

WOAH Reference Laboratory Reports Activities 2024

This report has been submitted: 31 janvier 2025 14:50

LABORATORY INFORMATION

*Name of disease (or topic) for which you are a designated WOAH Reference Laboratory:	Mammalian tuberculosis
*Address of laboratory:	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
*Tel:	+330149771350
*E-mail address:	Maria-laura.boschioli@anses.fr
Website:	https://www.anses.fr/fr
*Name (including Title) of Head of Laboratory (Responsible Official):	Dr. Stéphan ZIENTARA , Head of the Animal Health Laboratory, Anses, Maisons-Alfort
*Name (including Title and Position) of WOAH Reference Expert:	Dr. María Laura Boschioli-Cara, Research Director, Head of the Tuberculosis National Reference Laboratory
*Which of the following defines your laboratory? Check all that apply:	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	
Indirect diagnostic tests		Nationally	Internationally
Serology (Suidae)	No	63	0
IGRA (IFNg test)	Yes	48	0
Tuberculin batch control	Yes	2	0

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IGRA kit batch control	No	4	0
TB serology in Suidae kit batch control	No	2	0
Direct diagnostic tests		Nationally	Internationally
Culture	Yes	28	0
Mycobacterium strain/isolate identification	Yes	369	0
Spoligotyping	Yes	1056	0
MLVA	Yes	126	0
Whole genome sequencing	Yes	576	0
Molecular diagnosis (tissues)	Yes	1318	0
TB PCR kit batch control	No	3	0

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?

Yes

Type of reagent available	Related diagnostic test	Produced/ provide	Amount supplied nationally (ml, mg)	Amount supplied internationally (ml, mg)	No. of recipient WOA?H Member Countries	Country of recipients
Plasma containing bovine IFNg	IFNg test -Elisa)	Bovine tuberculosis national reference laboratory - France	18 (1 ml each)	0	1	FRANCE,
Crushed lymph node spiked with titrated M. bovis	molecular diagnosis - PCR	Bovine tuberculosis national reference laboratory - France	1 (1 ml)	0	1	FRANCE,
Lyophilised TB positive Suidae serum	Serology (Elisa)	Bovine tuberculosis national reference laboratory - France	16	0	1	FRANCE,
Infected suidae blood-soaked filter papers	Serology (Elisa)	Bovine tuberculosis national reference laboratory - France	380	0	1	FRANCE,

4. Did your laboratory produce vaccines?

No

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

No

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 WOAHP Standards for the designated pathogen or disease?

No

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

No

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

No

TOR4: DIAGNOSTIC TESTING FACILITIES

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

No

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

Yes

Name of the WOAHP Member Country receiving a technical consultancy	Purpose	How the advice was provided
ALGERIA	TB diagnostics (direct) and genotyping	Advice expertise
GREECE	TB diagnostics (direct) and genotyping	Advice expertise (SOP)
MADAGASCAR	TB diagnostics (direct) and genotyping	Advice expertise (SOP)
MOROCCO	TB diagnostics (direct) and genotyping	Advice expertise (SOP)
THE NETHERLANDS	TB diagnostics (indirect)	Advice expertise
UNITED KINGDOM	BSL3 disinfection procedure	Advice expertise

TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES

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

Yes

Title of the study	Duration	Purpose of the study	Partners (Institutions)	WOAHP 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	Neiker IRTA- ANSES Laboratoire de Santé animale, UZB ANSES,	

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Innotub II	4 years (since January 2024)	and, in a new 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	Ecole 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 tuberculins at a global scale (different epidemiological and breeding contexts).

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

Relevance for the Code or Manual Code, Manual,

Field Epidemiology and Surveillance, Diagnostics,

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: Those in relationship with mammalian tuberculosis

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.
Gengotypic characterisation of TB causative agents.

WOAH Reference Laboratory Reports Activities 2024

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 2023

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:

2

Boschioli, M. L., F. J. Salguero, G. Jones et J. Bezos. 2024. "Editorial: Tuberculosis in domestic ruminants: towards eradication of zoonotic tuberculosis." *Front Vet Sci* 11: 1453876. <https://doi.org/10.3389/fvets.2024.1453876>.

Melgarejo, C., A. Cobos, M. Domingo, G. Cantero, X. Moll, I. A. Sevilla, J. M. Garrido, L. Michelet, M. L. Boschioli, E. Vidal et B. Perez de Val. 2024. "Experimental infection of goats with *Mycobacterium microti* induces subclinical pulmonary tuberculosis and mild responses to tuberculin skin tests." *Vet Microbiol* 290: 110009. <https://doi.org/10.1016/j.vetmic.2024.110009>.

b) International conferences:

0

c) National conferences:

7

Boschioli, M. L. 2024. "De la Tuberculose Bovine à la Tuberculose de Mammifères: les raisons du changement terminologique survenu ces dernières années." *Symposium pour la biodiversité 8ème édition, thème : "Faune sauvage et activités humaines : une relation conflictuelle?"*, Ecole nationale vétérinaire de Toulouse, 02/03/24.

Boschioli, M. L. 2024. "Mycobactéries, à la croisée des interactions multiples entre espèces." *Humanimal. Relations humain-animal : mêmes maladies, même environnement et même sensibilité ?*, Maisons-Alfort, 17 et 18 octobre 2024.

Boschioli, M. L. 2024. "Zoonoses respiratoires." *12èmes journées du GREPI, Chantilly, 14 et 15 novembre 2024*.

Boschioli, M. L. 2024. "La mycobactérie et ses conditions de survie." *Conférence « Tuberculose bovine en élevage et interface avec la faune sauvage. Actualités scientifiques et sanitaires », Institut Agro Dijon, 26/11/24*.

Boschioli, M. L., A. Hartmann et L. Michelet. 2024. "Études sur la présence et la survie des mycobactéries dans l'environnement : Résultats et recherches en cours." *Conférence « Tuberculose bovine en élevage et interface avec la faune sauvage. Actualités scientifiques et sanitaires », Institut Agro Dijon, 26/11/24*.

María Laura Boschioli-Cara - - FRANCE

Michelet, L. 2024. "Intérêt de la génomique pour la gestion de la tuberculose bovine. Conférence « Tuberculose bovine en élevage et interface avec la faune sauvage. »" Conférence « Tuberculose bovine en élevage et interface avec la faune sauvage. Actualités scientifiques et sanitaires », Institut Agro Dijon, 26/11/24.

Michelet, L. 2024. "Modélisation de la transmission de *Mycobacterium bovis* entre animaux domestiques et sauvages : comparaison de plusieurs zones d'endémie." Conférence « Tuberculose bovine en élevage et interface avec la faune sauvage. Actualités scientifiques et sanitaires », Institut Agro Dijon, 26/11/24.

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

1

Saisine n°2024-SA-0067: "l'évaluation du risque de transmission du complexe *Mycobacterium tuberculosis* à l'humain via la consommation de produits laitiers crus issus d'un élevage caprin infecté »

Saisines liées n°2023-AST-0130 et 2023-SA-0146

<https://www.anses.fr/fr/system/files/BIORISK2024SA0067.pdf>

TOR7: SCIENTIFIC AND TECHNICAL TRAINING

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

Yes

a) Technical visit : 0

b) Seminars : 0

c) Hands-on training courses: 1

d) Internships (>1 month) 0

Type of technical training provided (a, b, c or d)	Country of origin of the expert(s) provided with training	No. participants from the corresponding country
C	MADAGASCAR	1

TOR8: QUALITY ASSURANCE

18. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)	
ISO 17025	Portée détaillée v.5 de l'attestation N° 1-7341	1-7341_pde.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 biorisk manager, 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 WOAHP?

No

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

No

TOR10: NETWORK WITH WOAHP REFERENCE LABORATORIES

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

Yes

24. Do you network (collaborate or share information) with other WOAHP Reference Laboratories designated for the same pathogen?

Yes

NETWORK/DISEASE	ROLE OF YOUR LABORATORY (PARTICIPANT, ORGANISER, ETC)	NO. PARTICIPANTS	PARTICIPATING WOAHP REF. LABS
WOAHP 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 WOAHP 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 WOAHP Ref. Labs/ organising WOAHP Ref Lab
Direct extraction and microbiological culture	participant	unknown	Organising: Spain
Gamma interferon release assay	participant	unknown	Organising: Spain

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

Yes

Title of the project or contract	Scope	Name(s) of relevant WOAHP 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 WOAHP Reference Laboratories for the same pathogen during the past 2 years?

Yes

Purpose for inter-laboratory test comparisons ¹	Role of your reference laboratory (organizer/participant)	No. participating laboratories	Name of the test	WOAH Member Countries
Suidae TB - serology: indirect diagnosis	organiser	12	Elisa	FRANCE,

TOR12: EXPERT CONSULTANTS

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

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
Guidelines for the control of Mycobacterium tuberculosis complex in livestock	WOAH headquarters	Expertise on TB diagnostics/surveillance

29. Additional comments regarding your report:

No