

Rabies virus Antigen Test Device Package Insert

Language English



For Veterinary Use Only

INTENDED USE

The Rabies Virus Antigen Test Device is intended for the qualitative detection of rabies virus antigens (RV Ag) from feline or canine saliva sample.

PRINCIPLE

This product mainly uses immunochromatographic technology to detect rabies virus antigen. During testing, target antigens, if present in the corresponding secretions, will be released into the extraction buffer. As the specimen migrates along the strip by capillary action and then interacts with reagents on the Sample Pad, the target antigens will be bind to antibodies on the Conjugate Pad. Consequently, the antigen-antibody complex will be captured by the antibodies immobilized at the Test Regions. Excess colored particles will be captured at the Control Region of the NC membrane. The presence of a colored band in the test region indicates a positive result, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

MATERIALS PROVIDED

- Individually Packed Test Devices
- Dilute Buffer
- Individually Wrapped Swab
- Package Insert

PRECAUTIONS

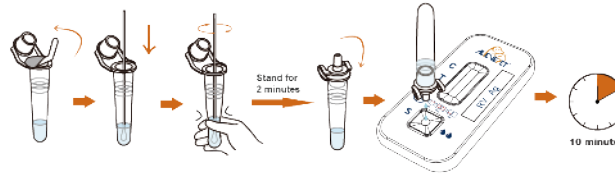
- Do not use kit or components beyond the expiration date.
- Do not reuse.
- Do not touch the membrane of the strip.
- Do not use the different samples to avoid cross contamination.
- Use only the supplied test components. Do not replace the buffer with any other liquid.
- The test contains material of animal origin and should be handled as a potential biohazard.

STORAGE AND STABILITY

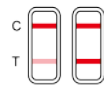
- Store the Rabies virus Antigen Test Device at 2-30°C(36-86°F) in a cool, dry place and keep out of direct sunlight when not in use.
- DO NOT FREEZE.
- The kit components are stable till the expiration dates marked on the corresponding outer packaging and containers.

TEST PROCEDURE

- 1. Sample collection**
Specimen: feline or canine saliva sample, collect the sample with the provided swab as below:
 - Swab the corners of your dog's mouth two or three times with the provided swab. Peel off the aluminum foil cover of the extraction buffer and place the swab into buffer tube and rotate 6 to 8 times along the sides of the buffer bottle. For best results, the sample should be performed within one hour
 - Mix thoroughly and stand for 2 minutes.
- 2. Testing**
Please read the instructions carefully before testing. Bring devices, reagents and specimens and/or controls to room temperature (15~30°C) before use.
 - a) Remove the test from its packing. Label the device with the pet's identification. For best results, the assay should be performed within one hour.
 - b) Put the the nozzle back to the buffer tube, transfer 2 drops of the specimen into the specimen well of the test device.
 - c) Read the results at 10 minutes. Do not read the results after 15 minutes.



INTERPRETATION OF RESULTS



Positive: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



Negative: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



Invalid: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

LIMITATIONS

The test is for veterinary use only, and should only be used for the qualitative detection of viral antigens for rabies virus. If there is a positive result, please confirm it with a confirmatory method. For other further clinical diagnosis, please consult the veterinarian.

PERFORMANCE

1) Clinical study

Table: Rabies Virus Antigen Test Device vs PCR

| | | PCR | | Total |
|----------------------------------|---|-----|-----|-------|
| | | + | - | |
| Rabies Virus Antigen Test Device | + | 51 | 3 | 54 |
| | - | 2 | 158 | 160 |
| | | 53 | 161 | 214 |

Relative Sensitivity: 96.2% (87.2%-99.0%)*
 Relative Specificity: 98.1% (94.7%-99.4%)*
 Overall Agreement: 97.7% (94.6%-99.0%)*
 *95% Confidence Interval

Specificity: This product has no cross reactivity with feline calicivirus, feline herpes virus, feline distemper virus, canine adenovirus and canine coronavirus.

INDEX OF SYMBOLS

| | | | |
|--|---|--|-----------------------------------|
| | Manufacturer | | Consult instructions for use |
| | Temperature limitation | | Catalog number |
| | Do not reuse | | Contains sufficient for <n> tests |
| | Batch code | | Used by |
| | Authorized representative in the European Community | | |



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