

WOAH Reference Laboratory Reports Activities 2023

Activities in 2023

This report has been submitted : 27 mai 2024 10:58

Laboratory Information

Name of disease (or topic) for which you are a designated WOA Reference Laboratory:	Paratuberculosis
Address of laboratory:	Via Strada della Faggiola, 1
Tel.:	+390523523491
E-mail address:	matteo.ricchi@izsler.it
Website:	www.izsler.it
Name (including Title) of Head of Laboratory (Responsible Official):	Dr. Varisco Giorgio, General Director
Name (including Title and Position) of WOA Reference Expert:	Dr. Ricchi Matteo, Professional Executive
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			
commercial ELISA		217171	9897
Direct diagnostic tests			
Cultural test		97	0
qPCR-IS900 test		2490	0

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 (nonWOA-approved) and/or other diagnostic reagents to WOA Members?

No

4. Did your laboratory produce vaccines?

No

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

Yes

NAME OF THE NEW TEST OR DIAGNOSTIC METHOD DEVELOPED	DESCRIPTION AND REFERENCES (PUBLICATION, WEBSITE, ETC.)
cultural Double method incubation assay from bovine faeces	This information is reported in the following documents: MP 01/207 rev 3, PSV 01/207 rev 1 and RV 01/207 rev 1. These documents should be requested to: Servizio Assicurazione Qualità IZSLER, via Bianchi n. 9, 25124 Brescia, Italy. Phone:03022901; Fax: 0302425251; Email: saq.doc@izsler.it
IS900-qPCR assay from bovine faeces	Russo S, Giorgio G, Leo S, Arrigoni N, Garbarino C, Ricchi M. Validation of IS900- qPCR assay to assess the presence of Mycobacterium avium subs. paratuberculosis in faecal samples according to the OIE procedure. Prev Vet Med. 2022 Nov;208:105732. doi: 10.1016/j.prevetmed.2022.105732. Epub 2022 Aug 6. PMID: 35988391.

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?

No

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
ITALY	Information about the EU regulation 426 relative to the paratuberculosis. The requests come from other official laboratories or other official authorities.	By phone
ITALY	Technical information about the methods. The requests come from other official laboratories part of the Italian Nation Health System	By phone

TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES

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

No

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

Yes

Research need : 1

Please type the Research need: Developing of Reference Standard material for testing purposes, such as ELISA certified sera for different ruminants, lyophilised faecal specimens containing certified amount of Mycobacterium avium subsp. paratuberculosis to be used as reference material.

Relevance for WOAHS Standard Setting,

Relevance for the Codes or Manual Manual,

Field Diagnostics,

Animal Category Terrestrial,

Disease:

Paratuberculosis

Kind of disease (Zoonosis, Transboundary diseases) 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 - Chapter 3.1.16. Paratuberculosis (Johne's disease)

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:

Data are collected in the diagnostic management system in force in IZSLER and could be easily consulted. For every request, please refer to the expert.

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:

See for exemple these paper:s

Turco S, Russo S, Pietrucci D, Filippi A, Milanese M, Luzzago C, Garbarino C, Palladini G, Chillemi G, Ricchi M. High clonality of *Mycobacterium avium* subsp. *paratuberculosis* field isolates from red deer revealed by two different methodological approaches of comparative genomic analysis. *Front Vet Sci.* 2024 Feb 6;11:1301667. doi: 10.3389/fvets.2024.1301667. PMID: 38379925; PMCID: PMC10876796.

Filippi A, Garbarino C, Nava M, Russo S, Soares Filipe JF, Bianchi A, Corlatti L, Gugiatti A, Buccheri Pederzoli C, Pigoli C, Pedrotti L, Arrigoni N, Ricchi M, Bertoletti I, Luzzago C. Active surveillance of paratuberculosis in Alpine-dwelling red deer (*Cervus elaphus*). *Front Vet Sci.* 2024 Jan 25;11:1303096. doi: 10.3389/fvets.2024.1303096. PMID: 38332752; PMCID:

Gaffuri A, Barsi F, Magni E, Bergagna S, Dellamaria D, Ricchi M, De Paolis L, Galletti G, Arrigoni N, Lorenzi V, Fusi F, Prosperi A, Garbarino C. Paratuberculosis, Animal Welfare and Biosecurity: A Survey in 33 Northern Italy Dairy Goat Farms. *Animals (Basel).* 2023 Jul 18;13(14):2346. doi: 10.3390/ani13142346. PMID: 37508122; PMCID: PMC10376716.

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

1. Russo S, Cortimiglia C, Filippi A, Palladini G, Garbarino C, Massella E, Ricchi M. Validation of digital PCR assay for the quantification of *Mycobacterium avium* subsp. *paratuberculosis* in bovine faeces according to the ISO 20395:2019. *J Microbiol Methods.* 2023 Oct;213:106825. doi: 10.1016/j.mimet.2023.106825. Epub 2023 Sep 20. PMID: 37739126.

2. Gaffuri A., Barsi F., Magni E., Bergagna S., Dellamaria D., Ricchi M., De Paolis L., Galletti G., Arrigoni N., Lorenzi V., Fusi F., Prosperi A., Garbarino C.. Paratuberculosis, animal welfare and biosecurity: a survey in 33 northern Italy dairy goat farms – *Animals* 2023, 13, 2346. <https://doi.org/10.3390/ani13142346>

3. Scarpellini R., Giacometti F., Savini F., Arrigoni N., Garbarino C., Carnevale G., Mondo E., Piva S. Bovine paratuberculosis: results of a control plan in 64 dairy farms in a 4-year period. *Preventive Veterinary Medicine Volume 215, June 2023, 105923*

b) International conferences:

2

1. Filippi A., Garbarino C., Nava M., Russo S., Filipe J., Bianchi A., Corlatti L., Gugiatti A., Buccheri Pederzoli C., Pigoli C., Pedrotti L., Arrigoni N., Ricchi M., Bertoletti I., Luzzago C. "Sorveglianza attiva nei confronti della paratuberculosis nel cervo (*Cervus elaphus*) nel Parco Nazionale dello Stelvio". *Atti del 40èmes Rencontres de Groupe d'Etudes sur l'Eco-pathologie de la Faune Sauvage de Montagne, Saluzzo, 21-24 settembre 2023.*

2. Dellamaria D., Paiusco MC., Garbarino C., Bergagna S., Magni E., Lorenzi V., Fusi F., Gaffuri A. "Welfare and biosecurity evaluation in dairy goat farms". *International Sheep Veterinary Congress (ISVC) (10th: Seville, Spain: 6th-10th March 2023). AnimSci Proc. -Vol.14 1 (2023) – p 213-214 (P- 009) [Htttts://doi.org/10.1016/j.ansci.2023.01.287](https://doi.org/10.1016/j.ansci.2023.01.287)*

c) National conferences:

3

1) IX "Congresso nazionale sulla paratuberculosis", in collaboration with Milan University, Department of Veterinary Medicine and Animal Sciences, date 27.01.2023 in Lodi, Italy, with the following oral communications:

a) Linee guida Nazionali: novità alla luce di AHL e decreti attuativi (CA Garbarino, IZSLER).

b) Paratuberculosis in Lombardia: facciamo il punto (M.Boldini, IZSLER)

- c) *Paratuberculosis, benessere e biosicurezza nella capra da latte: indagine in allevamenti del Nord Italia* (A. Gaffuri, IZSLER)
 d) *MAP e Sicurezza Alimentare: focus* (M. Ricchi, IZSLER)

2) XXIV Congresso Nazionale SIPAOC (Società Italiana patologia ed allevamento ovino e caprino), Viterbo, 22-23 febbraio 2023, with the following oral communications:
 a) Garbarino C., Gaffuri A., Barsi F., Massella E., Ricchi M., Arrigoni N. "Linee guida per la paratuberculosis e Piano di gestione sanitaria negli ovini e caprini". Atti XXIV Congresso Nazionale SIPAOC (Società Italiana patologia ed allevamento ovino e caprino), Viterbo, 22-23 febbraio 2023.

b) Gaffuri A., Garbarino C., Bergagna S., Dellamaria D., Tranquillo V., Magni E., De Paolis L., Lorenzi V., Fusi F. "La check list ClassyFarm di valutazione della biosicurezza come strumento di prevenzione delle principali malattie infettive nella capra da latte". Atti XXIV Congresso Nazionale SIPAOC (Società Italiana patologia ed allevamento ovino e caprino), Viterbo, 22-23 febbraio 2023.

3) XXII Congresso of the "Nazionale della Società di Diagnostica di laboratorio Veterinaria" (SIDILV), Brescia, 11-13 ottobre 2023, with the following poster contribution:
 a) Cosciani-Cunico E., Dalzini E., Barsi F., Ducoi S., Russo S., Monastero P., Abdul ME., Arnaboldi S., Losio M.N., Ricchi M. "Riduzione logaritmica di *Mycobacterium avium* subsp. *paratuberculosis* durante la produzione di mozzarella: confronto tra dato predetto e osservato". Atti del XXII congresso Nazionale della Società di Diagnostica di laboratorio Veterinaria (SIDILV), Brescia, 11-13 ottobre 2023.

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

2

1) Technical workshop in the framework of the XXII congresso Nazionale della Società di Diagnostica di laboratorio Veterinaria (SIDILV), Brescia, 11-13 ottobre 2023. Title: "Tuberculosis e paratuberculosis: diagnosi di laboratorio". Lectures done by people of the WOAHP Reference Laboratory for Paratuberculosis:

- Paratuberculosis: eziopatogenesi, epidemiologia e test disponibili (C. Garbarino)
- Test diretti: coltura e PCR (M. Ricchi)
- Test indiretti: ELISA (M. Ricchi)
- Parte interattiva pratica (A. Filippi, S. Russo).

Materials relative to the paratuberculosis available on demand to the Matteo Ricchi

2) Arrigoni N., Cerioli M., Nassuato C., Farioli M., Boldini M., Gradassi M., Ventura G., Paterlini F., Rosignoli C., Vezzoli F., Garbarino CA., Bellini S., Santi A., Ruocco L., Lomolino R., Tamba M. "Bovine paratuberculosis in Italy: review of the national guidelines after eight years of their application." *Bull Int Dairy Fed* - Vol. 523 (2023). - p 22-32. - 9 bib ref. <https://doi.org/10.56169/UEAO1249> [Nr. Estr. 9210].

TOR7: SCIENTIFIC AND TECHNICAL TRAINING

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

Yes

- a) Technical visit : 0
 b) Seminars : 1
 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
B	KOSOVO	4

TOR8: QUALITY ASSURANCE

18. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)	
ISO17025	508908.pdf	508908.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
ELISA test from blood, sera and milk	ACCREDIA
qPCR-IS900 from faeces, milk and tissues	ACCREDIA
Culture from faeces	ACCREDIA
Culture from milk	ACCREDIA

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

Yes

The laboratory works according to the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Chapter 1.1.4 and WHO Laboratory biosafety manual.

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?

No

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

No

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
Material transfer agreements signed with the other two experts of the reference laboratories for paratuberculosis	The scope of these material transfer agreements is to exchange materials (sera for indirect test) and faeces (for direct test) in order to harmonise diagnostic procedures	Dr. Virginie Poisson from ANSES (France) Dr. Bernardo Alonso from SENASA (Argentina)

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?

Yes

Purpose for inter-laboratory test comparisons ¹	Role of your reference laboratory (organizer/participant)	No. participating laboratories	Name of the Test	WOAHP Member Countries
Direct diagnosis of paratuberculosis by bovine fecal specimens	Organizer	3	Cultural assay	ITALY,
Direct diagnosis of paratuberculosis by bovine fecal specimens	Organizer	18	qPCR	ITALY,
Indirect diagnosis of paratuberculosis test by serum	Participant	45	ELISA test for serum	BELGIUM, CZECH REPUBLIC, DENMARK, FRANCE, GERMANY, HUNGARY, IRELAND, ITALY, POLAND, SOUTH AFRICA, SPAIN, SWEDEN, SWITZERLAND, THE NETHERLANDS, UNITED KINGDOM,
Direct paratuberculosis test from bovine faecal specimens	Participant	7	IS900-qPCR	ITALY, UNITED KINGDOM,
Direct paratuberculosis test from bovine faecal specimens	Participant	7	Cultural assay	ITALY, UNITED KINGDOM,
				BELGIUM, DENMARK, FRANCE, GERMANY,

Indirect diagnosis of paratuberculosis test by milk	Participant	33	ELISA test for milk	HUNGARY, IRELAND, ISRAEL, ITALY, POLAND, SOUTH AFRICA, SPAIN, SWEDEN, SWITZERLAND, THE NETHERLANDS, UNITED KINGDOM,
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TOR12: EXPERT CONSULTANTS

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

No

29. Additional comments regarding your report:

No