

# WOAH Reference Laboratory Reports Activities 2025

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## LABORATORY INFORMATION

<b>*Name of disease (or topic) for which you are a designated WOAH Reference Laboratory:</b>	Mammalian tuberculosis
<b>*Address of laboratory:</b>	Laboratoire National de Référence Tuberculose, Unité Zoonoses Bactériennes, Laboratoire de Santé Animale de Maisons-Alfort, ANSES 14, rue Pierre et Marie Curie, 94701 Maisons-Alfort Cedex France
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<b>Website:</b>	<a href="https://www.anses.fr/fr">https://www.anses.fr/fr</a>
<b>*Name (including Title) of Head of Laboratory (Responsible Official):</b>	Dr. Stéphan ZIENTARA , Head of the Animal Health Laboratory, Anses, Maisons- Alfort
<b>*Name (including Title and Position) of WOAH Reference Expert:</b>	Dr. María Laura Boschiroli-Cara, Research Director, Head of the Tuberculosis National Reference Laboratory
<b>*Which of the following defines your laboratory? Check all that apply:</b>	Governmental

## TOR1: DIAGNOSTIC METHODS

1. Did your laboratory perform diagnostic tests for the specified disease/topic for purposes such as disease diagnosis, screening of animals for export, surveillance, etc.? (Not for quality control, proficiency testing or staff training)

Yes

Diagnostic Test	Indicated in WOAH Manual (Yes/No)	Total number of test performed last year	
		Nationally	Internationally
<b>Indirect diagnostic tests</b>			
Serology (Suidae)	No	45	0
IGRA (IFNg test)	Yes	160	0
Tuberculin batch control	Yes	2	0
IGRA kit batch control	No	2	0
TB serology in Suidae kit batch control	No	2	0
<b>Direct diagnostic tests</b>			
Culture	Yes	4	0
Mycobacterium strain/isolate identification	Yes	681	27
Spoligotyping	Yes	1154	27
MLVA	Yes	42	182
Whole genome sequencing	Yes	824	136
Molecular diagnosis (tissues)	Yes	1687	45
TB PCR kit batch control	No	3	

## TOR2: REFERENCE MATERIAL

2. Did your laboratory produce or supply imported standard reference reagents officially recognised by WOA?H?

No

3. Did your laboratory supply standard reference reagents (nonWOAH-approved) and/or other diagnostic reagents to WOA?H Members?

No

4. Did your laboratory produce vaccines?

Not applicable

5. Did your laboratory supply vaccines to WOA?H Members?

## TOR3: NEW PROCEDURES

6. Did your laboratory develop new diagnostic methods for the designated pathogen or disease?

No

7. Did your laboratory validate diagnostic methods according to WOA?H Standards for the designated pathogen or disease?

No

8. Did your laboratory develop new vaccines for the designated pathogen or disease?

9. Did your laboratory validate vaccines according to WOA?H Standards for the designated pathogen or disease?

## TOR4: DIAGNOSTIC TESTING FACILITIES

10. Did your laboratory carry out diagnostic testing for other WOA?H Members?

Yes

Name of WOA?H Member Country seeking assistance	Date	Which diagnostic test used	No. samples received for provision of diagnostic support	No. samples received for provision of confirmatory diagnoses
MADAGASCAR	2025-09-22	MTBC strain identification; spoligotyping; WGS	65	0
SPAIN	2025-06-23	Spoligotyping, MLVA, WGS	182	0

11. Did your laboratory provide expert advice in technical consultancies on the request of an WOA?H Member?

Yes

Name of the WOA?H Member Country receiving a technical consultancy	Purpose	How the advice was provided
ALGERIA	TB diagnostics (direct)	Advice expertise
MOROCCO	TB diagnostics and genomics	Advice expertise (SOP)
MADAGASCAR	TB diagnostics (direct) and genotyping	Advice expertise (SOP)
BRAZIL	BSL3 disinfection procedure	Advice expertise
KOREA (DEM. PEOPLE'S. REP. OF)	TB diagnostics (direct) and genotyping	Advice expertise
BELGIUM	Guinea pig's assays	Advice expertise

## TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES

12. Did your laboratory participate in international scientific studies in collaboration with WOA?H Members other than the own?

Yes

Title of the study	Duration	Purpose of the study	Partners (Institutions)	WOA?H Member Countries involved other than your country
		Evaluation of biosecurity practices on farms, the development of new tools for the diagnosis and prevention of tuberculosis and, in a new	ANSES Laboratoire de Santé animale, UZB ANSES, Ecole	

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Innotub II	3 years (since January 2024)	approach, the application of new genomic sequencing technologies to study the transmission of the disease between domestic and wild animals, as well as the study of antimicrobial resistance in the bacteria responsible for tuberculosis	nationale vétérinaire de Toulouse (ENVT), Institut de Recerca i Tecnologia Agroalimentàries (IRTA), Universitat Autònoma de Barcelona (UAB), Institut basque de recherche et de développement agricole (NEIKER)	SPAIN
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13. In exercising your activities, have you identified any regulatory research needs\* relevant for WOA?H?

Yes

Research need : 1

**Please type the Research need:** Creation of new standards with regards indirect diagnostic tests: absence of standards with regards TB serology or IGRA. -

Validation of synthetic tuberculin at a global scale (different epidemiological and breeding contexts).

**Relevance for WOA?H** Disease Control, Capacity Building, Standard Setting, Facilitation of international collaboration,

**Relevance for the Code or Manual** Code, Manual,

**Field** Epidemiology and Surveillance, Diagnostics, Vaccines,

**Animal Category** Terrestrial,

**Disease:**

Mammalian tuberculosis

**Kind of disease (Zoonosis, Transboundary diseases)** Zoonosis, Transboundary diseases,

**If any, please specify relevance for Codes or Manual, chapter and title**

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

**Answer:**

**Notes:**

**Answer:**

## TOR6: EPIZOOLOGICAL DATA

14. Did your Laboratory collect epidemiological data relevant to international disease control?

Yes

If the answer is yes, please provide details of the data collected:

Second line analyses confirming TB outbreaks in different wild or domestic-livestock species.

Genotypic characterisation of TB causative agents.

15. Did your laboratory disseminate epidemiological data that had been processed and analysed?

Yes

If the answer is yes, please provide details of the data collected:

The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2024

16. What method of dissemination of information is most often used by your laboratory? (Indicate in the appropriate box the number by category and list the details in the box)

## a) Articles published in peer-reviewed journals:

3

Boschiroli, M. L. 2025. "Mycobactéries et approche One Health : Liens entre l'homme, l'animal et l'environnement." *Bull. Acad. Vét. France*.

Bralet, T., R. Aaziz, J. Tornos, A. Gamble, A. Clessin, M. Lejeune, C. Galon, L. Michelet, C. Lesage, T. Jeanniard du Dot, G. Desoubeaux, M. Guyard, S. Delannoy, S. Moutailler, K. Laroucau et T. Boulmier. 2025. "High-throughput microfluidic real-time PCR as a promising tool in disease ecology." *J Anim Ecol* 94 (9): 1625-1637. <https://doi.org/10.1111/1365-2656.70088>.

Fernandez-Veiga, L., M. Fuertes, M. V. Geijo, N. Elguezabal, J. L. Serrano-Mestre, L. Vazquez-Iniesta, R. Prados-Rosales, L. Michelet, M. L. Boschiroli, B. Perez de Val, G. J. Jones, R. A. Juste, J. M. Garrido et I. A. Sevilla. 2025. "Protection and diagnostic interference induced by heat-inactivated, phage-inactivated and live vaccine prototypes against animal tuberculosis." *Front Vet Sci* 12: 1620497. <https://doi.org/10.3389/fvets.2025.1620497>.

## b) International conferences:

4

Hardouin, P., T. Cochard, L. Michelet, M. L. Boschiroli, J.-L. Moyen, A. Samba-Louaka, F. Biet et Y. Héchard. 2025. "Role of free-living amoebae in the environmental persistence of pathogenic mycobacteria: a mesocosm-based approach." *FLAM 2025, XXth International Meeting on the Biology and Pathogenicity of Free-Living Amoebae, Puerto Morelos, Mexique, 03-07 novembre*.

Boschiroli, M. L. 2025. "Tuberculosis at the Animal-Human Interface: Challenges, Trends, and the Role of WOAHP Reference Laboratories." *Symposium on zoonotic diseases in animal including tuberculosis, Gimcheon-si, Corée du Sud, 24 avril 2025*.

Boschiroli, M. L. 2025. "Best practices for tuberculosis diagnosis in non human primates." *23rd symposium of European Primate Veterinarians, Strasbourg, 18 septembre 2025*.

Boschiroli, M. L. 2025. "Twenty Years of IGRA Implementation in France: From Diagnostic Development and Network Coordination to Improved Bovine Tuberculosis Surveillance and Control." *Xeme EURL for bovine tuberculosis workshop, San Lorenzo del Escorial, Spain, 12-13 novembre 2025*.

## c) National conferences:

7

Boschiroli, M. L. 2025. "Dépistage et diagnostic de la Tuberculose " *Journée d'échanges et d'expertise autour de la tuberculose bovine organisée par le GDS Calvados et le GTV Normand Falaise, 09 septembre 2025*.

Boschiroli, M. L. 2025. "Généralités sur les mycobactéries et le complexe de *M. tuberculosis* " *Journée d'échanges et d'expertise autour de la tuberculose bovine organisée par le GDS Calvados et le GTV Normand Falaise, 09 septembre 2025*.

Boschiroli, M. L. 2025. "Nouveaux critères d'interprétation du test de dosage de l'IFNg " *Journée Tuberculose bovine organisée par la Chambre d'agriculture de la Charente et TED16-GDS, Villebois-Lavalette, 27 novembre 2025*.

Lanotte, P. et M. L. Boschiroli. 2025. "Regards croisés sur le complexe *Mycobacterium tuberculosis* chez l'homme et les animaux " *Séminaire « Quel regard sur la tuberculose en 2025 : les mycobactéries dans le concept One-Health » CHU d'Orléans, 16 octobre 2025*.

Michelet, L. 2025. "Intérêt de la génomique pour la gestion de la tuberculose bovine " *Journée d'échanges et d'expertise autour de la tuberculose bovine organisée par le GDS Calvados et le GTV Normand Falaise, 09 septembre 2025*.

Michelet, L. 2025. "Apports de la génomique à la surveillance de la tuberculose bovine." *Journée Tuberculose bovine organisée par la Chambre d'agriculture de la Charente et TED16-GDS, Villebois-Lavalette, 27 novembre 2025*.

Philizot, S. et M. L. Boschiroli. 2025. "Regards d'une vétérinaire et d'une chercheuse sur la tuberculose bovine : du Diagnostic au NGS." *Séminaire « Quel regard sur la tuberculose en 2025 : les mycobactéries dans le concept One-Health » CHU d'Orléans, 16 octobre 2025*.

## d) Other (Provide website address or link to appropriate information):

## TOR7: SCIENTIFIC AND TECHNICAL TRAINING

17. Did your laboratory provide scientific and technical training to laboratory personnel from other WOA Members?

No

## TOR8: QUALITY ASSURANCE

18. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)	
ISO17025	Portée détaillée	Portée détaillée V15_251211.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
PCR	COFRAC
Bacteriology	COFRAC

20. Does your laboratory maintain a "biorisk management system" for the pathogen and the disease concerned?

Yes

A biorisk department is in place in our institution. Our lab follows the guidelines layed out by the local bioriskmanager, which in turn are based on WHO's Laboratory biosafety guidelines and those for "highly dangerous pathogens" issued from French regulations.

## TOR9: SCIENTIFIC MEETINGS

21. Did your laboratory organise scientific meetings related to the pathogen in question on behalf of WOA?

No

22. Did your laboratory participate in scientific meetings related to the pathogen in question on behalf of WOA?

Yes

Title of event	Date	location	Role (speaker, presenting poster, short communications)	Title of the work presented
MASTERCLASSE TB 2, L'initiative, Expertise France	2025-11-30	Cotonou, Benine	speaker, member of the teaching staff	One Health - zoonotic tuberculosis

## TOR10: NETWORK WITH WOA REFERENCE LABORATORIES

23. Did your laboratory exchange information with other WOA Reference Laboratories designated for the same pathogen or disease?

Yes

24. Are you a member of a network of WOA Reference Laboratories designated for the same pathogen?

Yes

NETWORK/DISEASE	ROLE OF YOUR LABORATORY (PARTICIPANT, ORGANISER, ETC)	NO. PARTICIPANTS	PARTICIPATING WOA REF. LABS
WOAH Project to Replace the International Standards for tuberculins	organiser and participant	5	Argentina, United Kingdom, Spain, United States, France

25. Did you organise or participate in inter-laboratory proficiency tests with WOA Reference Laboratories designated for the same pathogen during the past 2 years?

Yes

Purpose of the proficiency test:	Role of your Reference Laboratory (organiser/ participant)	No. participating Laboratories	Participating WOA Ref. Labs/ organising WOA Ref Lab
Molecular characterization of MTBC	participant	unknown	participating: France Organising: Spain

26. Did your laboratory collaborate with other WOA Reference Laboratories for the same disease on scientific research projects for the diagnosis or control of the

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pathogen of interest?

Yes

Title of the project or contract	Scope	Name(s) of relevant WOA Reference Laboratories
OIE Project to Replace the International Standard for Avian and Bovine Tuberculin (ISBT)	Evaluate, calibrate and validate a replacement for the International Standard for Bovine (ISBT) and Avian (ISAT) Tuberculin	Argentina, United Kingdom, Spain, United States

## TOR11: OTHER INTERLABORATORY PROFICIENCY TESTING

27. Did your laboratory organise or participate in inter-laboratory proficiency tests with laboratories other than WOA Reference Laboratories for the same pathogen during the past 2 years?

Yes

Purpose for inter-laboratory test comparisons <sup>1</sup>	Role of your reference laboratory (organizer/participant)	No. participating laboratories	Name of the test	WOAH Member Countries
IGRA	ORGANISER	15	IGRA ELISA	AUSTRIA, SPAIN,

## TOR12: EXPERT CONSULTANTS

28. Did your laboratory place expert consultants at the disposal of WOA?

Yes

Kind of consultancy	Location	Subject (facultative)
ISBT and ISAT replacement ad hoc group	WOAH headquarters and virtual meetings	Since 2024, chair of the expert group

29. Additional comments regarding your report:

No