line and control("C") line on the surface of device. Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line has to appear every time when the test has performed. If the TGE and PED virus antigens are present in sample, a purple test line would appear in the result window.

The highly selective antibodies to TGE and PED virus are used as each capture and detector in the assay. These are capable of detecting TGE and PED virus antigen in sample with high accuracy.

Materials provided (10 Tests/Kit)

Reagent	10 Tests/Kit
Anigen Rapid TGE/PED Ag Test Device	10
Assay diluent tube	10
Disposable swab	10
Disposable dropper	10
Instructions for use	1

Materials required, but not provided

- 1) Timer

Precautions

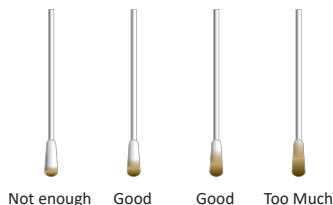
- 1) Test kit is for porcine only. Do not use for other animals.
- 2) The test device is sensitive to humidity as well as heat. Perform the test immediately after removing the test device from the foil pouch.
- 3) Do not re-use the test components.
- 4) Apply the sample using dropper vertically.
- 5) Do not touch the membrane in the result window of test device.
- 6) Do not use the test kit beyond the stated expiration date marked on the package label.
- 7) Do not use the test kit if the pouch is damaged or the seal is broken.
- 8) Do not mix components from different lot numbers because the components in this kit have been quality control tested as standard batch unit.
- 9) All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
- 10) Decontaminate and dispose of all samples, reaction kits and potentially contaminated materials safely in accordance with national and local regulations.

Storage and Stability

- 1) Store the test kit at 2~30°C. **DO NOT FREEZE.**
- 2) Do not store the test kit in the direct sunlight.
- 3) The test kit is stable within the expiration date that marked on the package label.

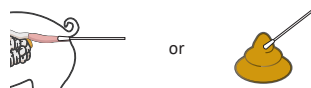
Collection and Preparation of Sample

- 1) The porcine feces should be used for this test.
- 2) The samples should be tested immediately after collection.
- 3) If samples are not tested immediately, they should be refrigerated at 2~8°C. For longer storage, freezing is recommended. Frozen samples should be brought to room temperature (15~30°C) prior to use.
- 4) The amount of fecal swab may affect the results. It is required to follow the swab amount of feces as shown in the picture on the below. Excessive fecal amount may induce a false positive result and slow migration.

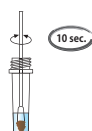


Procedure of the Test

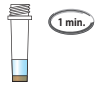
- 1) All reagents and samples must be at room temperature (15~30°C) before use.
- 2) Collect porcine feces samples by using a swab.



- 3) Insert the swab into the assay diluent tube. Mix the swab until the sample has been dissolved into the assay diluent (Approximately 10 sec.).



- 4) Wait for 1 minute to settle down the large particles.



- 5) Remove the test device from the foil pouch, and place it on a flat and dry surface.
- 6) Using the disposable dropper, take the supernatant sample in the tube.



- 7) Apply four(4) drops of sample into each sample hole, drop by drop vertically.



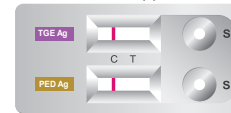
- 8) Start the timer. The sample will flow across the result window. If it does not appear after 1 minute, add one more drop of prepared sample to the sample hole.
- 9) Interpret test results at 10 minutes. Do not read the result after 20minutes.



Interpretation of the Result

1) Negative result

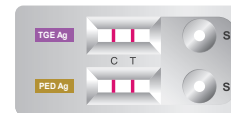
Only control("C") line in the result window appears.



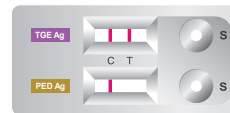
2) Positive result

Test("T") line and control("C") line within the result window indicate the presence of TGE and/or PED antigen.

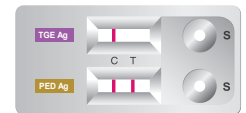
TGE and PED Ag Positive



TGE Ag Positive

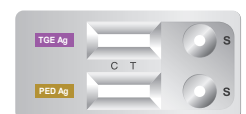
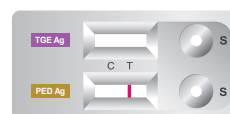
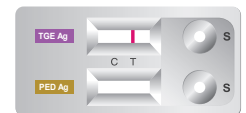
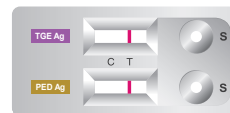


PED Ag Positive



3) Invalid Result

If the control("C") line does not appear, the result might be considered invalid. The sample should be re-tested.



Limitations of the Test

- 1) 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 or laboratory tests might be required if questionable results are obtained. As other diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be diagnosed by the veterinarian after all clinical and laboratory findings have been evaluated. The limit of TGE antigen detection of this kit is approximately $3.13 \times 10^{5.0} \text{TCID}_{50}/\text{mL}$. The limit of PED antigen detection is approximately $10^{5.0} \text{TCID}_{50}/\text{mL}$.
- 2) The reading window may show a light pink background coloration; this will not affect the accuracy of the results.
- 3) BioNote and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.

Doc. No.: I1403-9EC
Issued date: Nov. 12, 2019

Anigen Rapid TGE/PED Ag Test Kit

原理

猪传染性胃肠炎病毒/流行性腹泻病毒抗原检测试剂盒利用免疫层析法，准确检测猪粪便中含有的猪传染性胃肠炎病毒抗原、猪流行性腹泻病毒抗原。

本检测试纸选用具备高敏感性的抗体准确捕捉猪传染性胃肠炎病毒/流行性腹泻病毒抗原。试纸板表面标有“T”“C”两个字母，C线代表对照线，当C线出现时代表该检测有效，否则表示检测无效。T线代表检测线，当T线出现时为阳性结果，否则为阴性结果。

提供的材料

提供的材料	10份试纸
猪传染性胃肠炎病毒/流行性腹泻病毒检测试纸	10
装有反应缓冲液的样品收集管	10
样品收集棉签	10
一次性滴管	10
使用说明	1

需要但未提供的材料

计时器

注意事项

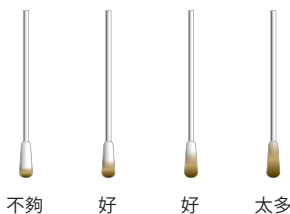
- 1) 仅用于猪，不要用于其他动物。
- 2) 该试纸对湿度和温度敏感，请临用前再打开包装。
- 3) 不要重复使用。
- 4) 请垂直使用吸管。
- 5) 请不要触摸试纸的窗口。
- 6) 请在有效期前使用。
- 7) 请不要使用包装破损的试纸。
- 8) 试纸的每个成分均进行质控，请勿混用不同批号的产品。
- 9) 请按具有潜在传染性的物质进行处理样品。
- 10) 请按照当地的法律来处理一次性医疗废弃物。

保存和稳定性

- 1) 试纸可以保存于室温(2~30°C)或者冷藏保存。不要冷冻。
- 2) 在有效期内的试纸是稳定的。
- 3) 不要将试纸放置于太阳直射处。

样品收集和准备

- 1) 该测试使用猪类的粪便。
- 2) 收集样品后必须立刻进行测试。
- 3) 如果样品不能马上检测，请置于2-8度可冷藏24小时，若放置于-20度可更久但使用时请恢复至室温。
- 4) 采集的样本量非常重要。请根据示意图来采集。过多的样本会显示假阳性和跑带缓慢。

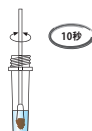


测试步骤

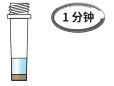
- 1) 反应要在室温进行。
- 2) 用棉签收集猪类的粪便。



- 3) 将棉签插入试管并搅拌 10秒。



- 4) 静置试管 1 分钟。



- 5) 取出试纸，将它平放于宽敞和干燥的表面。
- 6) 用提供的吸管小心吸取上清液(不要将粪便颗粒吸取出来)。



- 7) 用滴管向样品孔中垂直并且精确地加入4滴混合液。



- 8) 当反应进行时，你会看到紫色的条带在试纸中间的结果窗中移动。如果一分钟以后仍然没有条带移动，请再往样品孔中加入一滴混合液。

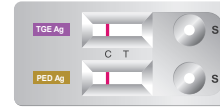
- 9) 10分钟后判断结果。不要超过 20分钟。



解释

1) 阳性结果

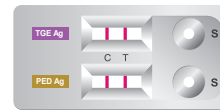
窗口中只出现控制线(“C”线)。



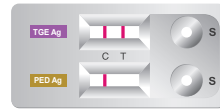
2) 阳性结果

在结果视窗中出现两条色线(“T”线和“C”线)，无论哪条线先出现，都表明为阳性。

TGE and PED Ag 阳性



TGE Ag 阳性

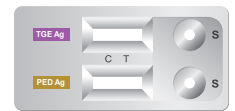
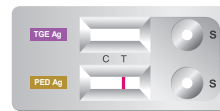
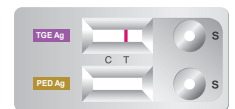
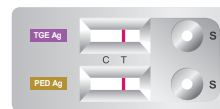


PED Ag 阳性



3) 无效的结果

如果试验操作完成后，未出现对照紫色线(“C”)，说明结果无效。可能操作不当造成，建议重新检测。



测试限度

- 1) 虽然本检测试纸具备高敏感性和特异性，但是也会有错误结果的出现。当出现可疑的结果时，请结合临床症状和实验室检测进行综合判断。最终的诊断结果不应以单项检测为基础，而应结合症状及综合检测由兽医作出诊断。
- 2) 阅读窗口可能会显示粉红色的背景，这不会影响结果的准确性。
- 3) 安捷公司和代理商不会对试纸的勿使用或误判断负责。

生产厂家：韩国安捷公司



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