

# WOAH Reference Laboratory Reports Activities 2023

## Activities in 2023

This report has been submitted : 26 avril 2024 16:01

### Laboratory Information

<b>Name of disease (or topic) for which you are a designated WOA Reference Laboratory:</b>	Mammalian Tuberculosis
<b>Address of laboratory:</b>	1920 Dayton Ave
<b>Tel.:</b>	+1515-337-7266
<b>E-mail address:</b>	tyler.thacker@usda.gov
<b>Website:</b>	<a href="https://www.aphis.usda.gov/labs/about-nvsl">https://www.aphis.usda.gov/labs/about-nvsl</a>
<b>Name (including Title) of Head of Laboratory (Responsible Official):</b>	Suelee Robbe-Austerman, Director of the National Veterinary Services Laboratories
<b>Name (including Title and Position) of WOA Reference Expert:</b>	Tyler C Thacker
<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 WOA Manual (Yes/No)	Total number of test performed last year	
		Nationally	Internationally
<b>Indirect diagnostic tests</b>			
Interferon-gamma release Assay		8655	15
Lateral Flow - Cervid		12479	1
Lateral Flow – Zoo species		88	0
<b>Direct diagnostic tests</b>			
Culture – Livestock & Wildlife		1339	11
Culture – Zoo species		2030	0
Direct PCR – Livestock & Wildlife		15936	666
Direct PCR – Zoo species		6247	0
Histopathology		6330	127

### TOR2: REFERENCE MATERIAL

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

No

## 3. Did your laboratory supply standard reference reagents (nonWOAH-approved) and/or other diagnostic reagents to WOA 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 MEMBER COUNTRIES	COUNTRY OF RECIPIENTS
Mycobacterium antigen – Mycobacterium bovis purified protein derivative (PPD)	Tuberculin used to test bovine and other species of animals for relative sensitivity to Mycobacterium bovis by the caudal fold test	Provided in 1, 5, and 10 mL volumes	9,118 mL	0	1	UNITED STATES OF AMERICA,
Mycobacterium antigen – Mycobacterium bovis purified protein derivative (PPD)	Tuberculin used to test bovine and other species of animals for relative sensitivity to Mycobacterium bovis by the cervical method	Provided in 2 mL volume	2,885 mL	0	1	UNITED STATES OF AMERICA,
Mycobacterium antigen – purified protein derivative (PPD) avian balanced tuberculin and bovis balanced tuberculin	Balanced tuberculins used to test bovine and other species of animals for relative sensitivity to Mycobacterium bovis and Mycobacterium avium by the comparative cervical test	Provided in 1 mL volume (0.4 protein/mL and 1 protein/mL)	2885 mL	0	1	UNITED STATES OF AMERICA,
Mycobacterium bovis direct PCR control, negative, bovine tissue	Ground bovine liver tissue in PBS used as a negative control in direct PCR applications.	Packaged as 10 vials containing 1 mL each	0	2 vials	1	MALAYSIA,
Mycobacterium bovis direct PCR control, positive, bovine tissue with BCG	Ground bovine liver tissue in PBS spiked with M. bovis BCG	Packaged as 10 vials containing 1 mL each	0	1 vial	1	COLOMBIA,
Mycobacterium bovis direct PCR control, positive, bovine tissue with Mtb H37a	Ground bovine liver tissue in PBS spiked with M. tuberculosis H37Ra	Packaged as 10 vials containing 1 mL each	0	3 vials	2	COLOMBIA, MALAYSIA,
Mycobacterium bovis serum panel	Serum samples from cattle and cervid species with known positive and negative bovine tuberculosis status	Provided in 0.5 mL volume	88 x 0.5 mL vial	0	1	UNITED STATES OF AMERICA,
Mycobacterium species DNA	Mycobacterium species DNA	varies	0	5 vials	1	MALAYSIA,
Mycobacterium reference culture	Mycobacterium isolates for use as reference strains.	Provided as glycerol stock	0	2 vials (BCG)	1	MALAYSIA,

## 4. Did your laboratory produce vaccines?

No

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

Yes

VACCINE NAME	AMOUNT SUPPLIED NATIONALLY	AMOUNT SUPPLIED NATIONALLY (ML, MG)	NAME OF RECIPIENT WOA MEMBERS
M. bovis vaccine strain BCG	1 mL	200 vials	MEXICO

**TOR3: NEW PROCEDURES**

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

Yes

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

Yes

NAME OF THE NEW TEST OR DIAGNOSTIC METHOD DEVELOPED	DESCRIPTION AND REFERENCES (PUBLICATION, WEBSITE, ETC.)
Real-Time PCR detection of Mycobacterium bovis DNA in bovine milk samples	Zeineldin, M. M., Lehman, K., Camp, P., Farrell, D., & Thacker, T. C. (2023). Diagnostic Evaluation of the IS1081-Targeted Real-Time PCR for Detection of Mycobacterium bovis DNA in Bovine Milk Samples. Pathogens, 12(8), 972.
Whole Genome Sequencing of Mycobacterium bovis direct from tissue samples without culture	Zeineldin, M., Camp, P., Farrell, D., Lehman, K., & Thacker, T. (2023). Whole genome sequencing of Mycobacterium bovis directly from clinical tissue samples without culture. Frontiers in Microbiology, 14, 1141651.

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

No

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

No

## TOR4: DIAGNOSTIC TESTING FACILITIES

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

Yes

NAME OF WOAHS 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
GUATEMALA	2023-12-31	Direct PCR, culture, whole genome sequencing	4	0
MEXICO	2023-12-31	Direct PCR, culture, whole genome sequencing	0	388

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

Yes

NAME OF THE WOAHS MEMBER COUNTRY RECEIVING A TECHNICAL CONSULTANCY	PURPOSE	HOW THE ADVICE WAS PROVIDED
MEXICO	USDA-APHIS SAGARPA project to conduct slaughter surveillance testing in Baja CA Mexico. Samples are split between the laboratories of USA and Mexico for test harmonization and whole genome sequencing database development.	Methods/Test comparison - virtual
GUATEMALA	Sample processing, colony identification, acid-fast staining, direct PCR, real-time PCR detection, interpretation of whole genome sequencing results	Virtual training

## TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES

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

Yes

Title of the study	Duration	PURPOSE OF THE STUDY	PARTNERS (INSTITUTIONS)	WOAHS MEMBER COUNTRIES INVOLVED OTHER THAN YOUR COUNTRY
			Comité Estatal para el Fomento y Protección Pecuaria de Baja California, Sanidad e Inocuidad de la Secretaría del Campo y Seguridad Alimentaria de Baja California, Dirección de Campañas Zoonositarias de la	

Prospective evaluation of BCG vaccine efficacy in naturally infected dairy cattle in Baja California, Mexico	5 years	Evaluate the efficacy of the M. bovis vaccine strain BCG to reduce disease burden in infected dairies	Dirección General de Salud Animal Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria, Dirección de Campañas Zoonositarias de la Dirección General de Salud Animal Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria, Productora Nacional de Biológicos Veterinarios	MEXICO
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13. In exercising your activities, have you identified any regulatory research needs\* relevant for WOA?H?

No

## 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:

The reference laboratory participates in diagnosis of mammalian TB, however, epidemiological data such as animal movements and field test data are stored outside of the laboratory, but within the parent agency of NVSL, USDA-APHIS-Veterinary Services. The Laboratory does work directly with our counterparts in other countries to coordinate strain/genotype information to inform investigations between our countries.

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:

Whole genome sequencing of cultured mammalian TB isolates were analyzed to determine the phylogenetic relationships between new isolates and isolates from previous outbreaks or detections. The analysis was distributed to federal and state animal health officials and epidemiologists to aid in disease tracing.

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

*Vaccination of White-Tailed Deer with Mycobacterium bovis Bacillus Calmette–Guérin (BCG): Effect of Mycobacterium avium ssp. paratuberculosis Infection; Mitchell V Palmer, Carly Kanipe, Kimberly A Lehman; Tyler C Thacker; Ellie J Putz; Paola M Boggiatto. PMC PubMed Central National Library of Medicine National Center for Biotechnology Information. PubMed Central*

*Advancing animal tuberculosis surveillance using culture-independent long-read whole-genome sequencing; Ghielmetti G, Loubser J, Kerr TJ, Stuber T, Thacker T, Martin LC, O'Hare MA, Mhlophe SK, Okunola A, Loxton AG, Warren RM, Moseley MH, Miller MA, Goosen WJ. Front Microbiol. 2023 Nov 21;14:1307440. doi: 10.3389/fmicb.2023.1307440. eCollection 2023. PMID: 38075895*

b) International conferences:

1

WOAH sponsored conference on tuberculosis in Birmingham, UK

c) National conferences:

1

Annual updates given at the United States Animal Health Association meeting (October 2023)

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

1

Monthly summary reports and affected herd maps: (<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/cattle-disease-information/tuberculosis-brucellosis-monthly-report/tb-bruc-reports>)

## TOR7: SCIENTIFIC AND TECHNICAL TRAINING

17. Did your laboratory provide scientific and technical training to laboratory personnel from other WOAHA 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)	
ISO 17025	Valid to June 30, 2025	2526-01.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
Bacterial Isolation (Culture)	A2LA
Microscopic Examination – Acid Fast Stain	A2LA
Real-time & Conventional PCR	A2LA
16s rDNA ITS, rpoB, hsp65 sequencing	A2LA
Whole Genome Sequencing	A2LA
Histopathology	A2LA
Lateral Flow (Dual Path Platform)	A2LA
Interferon-Gamma Release Assay	A2LA

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

Yes

We operate under campus and laboratory specific biorisk plans that comply with biosafety level 2 and 3 per the latest edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL) <https://www.cdc.gov/labs/BMBL.html> as well as Federal Select Agent Program Federal Select Agent Program ([selectagents.gov](https://www.selectagents.gov)) requirements for regulated pathogens including virulent Newcastle disease virus and highly pathogenic avian influenza.

## TOR9: SCIENTIFIC MEETINGS

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

No

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

No

## TOR10: NETWORK WITH WOAHA REFERENCE LABORATORIES

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

Yes

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

Yes

NETWORK/DISEASE	ROLE OF YOUR LABORATORY (PARTICIPANT, ORGANISER, ETC)	NO. PARTICIPANTS	PARTICIPATING WOAHA REF. LABS
mammalian tuberculosis	participant	4	UK, France, Argentina, USA

25. Did you organise or participate in inter-laboratory proficiency tests with WOAHA Reference Laboratories designated for the same pathogen?

No

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 pathogen of interest?

No

## 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?

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
Proficiency Testing	College of American Pathologists	0	Mycobacteriology Survey and Mycobacteriology - Limited Survey	UNITED STATES OF AMERICA,

## TOR12: EXPERT CONSULTANTS

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

Yes

KIND OF CONSULTANCY	Location	SUBJECT (FACULTATIVE)
Meeting attendance	Birmingham, United Kingdom	Tuberculosis

29. Additional comments regarding your report:

Yes