

One-step Rabies Antigen Test

Anigen Rapid Rabies Ag Test Kit

Principles

The Anigen Rapid Rabies Ag Test Kit is a chromatographic immunoassay for the qualitative detection of Rabies virus antigen in canine, bovine, raccoon dog's secretions of saliva, and brain homogenates.

The Anigen Rapid Rabies 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 appear 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 Rabies virus antigen in the specimen.

The specially selected Rabies virus antibodies are used in test band as both capture and detector materials. These enable the Anigen Rapid Rabies Ag Test Kit to identify Rabies virus antigen in canine, bovine, and raccoon dog's secretion of saliva, and brain homogenates with a high degree of accuracy.

Materials provided (10 tests/kit)

- 1) Ten(10) Anigen Rapid Rabies 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) For veterinary diagnostic use only.
 - 2) For best results, strict adherence to these instructions is required.
 - 3) All specimens should be handled as being potentially infectious.
 - 4) Do not open or remove test kit 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 kit.
 - 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 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) The samples from saliva and brain homogenates should be used for this test.
- 2) The specimens should be tested immediately as soon as collect the samples from canine, bovine, and raccoon dog.

Procedure of the test

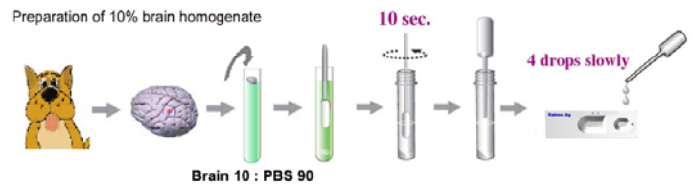
- 1) Collect the samples from saliva, and brain homogenates using the swab.
- 2) Insert the swab into the specimen tube containing 1ml of assay diluent.
- 3) Mix the swab samples with assay diluent to extract well.
- 4) Remove the test device from the foil pouch, and place it on a flat and dry surface.
- 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.
- 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) Interpret test results at 5 ~ 10 minutes. Do not decide after 10 minutes.

[Figure for test procedure]

1) Test procedure of a saliva specimen



2) Test procedure of Brain homogenate specimen

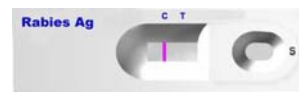


Interpretation of the test

A color band will appear in the left section of the result window to show 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. This band is the test band.

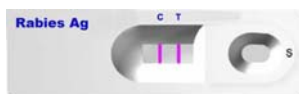
1) Negative result

The presence of only one band within the result window indicates a negative result.



2) Positive result

The presence of two color bands ("T" and "C") within the result window, no matter which band appears first indicates a positive result.



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 Rabies Ag Test kit is very accurate in detecting Rabies virus 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 detection limit of this kit is about 10^{2.0}LD₅₀/0.03ml in mice and 10⁵~10⁶ TCID₅₀/ml of CVS-II and EBL- I**