

WOAH Reference Laboratory Reports Activities 2025

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LABORATORY INFORMATION

*Name of disease (or topic) for which you are a designated WOA Reference Laboratory:	Mammalian tuberculosis
*Address of laboratory:	New Haw, Addlestone, Surrey, KT15 3NB, Weybridge UNITED KINGDOM
*Tel:	+44-1932 34.11.11
*E-mail address:	mark.chambers1@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 Richard Lewis. CEO APHA
*Name (including Title and Position) of WOA Reference Expert:	Professor Mark Chambers, Head of TB Research & Development Group, APHA Weybridge
*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 WOA Manual (Yes/No)	Total number of test performed last year	
		Nationally	Internationally
Indirect diagnostic tests			
Gamma interferon ELISA for mycobacteria - micro 2Ag assay (cattle)	Yes	221459	0
Gamma interferon ELISA for mycobacteria - extended micro 3Ag assay (cattle)	Yes	6208	2
Lateral flow serology test - camelid	No	340	0
Lateral flow serology test - badger	No	305	0
Lateral flow serology test - other	No	51	0
IDEXX ELISA serology test - bovine	Yes	6338	0
IDEXX ELISA serology test - camelid	Yes	363	0
IDEXX ELISA serology test - deer	Yes	590	0
EnferPlex serology ELISA	Yes	545	0
Direct diagnostic tests		Nationally	Internationally

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Culture (bovine)	Yes	1628	4
Culture (non-bovine)	Yes	187	1
PCR (bovine)	Yes	5819	2
PCR (non-bovine)	Yes	373	1
Whole genome sequencing (bovine)	Yes	3890	2
Whole genome sequencing (non-bovine)	Yes	357	0
Culture (badgers)	Yes	2406	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
DST-F TB DIVA reagent	IGRA	Provide	0	122 x 1 mL	1	ITALY,
Bovine and avian tuberculin	IGRA and skin test	Provide	0	240 x 2ml PPDA vials 240 x 2ml PPDB vials	1	ETHIOPIA,
Bovine and avian tuberculin	IGRA and skin test	Provide	0	25 x 2ml PPDA vials 25 x 2ml PPDB vials	1	UNITED STATES OF AMERICA,
Molecularly defined tuberculin (MDT) reagent	IGRA	Produced/provide	0	8 x 0.2ml vial	1	SPAIN,
Serum from confirmed TB reactor and control cattle	Serology	Provide	0	25 x 6ml 30 x 1ml	1	SWITZERLAND,
Serum from BCG vaccinated and experimentally infected cattle	Serology	Provide	1	124 x 0.5ml	1	UNITED KINGDOM,

4. Did your laboratory produce vaccines?

No

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?

Yes

Name of the new test or diagnostic method developed	Description and References (Publication, website, etc.)
A molecularly defined tuberculin reagent based on recombinant proteins for use in skin testing and IGRA	https://journals.asm.org/doi/epub/10.1128/jcm.00552-25

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 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
CHINA (PEOPLE'S REP. OF)	As part of a WOAHP 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 to discuss policy areas, eradication strategy and research Technical visit by APHA staff to CAHEC to discuss policy areas, eradication strategy and research
KOREA (REP. OF)	South Korea TB National Reference lab approached us to request a visit to APHA to learn from our TB control programme	A week long visit was organised and included presentation and discussions to cover the different aspects from our TB programme, from policy advice and delivery of the programme, to test diagnostics development & usages, use of whole genome sequencing to inform epidemiology and outbreak management, TB epidemiology component, our R&D work and cattle vaccination programme. Tours of our research lab and animal facilities were also held. The visit centred on knowledge exchange across both of our institutions, and was followed up by exchanging key facts about our programme of work.
NORWAY	Approached by the Norwegian Veterinary Institute to provide more information and advice on the use of the Enferplex Antibody Test for TB	Provided written feedback (via email) with input from government Veterinary Advice Services.
ZAMBIA	Knowledge exchange	In person meeting with representatives from Zambia visiting APHA to have an exchange on our TB control programmes.

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
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
Improving the diagnosis of		To improve the diagnosis of	Complutense University of Madrid, University College Dublin, Instituto Zooprofilattico	

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tuberculosis in domestic ruminants through the use of new antigens and test platforms	Ongoing	tuberculosis in domestic ruminants through the use of new antigens and test platforms	Sperimentale della Lombardia e dell'Emilia Romagna, Istituto Zooprofilattico Sperimentale de Mezzogiorno, Instituto de Salud Carlos III, Istanbul University-Cerrahpasa	IRELAND ITALY SPAIN TURKEY
Protection and diagnostic interference induced by heat-inactivated, phage-inactivated and live vaccine prototypes against animal tuberculosis	Completed	Evaluation of the diagnostic interference and protective efficacy of novel vaccines for animal tuberculosis	Neiker-Instituto Vasco de Investigacion y Desarrollo Agrario	SPAIN

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: Sensitivity and specificity of DIVA skin test reagent and molecularly defined tuberculin

Relevance for WOA?H Disease Control, Standard Setting,

Relevance for the Code or Manual Manual,

Field 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: Terrestrial Manual Section 2.2 - Validation of diagnostic tests and Terrestrial Manual Chapter 3.4.6 - Bovine 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:

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:

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- 1) Can biosecurity on farms reduce bovine tuberculosis risks in cattle in England? A review of observational and literature-based evidence. <https://doi.org/10.1002/vetr.4912>
- 2) Detection of genetic variability in dairy cattle infectivity for bovine tuberculosis. Madenci, D. et al. *Journal of Dairy Science*, Volume 108, Issue 4, 3835 - 3849
- 3) Effects of different vaccination regimes on the immunodiagnosis of tuberculosis in goats and evaluation of defined antigens. <https://doi.org/10.3389/fvets.2024.1524461>
- 4) Anti-phenolic glycolipid antibodies in *Mycobacterium bovis* infected cattle. <https://doi.org/10.1016/j.onehlt.2025.100982>
- 5) Fromsa, A., Conlan, A.J.K., Srinivasan, S. et al. Comparative performance of tuberculin and defined-antigen cocktails for detecting bovine tuberculosis in BCG-vaccinated cattle in natural settings. *Sci Rep* 15, 4564 (2025). <https://doi.org/10.1038/s41598-025-85389-1>
- 6) Immune response to co-administration of *Bacillus Calmette-Guérin* (BCG) and contraceptive vaccines in badgers (*Meles meles*). <https://doi.org/10.1016/j.vaccine.2025.128069>
- 7) High *Mycobacterium bovis* Exposure but Low IGRA Positivity in UK Farm Workers. <https://doi.org/10.1111/zph.13214>
- 8) Development and characterization of monoclonal antibodies specific for bovine IP-10. <https://doi.org/10.21203/rs.3.rs-6304513/v1>
- 9) Evaluating sensitivity and specificity of the DPP Vet TB assay in badgers using Bayesian latent class models. <https://doi.org/10.1371/journal.pone.0313825>
- 10) Enhanced analysis of the genomic diversity of *Mycobacterium bovis* in Great Britain to aid control of bovine tuberculosis. <https://doi.org/10.3389/fmicb.2025.1515906>
- 11) Powell, S.M., Dessi, N., Bennett, M. et al. Tuberculosis in found dead badgers at the edge of the expanding bovine tuberculosis epidemic. *Sci Rep* 15, 10547 (2025). <https://doi.org/10.1038/s41598-025-86930-y>
- 12) Characterization of the global bovine microRNAome of peripheral blood mononuclear cells isolated from *Mycobacterium bovis* exposed cattle. <https://doi.org/10.1016/j.tube.2025.102639>
- 13) Can badger vaccination contribute to bovine TB control? A narrative review of the evidence. <https://doi.org/10.1016/j.prevetmed.2025.106464>
- 14) Serological Methods and *Mycobacterium bovis* Infection in Deer. <https://doi.org/10.1002/9781394221370.ch15>
- 15) Holder, T.; Robinson, N.; Jones, G.J. The Impact of *Bacillus Calmette-Guérin* Vaccination and *Mycobacterium bovis* Infection on Diagnostic Antibody Tests for Mycobacterial Infections. *Vaccines* 2025, 13, 578. <https://doi.org/10.3390/vaccines13060578>
- 16) Improving the diagnosis of tuberculosis in domestic ruminants through the use of new antigens and test platforms: the imdiTBap project. https://eavld.org/wp-content/uploads/2025/06/4Template-newsletter-EAVLD_Final-Version_060625.pdf
- 17) George BM, Duncan D, Waller E, Marriott E, Payne MC, Withenshaw S, Brouwer A, Harris KA, May HE, Avigad R. Bovine TB infection status in cattle in Great Britain in 2023. *Vet Rec.* 2025 Jun 21;196(12):e5696. doi: 10.1002/vetr.5696.
- 18) Protection and diagnostic interference induced by heat-inactivated, phage-inactivated and live vaccine prototypes against animal tuberculosis. <https://doi.org/10.3389/fvets.2025.1620497>
- 19) Bovine tuberculosis model validation against a field study of badger vaccination with selective culling. <https://doi.org/10.1371/journal.pone.0320830>
- 20) Protection and diagnostic interference induced by heat-inactivated, phage-inactivated and live vaccine prototypes against animal tuberculosis. <https://doi.org/10.3389/fvets.2025.1620497>
- 21) Clare H Benton, Richard Delahay, Barbara Shih, Rowland R. Kao, Robbie A. McDonald, Dave J Hodgson; Sociality and kinship constrain the free-mixing of pathogens in a wild mammal host population. *Proc Biol Sci* 1 July 2025; 292 (2051): 20251242. <https://doi.org/10.1098/rspb.2025.1242>
- 22) Middleton S, Singh M, Coad M, Palmer S, Holder T, Steinbach S, Hardiman R, Vordermeier HM, Jones GJ. 2025. Optimization of a molecularly defined tuberculin formulation: recombinant fusion proteins and epitope surgery. *J Clin Microbiol* 63:e00552-25. <https://doi.org/10.1128/jcm.00552-25>
- 23) Uncovering the Genomic Landscape of *Mycobacterium bovis* in Wales. <https://doi.org/10.1101/2025.10.07.680915>
- 24) Smith-Langridge, R., Jinks, R., Konold, T. et al. Comparing the use of different environmental enrichment items by Hereford-Holstein cattle in a high containment facility. *BMC Vet Res* (2025). <https://doi.org/10.1186/s12917-025-05211-y>

25) Estimating the seroprevalence of tuberculosis (*Mycobacterium bovis*) infection in a wild deer population in southwest England. <https://doi.org/10.1101/2024.10.03.613747>

26) Barroso, P., Juste, R., Sañudo, B. et al. Differences in local immune response of bait *Mycobacterium bovis* heat-inactivated vaccinated badgers showing exacerbated tuberculous lesions after challenge. *Sci Rep* 15, 36329 (2025). <https://doi.org/10.1038/s41598-025-20278-1>

b) International conferences:

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1) A presentation titled "pathology of a temporal cluster of feline tuberculosis cases caused by *Mycobacterium caprae* in the United Kingdom following consumption of a raw meat-based diet" was presented at the ECVPH conference.

2) A poster titled "Prior history of bovine tuberculosis as a risk factor for future recurrence in infected cattle herds in endemic areas of England" was presented at the SVEPM conference.

3) A poster titled "imdiTBap: Improving the diagnosis of tuberculosis in domestic ruminants through the use of new antigens and test platforms" was presented at the ICRAD meeting.

4) A poster titled "Are DST-F and P22 useful for the in vivo diagnosis of tuberculosis in Water buffalo?" was presented at the SISVET conference.

5) An abstract titled "Historical cattle movements have driven global *Mycobacterium bovis* transmission" was shared at the SMBE conference.

6) A poster titled "Temporal cluster of feline *Mycobacterium caprae* infection in Great Britain following consumption of a raw meat-based diet" was presented at the ECVPH conference.

7) A presentation titled "Progress of the CattleBCG Vaccine and the companion DIVA Test Field Trials" was presented at the AberTB conference.

8) A poster titled "Developing Bovine Immune Organoids for the Screening of Bovine Tuberculosis Vaccine Candidates" was presented at the VALIDATE Annual General Meeting.

c) National conferences:

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1) A presentation titled "Temporal cluster of feline *Mycobacterium caprae* infection in Great Britain following consumption of a raw meat-based diet" was presented at the NEEG training workshop.

2) A presentation titled "Evaluation of DST-F and P22 antigens for the immunological diagnosis of caprine tuberculosis" was presented at the AVEDILA National Symposium.

3) A presentation titled "Large-scale evaluation of the experimental DST-F antigen in the interferon-gamma release assay for the diagnosis of bovine tuberculosis" was presented at the AVEDILA National Symposium.

4) A presentation titled "Progress of the CattleBCG Vaccine and the companion DIVA Test Field Trials" was presented at the XL Farmcare vets meeting.

5) A presentation "An update on TB vaccination in badgers" was published as an online webinar on the Official Vet Conference website. Official Vet Conference Online - Official Vet Conference.

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

8

1) Next phase of cattle TB vaccine field trials. <https://doi.org/10.1002/vetr.5295>

2) A report titled "Vaccinating East Sussex Badgers – Descriptive epidemiological report on bovine tuberculosis in cattle herds from 2018 to 2023" was produced and shared with the external Vaccinating East Sussex Badgers (VESBA) project team via the Defra TB Programme.

3) 1. A written interview was given for the new WOAHA led publication "The State of the World's Animal Health": <https://www.woah.org/app/uploads/2025/05/the-state-of-the-worlds-animal-health-2025.pdf>

4) Herds needed for final phase of cattle vaccine field trial. <https://doi.org/10.1002/vetr.5633>

5) Bovine TB in cattle: badger control areas monitoring data up to 2024. <https://www.gov.uk/government/publications/bovine-tb-in-cattle-badger-control-areas-monitoring-data-up-to-2024>

6) Reports titled "2024 TB Epi reports for the Low-Risk Area (x7)" were uploaded to the .gov website. <https://www.gov.uk/government/publications/bovine-tb-epidemiology-reports-2024>

7) Reports titled "2024 TB Epi reports for the Edge Area (x11)" were uploaded to the .gov website. <https://www.gov.uk/government/publications/bovine-tb-epidemiology-reports-2024>

8) Reports titled "2024 Explanatory Supplement to the TB epi reports" were uploaded to the .gov website. <https://www.gov.uk/government/publications/bovine-tb-epidemiology-reports-2024>

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 : 2

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)	6
A	KOREA (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
ISO17025	PDF	ANIMAL PLANT HEALTH AGENCY - Certificate UK013916 - ISO 9001 - exp. 25-07-2026.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 WOA?H?

No

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

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 ISAT tuberculin standards	2025-06-02	Online	Participant	N/A
WOAH Ad-hoc committee on replacement of ISBT and ISAT tuberculin standards	2025-09-03	Online	Participant	N/A
WOAH Ad-hoc committee on replacement of ISBT and ISAT tuberculin standards	2025-11-25	Online	Participant	N/A

TOR10: NETWORK WITH WOA?H REFERENCE LABORATORIES

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

Yes

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

Yes

NETWORK/DISEASE	ROLE OF YOUR LABORATORY (PARTICIPANT, ORGANISER, ETC)	NO. PARTICIPANTS	PARTICIPATING WOA?H REF. LABS
Mammalian TB Reference Laboratories	Participant	5	UK, France, Spain, Argentina and USA

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

No

26. Did your laboratory collaborate with other WOA?H 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 WOA?H Reference Laboratories
Improving the diagnosis of tuberculosis in domestic ruminants through the use of new antigens and test platforms	To improve the diagnosis of tuberculosis in domestic ruminants through the use of new antigens and test platforms	Centro de Vigilancia Sanitaria Veterinaria (VISAVET), VISAVET Health Surveillance Centre, Universidad Complutense Madrid, Avenida Puerta de Hierro s/n, 28040 Madrid

TOR11: OTHER INTERLABORATORY PROFICIENCY TESTING

27. Did your laboratory organise or participate in inter-laboratory proficiency tests with laboratories other than WOA?H 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
VETQAS run a Gamma Interferon proficiency testing scheme (PT0065 Bovine TB) with two	Samples for scheme produced/provided by APHA	31	Gamma Interferon FI ISA	IRELAND, ISRAEL, ITALY, NEW ZEALAND, PORTUGAL, SWITZERLAND, UNITED

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distributions a year	produced/provided by APHA	15	Gamma Interferon ELISA	KINGDOM, UNITED STATES OF AMERICA,
For establishing a non-animal derived scheme (PT0215 Gamma Interferon mimetic assay for T cell activation) using spiked recombinant IFNg to overcome importation issues experienced with PT0065				

TOR12: EXPERT CONSULTANTS

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

Yes

Kind of consultancy	Location	Subject (facultative)
APHA participates in the WOAHP ad-hoc committee on replacement of international reference standards for tuberculin	online	Attended regular meeting of ad-hoc committee on replacement on international tuberculin standards. APHA facilitated laboratory work to support this effort by obtaining funding for guinea pig potency testing to be carried out at UKHSA Porton Down and testing reagents in APHA laboratories. Involved in discussions about freeze drying and storage of international tuberculin standards.
Contributed to the production of a roadmap for replacement of tuberculin with defined antigens at WOAHP's request	on line	Document sets out the strategic context, problem statement, solution overview, current status, transformative impact represented by seeking to replace tuberculin with DIVA compatible Tuberculin (DSTs) containing only RD1-dependent antigens for DIVA-capable testing in vaccination programs, and broader Molecularly Defined Tuberculin (MDTs) as PPD replacements for non-vaccinating regions. Roadmap produced for WOAHP ad-hoc committee on replacement of international reference standards for tuberculin.

29. Additional comments regarding your report:

No