WOAH Rabies Reference Laboratory Network's (RABLAB) overview of LFD tests for field application

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United Against Rabies

2025 United Against Rabies Meeting
7 – 9 October 2025, Bangkok, Thailand

Disclosure

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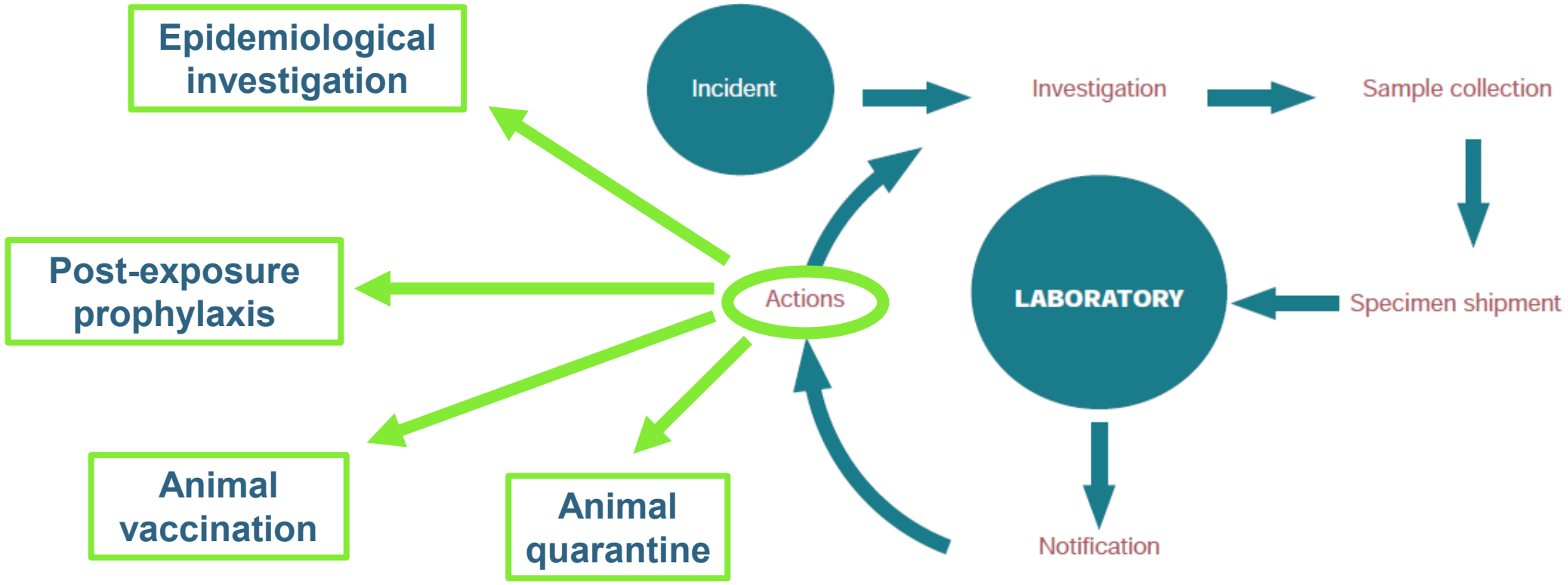
- This presentation summarises the current knowledge of the WOAH Rabies Reference Laboratory Network (RABLAB) on commercially available Point of Care (POC) tests that has been published online at https://www.woah.org/app/uploads/2025/08/woah-rablab-v4-sr.pdf
- The mention of specific companies or products of manufacturers, and whether these have been patented, does not imply that these have been endorsed or recommended by WOAH in preference to others of a similar nature that are not mentioned.

- All commercial kits should be validated according to WOAH's international standards. None of the POC tests included in this document are in the WOAH Register nor are they as yet specifically described as a primary diagnostic test in the WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

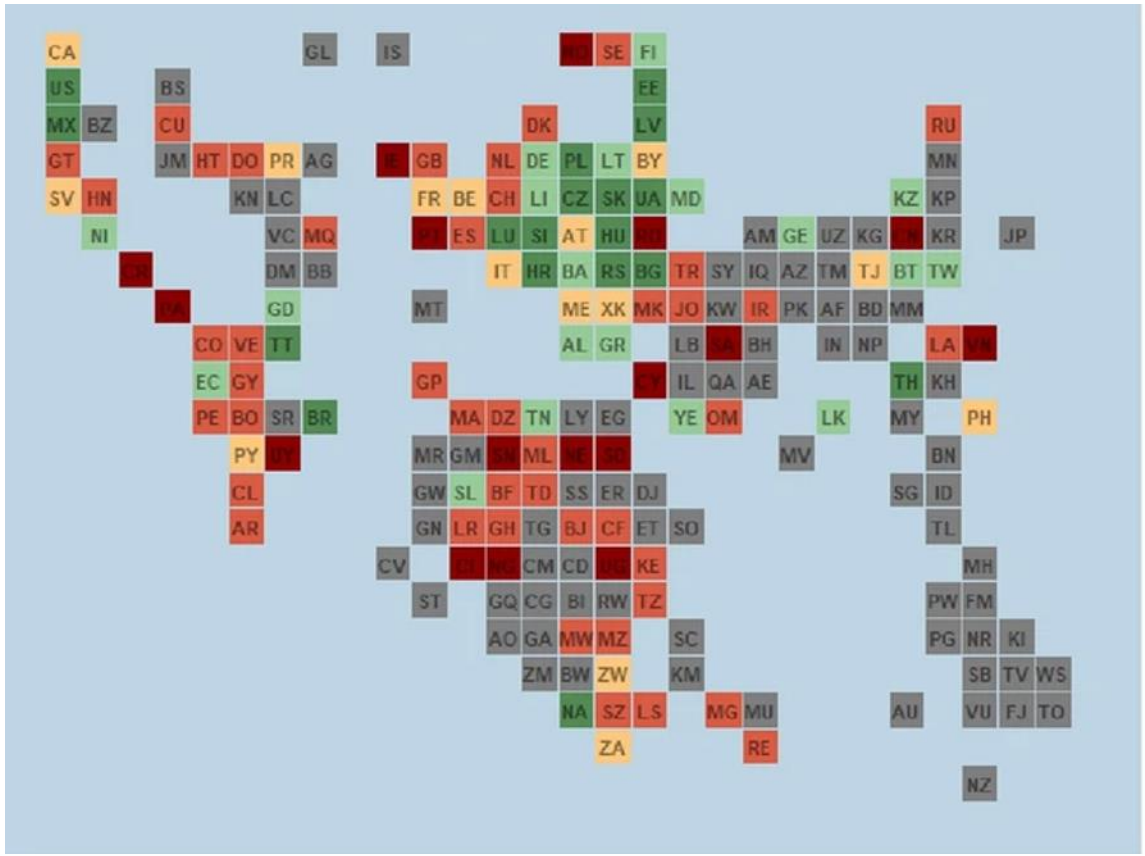
- I declare that there are no conflicts of interest. The study involved the use of commercially available kits, and no financial support, sponsorship, or other benefits were received from the manufacturer or any other commercial entity.

Breaking the cycle of neglect: the importance of field surveillance



World Health Organization, Rupprecht, Charles E, Fooks, Anthony R & Abela-Ridder, Bernadette. (2018). Laboratory techniques in rabies, volume 1, 5th ed. World Health Organization.

Rabies surveillance - reporting



Minhaj et al., 2023

- No reported surveillance in 169/183 WOAH members
- Countries at the greatest risk had a 16-fold lower rate of rabies testing
- Doubts about the actual burden.

Laboratory diagnostic tools

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Could lateral flow devices have a role in enhancing field investigations and screening?

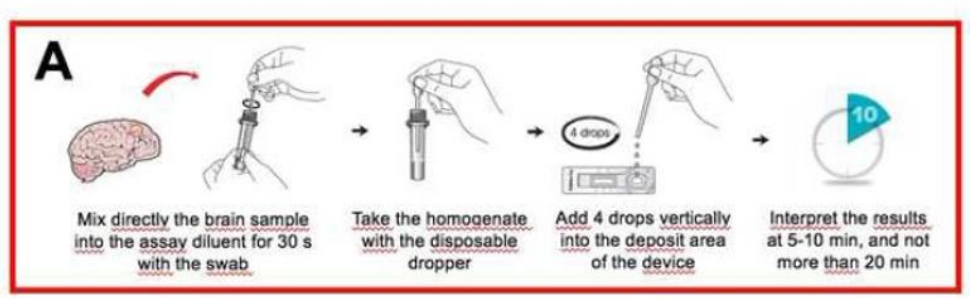
Table 1. Test methods available for the diagnosis of rabies and their purpose

Method	Purpose					
	Population freedom from infection	Individual animal freedom from infection prior to movement	Contribute to eradication policies	Confirmation of clinical cases	Prevalence of infection – surveillance	Immune status in individual animals or populations post-vaccination
Detection and identification of the agent						
DFA (antigen detection)	+++	–	+++	+++	+++	–
dRIT (antigen detection)	+++	–	+++	+++	+++	–
RTCIT (virus isolation)	–	–	+++	+++	+++	–
MIT (virus isolation)	–	–	+	+	+	–
Conventional RT-PCR (RNA detection)	+++	–	+++	+++	+++	–
Real-time RT-PCR (RNA detection)	+++	–	+++	+++	+++	–

WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2023. Chapt. 3.1.18. Rabies (infection with rabies virus and other lyssaviruses)

- No available diagnostic tools adaptable in the field and in the absence of specific laboratory equipment
- Most of cases might occur in rural areas
- Logistical challenges often hinder sample submission to laboratories. Fast delivery and turnaround cannot be ensured.

State of the art



Mauti et al., 2020

- Manufacturer instructions often inaccurate, and inconsistency between batches
- Increased sensitivity if manufacturer instructions are modified
- Depending on the product-specific sensitivity and specificity, additional confirmation of results should be undertaken using other primary test methods
- Nevertheless, positive LFD results should be a strong indication for bite victims to seek post-exposure prophylaxis.

Factors influencing the performance of the rabies LFDs

- Kits or lots-specific factors
  - Efficiency of detection labels
  - Membrane quality
  - Flow rate
  - Signal amplification methods
  - Clarity/consistency of the manufacturer's instructions

Factors influencing the performance of the rabies LFDs

Mauti et al., 2020

- Environmental and handling conditions
  - Storage temperature and humidity
  - Compliance with instructions
  - Operator skills in sample collection
  - Ease of interpreting results

Attention must be payed to…

- Affinity and specificity of anti-rabies Abs used in the kit
- Overall Limit of Detection (LoD) of the kit
- The significance of the control lines

Comparison with two primary tests for rabies diagnosis

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Test	Rapid test (LFD)	DFA	rRT-PCR
Intended use	Screening test	Confirmatory test	Confirmatory test
Specimen type(s)	Brain tissue	Brain tissue	Brain tissue
Sensitivity	Variable	High	High
Specificity	Variable	High	High
Training	Minimal	Yes – specialised	Yes – generalised
Testing time	15 to 30 minutes plus brain biopsy collection	60 to 90 minutes plus brain biopsy and sample transportation time	60 to 90 minutes plus brain biopsy and sample transportation time
Costs/test (EURO)	7–10	10–15	20–30
Cost of equipment (EURO)	Not applicable	10,000 to 15,000	10,000 to 30,000+

Comparison with two primary tests for rabies diagnosis (cntd)

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Test	Rapid test (LFD)	DFA	RT-PCR
Advantages	Rapid (early detection) Field application	sensitivity and specificity	High sensitivity and specificity
Disadvantages	High variation in sensitivity Not a standardised method No positive/negative control run with the sample	Laboratory facilities needed Relatively high equipment cost	Laboratory facilities needed Relatively high equipment cost
Use	Screening test for surveillance	Stand-alone test for surveillance	Stand-alone test for surveillance
Comments	Available and new products need evaluation	Gold standard	Gold standard

Only two commercial kits have proven acceptable performances

Rabies LFDs: instructions for use

Purpose	LFD result	Immediate actions	Laboratory confirmation	Laboratory result	Final interpretation	Deferred actions
Animal testing in the context of a biting incident	Positive	Inform authorities Initiate PEP	Not necessarily required	Not applicable	Positive case	None
	Negative	Inform authorities Conduct WHO Risk assessment and initiate PEP if indicated	Immediately required	Positive	Positive case	Inform authorities PEP needs to be completed
				Negative	Negative case	None PEP can be discontinued

Rabies LFDs: instructions for use

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				Negative	Negative case	None PEP can be discontinued
Screening in the context of passive surveillance (including wildlife)	Positive	Inform authorities	Not necessarily required*	Not applicable	Positive case	Inform authorities
	Negative	None	Recommended	Positive	Positive case	Inform authorities
				Negative	Negative case	None

Rabies LFDs: instructions for use (contd)

- Brain material only
- Choose high-performance LFDs
- Establish the high-performance protocol
- Undertake prior in-house evaluation to assess DSe
- Clearly define the purpose of the test
- Appropriately train the field staff (including brain collection)

Acknowledgements

Halo, South Africa

- Christine Fehlner-Gardiner
- Conrad Freuling
- Thomas Müller
- Ryan Wallace
- Rachel Tidman
- And the entire RABLAB group of experts

For any doubts contact the RABLAB experts