World Organisation for Animal Health

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WOAH Reference Laboratory Reports Activities 2024

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LABORATORY INFORMATION

***Name of disease (or topic) for which you are a designated WOAH Reference Laboratory:**	Mammalian tuberculosis
***Address of laboratory:**	1920 Dayton Ave, Ames, Iowa 50010 USA
***Tel:**	15153377266
***E-mail address:**	kimberly.lehman@usda.gov
Website:	https://www.aphis.usda.gov/labs
***Name (including Title) of Head of Laboratory (Responsible Official):**	Dr. Suelee Robbe-Austerman, Director, National Veterinary Services laboratories (NVSL) - USDA APHIS
***Name (including Title and Position) of WOAH Reference Expert:**	TBD
***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
Interferon-gamma release assay	Yes	4746	93
Lateral flow - Cervid	Yes	9407	0
Lateral flow - Zoo species	Yes	54	0
Direct diagnostic tests		Nationally	Internationally

Culture - Livestock/Domestic & Wildlife	Yes	961	18
Culture - Zoo species	Yes	4278	0
Direct PCR - Livestock/Domestic & Wildlife	Yes	5664	9507
Direct PCR - Zoo species	Yes	21112	0
Histopathology	Yes	8515	784

TOR2: REFERENCE MATERIAL

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

No

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

Yes

Type of reagent available	Related diagnostic test	Produced/ provide	Amount supplied nationally (ml, mg)	Amount supplied internationally (ml, mg)	No. of recipient WOAH 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	122,945 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	16 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)	6,864 mL	0	1	UNITED STATES OF AMERICA,

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	104 mL	0	1	UNITED STATES OF AMERICA,
Mycobacterium species DNA	Mycobacterium species DNA	Varies	1 vial	0	1	UNITED STATES OF AMERICA,

4. Did your laboratory produce vaccines?

No

5. Did your laboratory supply vaccines to WOAH Members?

Yes

Vaccine name	Amount supplied nationally (ml, mg)	Amount supplied nationally (ml, mg)	Name of recipient WOAH Members
Bacille Calmette-Guerin (BCG) vaccination	0	6048	MEXICO

TOR3: NEW PROCEDURES

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

Yes

Name of the new test or diagnostic method developed	Description and References (Publication, website, etc.)
Interferon gamma	Evaluate modernized TB cell mediated immunity tests, including tests that can differentiate infected from vaccinated animals (DIVA) – evaluate the test performance of the Quantiferon Gold Plus in-tube gamma interferon (QFT). Validation in process.
PCR	Develop assays to detect bovine tuberculosis shedding – evaluate the potential of PCR in milk or mucosal swabs to evaluate shedding. Validation in process.
ELISA	In process – development of an ELISA for use in detecting tuberculosis in cervids

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

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

No

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

No

TOR4: DIAGNOSTIC TESTING FACILITIES

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

Yes

Name of WOAH 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
MEXICO	2024-01-01	PCR	9507	0
NIGERIA	2024-01-01	Histopathology	0	784
MEXICO	2024-01-01	culture	18	0
CANADA	2024-01-01	interferon-gamma release assay	93	0

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

Yes

Name of the WOAH Member Country receiving a technical consultancy	Purpose	How the advice was provided
MEXICO	USDA-APHIS SAGARPA project to conduct slaughter surveillance testing in Baja California, Mexico. Samples are split between the laboratories of the USA and Mexico for test harmonization and whole genome sequence database development.	Methods/Testing comparison – virtual meetings and written correspondence
INDONESIA	Requested support in delivering laboratory diagnostic training for animal health laboratories	Ongoing – Virtual meetings and written correspondence
GERMANY	Requested consultation on management of tuberculosis infected large dairy (test and remove model as well as agent characterization)	Virtual meetings and written correspondence
NIGERIA	Requested support testing formalin fixed paraffin embedded tissue blocks for Mycobacterium tuberculosis complex organisms	Written communication and diagnostic testing

TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES

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

Yes

Title of the study	Duration	Purpose of the study	Partners (Institutions)	WOAH Member Countries involved other than your country
Five-year prospective evaluation of BCG vaccine efficacy in naturally infected dairy cattle, Baja California, Mexico	5-year project	To evaluate the efficacy of the Bacille Calmette-Guerin (BCG) vaccination in bTB affected dairy herds.	PRONABIVE, SENASICA, University of Baja California	MEXICO

Zoonotic TB in cattle slaughtered in abattoirs in Abuja, Nigeria	1 year	Characterize zoonotic tuberculosis identified in cattle slaughtered in Abuja, Nigera	University of Abuja	NIGERIA

13. In exercising your activities, have you identified any regulatory research needs* relevant for WOAH?

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. Additional epidemiologic information is reported publicly via 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).

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

Marshall, K. E., Free, R. J., Filardo, T. D., Schwartz, N. G., Hernandez-Romieu, A. C., Thacker, T. C., Lehman, K.A., ... & Basavaraju, S. V. (2024). Incomplete tissue product tracing during an investigation of a tissue-derived tuberculosis outbreak. American Journal of Transplantation, 24(1), 115-122.

Wortham JM, Haddad MB, Stewart RJ, et al. Second Nationwide Tuberculosis Outbreak Caused by Bone Allografts Containing Live Cells — United States, 2023. MMWR Morb Mortal Wkly Rep 2024;72:1385–1389. DOI: http://dx.doi.org/10.15585/mmwr.mm725253a1

Outbreak of Mycobacterium orygis in a Shipment of Cynomolgus Macaques Imported from Southeast Asia — United States, February–May 2023; Samantha D. Swisher, Sara J. Taetzsch, Mark E. Laughlin, William L. Walker, Adam J. Langer, Tyler C. Thacker, Jessica L. Rinsky, Kimberly A. Lehman, Anne Taffe, Nancy Burton, Doris M. Bravo, Emily McDonald, Clive M. Brown, Emily G. Pieracci; MMWR Morb Mortal Wkly Rep 2024;73:145–148; Outbreak of Mycobacterium orygis in a Shipment of Cynomolgus Macaques Imported from Southeast Asia — United States, February–May 2023 | MMWR (cdc.gov)

b) International conferences:

1
U.S.-Mexico Binational Committee for Tuberculosis and brucellosis "Investigating the efficacy of new approaches to TB control: Update on the five-year prospective evaluation of BCG vaccine efficacy in naturally infected dairy cattle in Baja California, Mexico"

c) National conferences:

1
Annual updates given at the United States Animal Health Association meeting on bovine tuberculosis eradication program activities and progress with the TB Initiative projects (BCG vaccine field trials, antemortem diagnostic testing evaluations, source attribution activities, etc.) (October 2024)

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

1
There was also an article in the American Public Health Association's One Health newsletter "A New Perspective on an Old Vaccine – International Collaboration to Control Bovine Tuberculosis in Northwestern Mexico"

TOR8: QUALITY ASSURANCE

18. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)	
ISO/IEC 17025:2017	A2LA Accreditation valid to June 30, 2025	A2LA Accreditation Testing.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
Bacterial Isolation (Culture)	NVSL is accredited by the American Association for Laboratory Accreditation (A2LA) to ISO standards
Microscopic Examination - Acid Fast Stain	NVSL is accredited by the American Association for Laboratory Accreditation (A2LA) to ISO standards
Real-time & Conventional PCR	NVSL is accredited by the American Association for Laboratory Accreditation (A2LA) to ISO standards

16s rDNA ITS, rpoB, hsp65 sequencing	NVSL is accredited by the American Association for Laboratory Accreditation (A2LA) to ISO standards
Whole Genome Sequencing	NVSL is accredited by the American Association for Laboratory Accreditation (A2LA) to ISO standards
Histopathology	NVSL is accredited by the American Association for Laboratory Accreditation (A2LA) to ISO standards
Lateral Flow (Dual Path Platform)	NVSL is accredited by the American Association for Laboratory Accreditation (A2LA) to ISO standards
Interferon-gamma release assay	NVSL is accredited by the American Association for Laboratory Accreditation (A2LA) to ISO standards

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) requirements for regulated pathogens.

TOR9: SCIENTIFIC MEETINGS

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

No

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

No

TOR10: NETWORK WITH WOAH REFERENCE LABORATORIES

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

Yes

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

No

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

No

No proficiency tests available from other WOAH reference laboratories

26. Did your laboratory collaborate with other WOAH 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 WOAH Reference Laboratories for the same pathogen during the past 2 years?

Yes

Purpose for inter-laboratory test comparisons1	Role of your reference laboratory (organizer/participant)	No. participating laboratories	Name of the test	WOAH Member Countries
Proficiency Test	Participant - Provided by 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 WOAH?

No

29. Additional comments regarding your report:

Yes

Lateral flow test numbers are lower than average due to an extended backorder of the test kit from the manufacturer
We want to support WOAH request with providing the training videos we created for diagnostic methods. We have been overwhelmed with outbreak response and were unable to provide WOAH with the videos by their deadline of 27 December 2024. We would like to continue to coordinate with WOAH to be able to provide this valuable resource.
We intend to put Dr. Suelee Robbe-Austerman forward as a replacement for Dr. Tyler Thacker as the WOAH Reference Laboratory