

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:	New Haw, Addlestone, Surrey, KT15 3NB, Weybridge UNITED KINGDOM
*Tel:	+44(0)20882257611
*E-mail address:	Jason.Sawyer@apha.gov.uk
Website:	https://www.gov.uk/government/organisations/animal-and-plant-health-agency
*Name (including Title) of Head of Laboratory (Responsible Official):	Dr Jenny Stewart, Chief Executive (interim) APHA
*Name (including Title and Position) of WOAH Reference Expert:	Dr Jason Sawyer, Head of Surveillance and Laboratory Department (SLSD), APHA Weybridge
*Which of the following defines your laboratory? Check all that apply:	Governmental

TOR1: DIAGNOSTIC METHODS

 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
Gamma Interferon micro (2 antigen) assay	Yes	220002	0



Gamma interferon extended micro (3 antigen) assay	Yes	8214	53
Lateral flow serology test - camelid	No	365	0
Lateral flow serology test - badger	No	261	0
Lateral flow serology test - other	No	35	0
IDEXX ELISA serology test - bovine	Yes	9199	0
IDEXX ELISA serology test - camelid	Yes	395	0
IDEXX ELISA serology test - deer	Yes	2308	1
EnferPlex serology ELISA	No	364	0
Direct diagnostic tests		Nationally	Internationally
Direct diagnostic tests Culture (bovine)	Yes	Nationally 2550	Internationally 4
Direct diagnostic tests Culture (bovine) Culture (non-bovine)	Yes Yes	Nationally 2550 121	Internationally 4 0
Direct diagnostic tests Culture (bovine) Culture (non-bovine) PCR (bovine)	Yes Yes Yes	Nationally 2550 121 5752	Internationally 4 0 0
Direct diagnostic testsCulture (bovine)Culture (non-bovine)PCR (bovine)PCR (non-bovine)	Yes Yes Yes Yes	Nationally 2550 121 5752 308	Internationally 4 0 0 0 0
Direct diagnostic testsCulture (bovine)Culture (non-bovine)PCR (bovine)PCR (non-bovine)Whole genome sequencing (bovine)	Yes Yes Yes Yes Yes	Nationally 2550 121 5752 308 2582	Internationally 4 0 0 0 0 0
Direct diagnostic testsCulture (bovine)Culture (non-bovine)PCR (bovine)PCR (non-bovine)Whole genome sequencing (bovine)Whole genome sequencing (non-bovine)	Yes Yes Yes Yes Yes Yes	Nationally 2550 121 5752 308 2582 422	Internationally 4 0 0 0 0 0 0 0
Direct diagnostic testsCulture (bovine)Culture (non-bovine)PCR (bovine)PCR (non-bovine)Whole genome sequencing (bovine)Whole genome sequencing (non-bovine)DNA testing of cattle to confirm individual identity	Yes Yes Yes Yes Yes No	Nationally 2550 121 5752 308 2582 422 0	Internationally 4 0 0 0 0 0 0 0 1

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
DST-F TB DIVA reagent	IGRA	Produced & provide	0	55 x 1 mL vial	1	SPAIN,
DST-F TB DIVA reagent	IGRA	Produced & provide	0	172 x 1 mL vial	1	ITALY,
DST-F TB DIVA reagent	IGRA	Produced & provide	0	50 x 1 mL vial	1	IRELAND,



DST-F TB DIVA reagent	IGRA	Produced & provide	0	55 x 1 mL vial	1	TURKEY,
DST-F TB DIVA reagent	IGRA	Produced & provide	0	110 x 1 mL vial	1	ITALY,
Cattle sera and supernatants	Cattle TB research and diagnostics	Produced & provide	280 x 1 mL	0	1	UNITED KINGDOM,
BCG vaccine	Vaccination	Provide	0	120 x 1 mL	1	ETHIOPIA,
Tuberculin	Skin test and IGRA	Provide	0	120 x 2 mL	1	ETHIOPIA,
Molecularly defined tuberculin (MDT)	IGRA and skin test	Produced & provide	0	10 vials, 9.4 mL total	1	ETHIOPIA,
BCG vaccine and tuberculin	Vaccination, IGRA and skin test	Provide	0	50 x 1 mL BCG, 20 x 2 mL Tuberculin	1	CANADA,
BCG vaccine and tuberculin	Vaccination, IGRA and skin test	Provide	0	30 x 1 mL BCG, 10 x 2 mL Tuberculin	1	UNITED STATES OF AMERICA,
Tuberculin	Skin test and IGRA	Provide	0	400 x 2 mL vials	1	INDIA,
M.bovis stock	Cattle TB research and diagnostics	Produced & provide	0	2 x 1 mL vials	1	UNITED STATES OF AMERICA,

4. Did your laboratory produce vaccines?

No

5. Did your laboratory supply vaccines to WOAH 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 WOAH Standards for the designated pathogen or disease?

No

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

8. L No

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

Yes

Name of the new vaccine developed	Description and References (Publication, website, etc)
BCG vaccine with companion DIVA test	APHA is currently conducting field trials of BCG vaccination of cattle alongside a companion DIVA test. The aim is to obtain marketing authorisation for these products, allowing their routine use. UK government site with details: https://www.gov.uk/government/news/field-trials-for-leading-cattle-vaccine-and-skintest- for-btb A technical paper describing the work conducted at APHA has also been submitted to WOAH.

TOR4: DIAGNOSTIC TESTING FACILITIES



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

No

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
CHINA (PEOPLE'S REP. OF)	As part of a WOAH sponsored twinning project between APHA and CAHEC (China Animal Health and Epidemiology Centre) in the area of bovine TB	Technical visit by CAHEC staff to APHA TB testing laboratories and field operations

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
Replacement of the International Standard Bovine Tuberculin	Ongoing	Replacement of the International Standard Bovine and Avian Tuberculin	This is an international study coordinated by WOAH	ARGENTINA FRANCE SPAIN UNITED STATES OF AMERICA
Accelerating Bovine TB control in LMICs: Phase 2	Ongoing	To accelerate the development and implementation of rational evidence-based approaches to control bTB in India and other developing countries	Penn State University Department of Agriculture (ARS-NADC) Animal Health Institute Lala Lajpat Rai University of Veterinary and Animal Science The Pirbright Institute Vaccine and Infectious Disease Organisation University of Cambridge CISGEN Biotech Discoveries	CANADA ETHIOPIA INDIA UNITED STATES OF AMERICA
Routine IGRA cattle screening programme	Ongoing	To assess the utility of a defined antigen diagnostic reagent for use in a blood-based bovine TB test	Centro de Vigiancia Sanitaria	SPAIN
Immunodiagnosis of tuberculosis in goats	Completed	To assess the effect of different TB vaccination schedules on regular TB diagnostic methods and new diagnostic reagents	Campus de la Universitat Autonoma de Barcelona Neiker-Instituto Vasco de Investigacion y Desarrollo Agrario	SPAIN

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:

APHA is involved in the collection and analysis of data relevant to the bovine TB disease situation in Great Britain.

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:

Statistics and analysis of bovine TB disease situation in Great Britain are available at the following website: https://www.gov.uk/government/collections/bovine-tb

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:

21

Temporal dynamics of the early immune response following Mycobacterium bovis infection of cattle. Journal Nature Communications https://doi.org/10.1038/s41598-024-52314-x

Difference in differences analysis evaluates the effects of the badger control policy on bovine tuberculosis in England. Journal Scientific Reports https://doi.org/10.1038/s41598-024-54062-4

Comparative analysis of tuberculin and defined antigen skin tests for detection of bovine tuberculosis in buffaloes (Bubalus bubalis) in Haryana state, India. Journal BMC Veterinary Research 20 (1) https://doi.org/10.1186/s12917-024-03913-3

An ELISA using synthetic mycolic acid based antigens with 2 DIVA potential for diagnosing Johne's disease in cattle Journal Animals https://doi.org/10.3390/ani14060848

Machine learning augmented diagnostic testing to identify sources of variability in test performance Journal PloS Computational Biology https://doi.org/10.48550/arXiv.2404.03678

Use of an expert elicitation methodology to compare welfare impacts of two approaches for blood sampling European badgers (Meles meles) in the field. Journal Animal Welfare 33 https://doi.org/10.1017/awf.2024.16

Performance of fur clips and livestock markers for identifying vaccinated badgers. Journal European Journal of Wildlife Research 70 (2) https://doi.org/10.1007/s10344-024-01789-0



BCG vaccination reduces bovine tuberculosis transmission, improving prospects for elimination. Journal Science 383 (6690) 1433-1441 https://doi.org/10.1126/science.adl3962

Corrigendum: Lack of methoxy-mycolates characterizes the geographically restricted lineage 7 of Mycobacterium tuberculosis complex Journal Microbial Genomics 10 (3) https://doi.org/10.1099/mgen.0.001226

Comparative performance of tuberculin and defined-antigen cocktails for detecting bovine tuberculosis in BCG-vaccinated cattle in natural settings. Journal Research Square https://doi.org/10.21203/rs.3.rs-4548496/v1

High Mycobacterium bovis exposure but low IGRA positivity in UK farm workers Journal British Medical Journal https://doi.org/10.1101/2024.06.27.24309580

Bovine TB infection status in cattle in Great Britain in 2022. Journal Veterinary Record 194 (12) https://doi.org/10.1002/vetr.4420

The safety of overdose and repeat administrations of BCG Danish strain 1331 vaccine in calves and pregnant heifers. Journal Heliyon 10.1016/j.heliyon.2024.e34683

Editorial: Tuberculosis in domestic ruminants: towards eradication of zoonotic tuberculosis Journal Frontiers 10.3389/fvets.2024.1453876

Tuberculosis in young, raw-fed cats in the UK. Journal Veterinary Record 195 (4) 156 https://doi.org/10.1002/vetr.4625

Detection of Mycobacterium tuberculosis complex in saliva by quantitative PCR: A potential alternative specimen for pulmonary tuberculosis diagnosis Journal Tuberculosis 10.1016/j.tube.2024.102554

Estimating the seroprevalence of tuberculosis (Mycobacterium bovis) in a wild deer population in southwest England Journal Biology and Veterinary record https://doi.org/10.1101/2024.10.03.613747

Mycobacterium bovis vaccination and subsequent experimental infection outcomes are associated with changes in vitamin D status in dairy cattle Journal J Dairy Science 10.3168/jdsc.2024-0547

Efficient modelling of infectious diseases in wildlife: A case study of bovine tuberculosis in wild badgers. Journal PLoS Computational Biology https://doi.org/10.1371/journal.pcbi.1012592

Mycobacterium bovis vaccination and subsequent experimental infection outcomes are associated with changes in vitamin D status in dairy calves. Journal JDS Communications 5 (6) 622-627 https://doi.org/10.3168/jdsc.2024-0547

Bovine tuberculosis trends in Wales between 2010 and 2021. Journal Veterinary Record 195 (9) https://doi.org/10.1002/vetr.4600

b) International conferences:

5

Preliminary descriptive effects of supplementary interferon gamma testing on the control of bovine tuberculosis in English cattle herds Talk ISVEE 2024 Full Program | 17th International Symposium on Veterinary Epidemiology and Economics

Forward planning of the deployment of CattleBCG and the companion DIVA test in the fight against bovine tuberculosis in GBTalk ISVEE 2024 17th International Symposium on Veterinary Epidemiology and Economics | 11 - 15 November 2024



Exploring an apparent reduction in persistent bovine tuberculosis breakdowns among cattle herds in England Talk ISVEE 2024 Full Program | 17th International Symposium on Veterinary Epidemiology and Economics

Modelling vaccination of cattle against tuberculosis in England and Wales: assessing the impact of different strategies. Talk ISVEE 2024 Full Program | 17th International Symposium on Veterinary Epidemiology and Economics

Designing a study to evaluate the effects of badger vaccination on bovine tuberculosis in cattle in England and Wales Talk ISVEE 2024 Full Program | 17th International Symposium on Veterinary Epidemiology and Economics

c) National conferences:

0

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

4

Analysis of bovine tuberculosis surveillance in cattle at slaughter in Great Britain 2019 to 2022 Report Gov.com Analysis of bovine tuberculosis surveillance in cattle at slaughter in Great Britain 2019 to 2022 Explanatory Supplement to the annual TB Surveillance Reports Report Gov.com https://assets.publishing.service.gov.uk/media/66eaba069975b7a980b304e1/ExplanatorySupplement_FINAL.pdf

2023 TB Epidemiology Reports for the Low Risk Area (x7): Lincolnshire, Cumbria, Isles of Scilly, North East, North West, Yorkshire and Humberside, and South East. Report Gov.com Bovine TB: epidemiology reports, 2023 - GOV.UK

Bovine tuberculosis in England in 2023: Epidemiological analysis of the 2023 data and historical trends Report Gov.com APHA corporate document – branded, with cover

Bovine tuberculosis in Great Britain: surveillance data for 2023. Report Gov.com https://assets.publishing.service.gov.uk/media/679255cfa0bd2a64fc27fc28/GBDataReportAccessible_2023_v2.ods

TOR7: SCIENTIFIC AND TECHNICAL TRAINING

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

a) Technical visit : 1

b) Seminars : 0

c) Hands-on training courses: 0

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
A	CHINA (PEOPLE'S REP. OF)	2



TOR8: QUALITY ASSURANCE

18. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)	
ISO 9001:2015	PDF	ANIMAL PLANT HEALTH AGENCY - Certificate UK013916 - ISO 9001 - exp. 25-07- 2026.pdf
IS017025	PDF	APHA UKAS cert to 25 Nov 25.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
Detection of gamma interferon (IFN- γ) in whole blood culture supernatants	UKAS United Kingdom Accreditation Service
The detection and differentiation of pathogenic Mycobacterium spp by PCR	UKAS United Kingdom Accreditation Service
Assignment of sequence cluster using whole genome sequencing (WGS) of Mycobacterium bovis isolates	UKAS United Kingdom Accreditation Service
Detection of Mycobacteria by Kinyoun cold stain for Acid Alcohol Fast Bacilli (AAFB)	UKAS United Kingdom Accreditation Service
Isolation of Mycobacterium spp in badgers	UKAS United Kingdom Accreditation Service
Detection of antibodies to Mycobacterium bovis in cattle and badger serum	UKAS United Kingdom Accreditation Service
Detection of Mycobacteria by culture in tissues	UKAS United Kingdom Accreditation Service

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

APHA operates a biorisk management system which aligns with recognised good and best practice standards including the Laboratory Biorisk Management Standard (CWA 15793). This includes a dedicated Health and Safety Team and detailed Health, Safety and Biorisk policies and practices

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?

Yes

Title of event	Date	location	Role (speaker, presenting poster, short communications)	Title of the work presented
WOAH Ad-hoc				



committee on replacement of ISBT and	2024-12-31	online	participant	NA
ISAT tuberculin standards				

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? Yes

NETWORK/DISEASE	ROLE OF YOUR LABORATORY (PARTICIPANT, ORGANISER, ETC)	NO. PARTICIPANTS	PARTICIPATING WOAH REF. LABS
Informal & ad-hoc meetings with network of TB WOAH reference laboratories	Participant	5	Argentina, US, Spain and France

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

NA

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?

No

NA

Voc

TOR12: EXPERT CONSULTANTS

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

Kind of consultancy	Location	Subject (facultative)				
		Attended regular meeting of ad-hoc				
		committee on replacement on international				
		tuberculin standards. APHA facilitated				
ARHA participator in the WOAH ad bor		laboratory work to support this effort by				
committee on replacement of international		obtaining funding for guinea pig potency				
reference standards for tuberculing	Virtual; multiple meetings	testing to be carried out at UKHSA Porton				
reference standards for tubercullits		Down and testing reagents in APHA				
		laboratories. Involved in discussions about				



freeze drying and storage of international tuberculin standards.

29. Additional comments regarding your report:

No