

Rabies Antigen Test

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST



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INTENDED USE

The Rabies Antigen Test is a rapid chromatographic immunoassay designed to qualitatively detect rabies virus antigens in salivary specimens and brain homogenates obtained from canines, bovines, and raccoon dogs. This test is intended for veterinary use as a preliminary screening tool to aid in the diagnosis of rabies virus infection in suspect animals. It provides results within minutes, facilitating timely clinical decisions regarding confirmatory testing and requisite public health interventions. Results must be interpreted by trained veterinary professionals in conjunction with clinical presentation, exposure history, and mandatory confirmatory testing as stipulated by local regulatory authorities.

Summary

Rabies is a fatal zoonotic viral disease affecting the central nervous system of mammals, posing significant global public health concerns. The Dvot® Rabies Antigen Test provides a rapid, reliable, and field-deployable solution for detecting rabies virus antigens in both antemortem (saliva) and postmortem (brain tissue) samples. Utilizing highly specific monoclonal antibodies, this immunochromatographic assay delivers results within 10-15 minutes, enabling prompt initial assessment of suspected rabies cases. The complete kit contains all necessary components for safe and efficient testing in diverse field and laboratory settings.

Test Principle

The assay employs a sandwich immunochromatographic principle utilizing highly specific monoclonal antibodies targeting rabies virus antigens. Gold-conjugated anti-rabies antibodies are embedded on the conjugate pad, while distinct anti-rabies antibodies are immobilized at the test line (T) region. Upon sample application, any rabies virus antigens present bind to the gold-conjugated antibodies. This antigen-antibody complex migrates

chromatographically along the membrane via capillary action and is captured by the immobilized antibodies at the test line (T), generating a visible purple band. A control line (C), containing species-specific antibodies, verifies correct procedural execution and reagent functionality. The monoclonal antibodies exhibit high specificity for conserved epitopes of the rabies virus nucleoprotein, ensuring accurate detection across diverse viral strains.

Storage & Stability

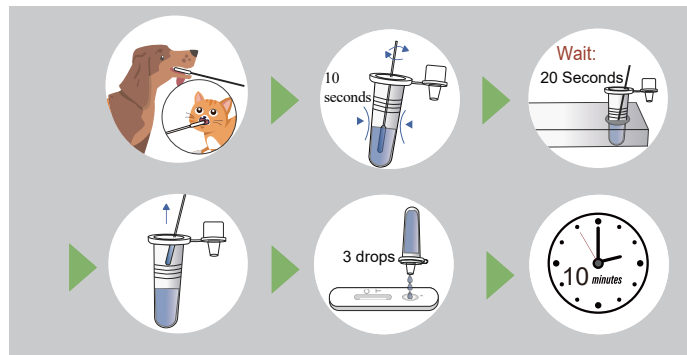
- Store in a dry place at 2-30°C
- Do not freeze
- Keep away from direct sunlight
- 24 months of shelf life (Production date to the expiration date).

Sample Preparation

1. Specimen (nasal or pharyngeal secretions) should be collected by using a swab.
2. The samples should be tested immediately after collection.
3. If samples cannot be tested immediately, they should be stored at 2~8°C (35.6~46.4 °F) for up to 24 hours. For longer storage, freeze at -20°C (-4 °F) or below. Frozen samples should be brought to room temperature (15~30°C/59~86 °F) before use.

Test Procedure

1. All reagents and samples must be at room temperature (15~30 °C/59~86 °F) before use.
2. Collect nasal or pharyngeal samples using a swab.
3. Put the swab into the sample dilution buffer and stir the solution with the swab to disperse the sample into the buffer (approximately 10 seconds).
4. Wait for 20 seconds to settle down the large particles.
5. Remove the swab from the sample dilution buffer.
6. Remove the test device from the pouch and place it on a flat and dry surface.
7. Apply 3 drops of the mixed sample solution into the sample hole, drop by drop vertically
8. Read test results at 10 minutes.



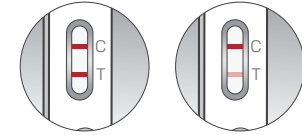
[Summary of Test Procedure]

Interpretation of Results

Positive(+)

Presence of two color bands "T" and "C"

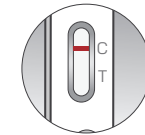
Two lines, one next to C and one next to T, even faint lines, shows the test is positive.



Negative (-)

No presence of color band ("T")

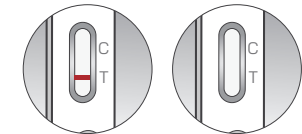
One red-colored line only next to "C" indicates a negative result.



Invalid

No presence of color band ("C")

If the red-colored line in the control region "C" is not visible, the result is invalid. Run a new test.



Precautions & Warnings

1. Intended Use & Validity

- For veterinary in vitro diagnostic use only. Not for human or other animal use.
- Do not use beyond the expiration date printed on the package label.
- Do not use if the foil pouch is damaged or already open.

2. Handling & Storage

- Store at 2~30°C. Do not freeze or expose to direct sunlight.
- Once opened, use the test device within 10 minutes.
- Avoid touching the membrane area of the test device.

3. Operational Guidelines

- Use only components provided in the kit. Do not reuse any items.
- Do not mix components from different lot numbers.
- Ensure all reagents and samples are at room temperature (15~30°C) before use.

4. Safety & Disposal

- Treat all samples as potentially infectious.
- Wear protective gloves during handling and wash hands thoroughly afterward.
- Dispose of used kits and samples in accordance with local biohazard regulations.

Test Limitations

- 1. This test provides preliminary results only; confirmation through official laboratory methodologies (e.g., Fluorescent Antibody Test (FAT), Polymerase Chain Reaction (PCR), or virus isolation) is mandatory as per national and international health regulations.
- 2. Negative results do not exclude rabies infection, particularly during early disease stages when viral shedding may be intermittent or below the assay's detection threshold.
- 3. Sample integrity significantly impacts test performance; improper collection, storage, or handling may yield false-negative results.
- 4. Test sensitivity may vary across different animal species and rabies virus variants.
- 5. Postmortem brain tissue samples generally exhibit higher analytical sensitivity compared to antemortem saliva specimens.
- 6. Results require interpretation by qualified veterinary professionals within the context of clinical presentation and epidemiological circumstances.
- 7. This test is not validated as a diagnostic tool for human rabies or for testing in living animals intended for human consumption.

Clinical Evaluation:

The Rabies Antigen Test demonstrates high diagnostic accuracy for simultaneous detection of Rabies antigens in canine fecal samples. Validation studies comparing against RT-PCR show excellent sensitivity and specificity for the targets, providing reliable results for clinical use. The following data summarize the clinical performance characteristics:

Rabies Antigen Test	Contrast Reagent (PCR)		
	Positive	Negative	Total
Positive	95	2	97
Negative	6	105	111
Total	101	107	208
Sensitivity	95/101,94.06%(95%C1: 87.64% to 97.25%)		
Specificity	105/107,98.13%(95%C1: 93.44% to 99.49%)		
Total coincidence rate	200/208,96.15%(95%C1:92.60% to 98.04%)		

Limit of Detection (Analytical Sensitivity)

The analytical sensitivity of the Rabies Antigen Test was established as 10² LD₅₀ per 0.03 mL through mouse inoculation tests. This level corresponds to approximately 100-1000 infectious particles per milliliter, enabling reliable detection of rabies virus antigens in clinical specimens derived from infected animals.

Cross Reactivity

The following potentially cross-reactive pathogens were evaluated at high concentrations and showed no cross-reactivity with the Rabies Antigen Test:

Pathogen	Concentration	Result
Canine distemper virus	1.0x10 ⁸ TCID ₅₀ /mL	Negative
Canine parvovirus	1.0x10 ⁸ TCID ₅₀ /mL	Negative
Canine adenovirus	1.0x10 ⁸ TCID ₅₀ /mL	Negative
Canine coronavirus	1.0x10 ⁸ TCID ₅₀ /mL	Negative
Pseudorabies virus	1.0x10 ⁸ TCID ₅₀ /mL	Negative
West Nile virus	1.0x10 ⁸ PFU/mL	Negative
Eastern equine encephalitis virus	1.0x10 ⁸ PFU/mL	Negative
Listeria monocytogenes	1.0x10 ⁸ CFU/mL	Negative
Toxoplasma gondii	1.0x10 ⁸ organisms/mL	Negative

Interfering Substances

The following substances have been evaluated for potential interference with the Rabies Antigen Test:

Substance Category	Specific Substance	Concentration tested	Effect on Assay
Endogenous Substances	Hemoglobin (Whole Blood)	5%(v/v)	No Interference
	Salivary mucins	10%(v/v)	No Interference
	Brain tissue lipids	10%(w/v)	No Interference
	Cellular debris	15%(v/v)	No Interference
Preservatives	Sodium azide	0.1%(w/v)	No Interference
	Trimeroal	0.01%(w/v)	No Interference
	Formalin	0.1%(v/v)	No Interference
Medications	Antiviral drugs	1mg/mL	No Interference
	Antibiotics	1mg/mL	No Interference
	Sedatives	0.1mg/mL	No Interference
Environmental Contaminants	Dirt/soil particles	5%(w/v)	No Interference
	Plant material	5%(w/v)	No Interference
	Water contaminants	1%(v/v)	No Interference

Index of Symbols

	Consult Instruction for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Do not desterilize		



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