

# WOAH Reference Laboratory Reports Activities 2025

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## LABORATORY INFORMATION

<b>*Name of disease (or topic) for which you are a designated WOAHO Reference Laboratory:</b>	Paratuberculosis
<b>*Address of laboratory:</b>	Via Strada della Faggiola, 1
<b>*Tel:</b>	+390523524253
<b>*E-mail address:</b>	matteo.ricchi@izsler.it
<b>Website:</b>	www.izsler.it
<b>*Name (including Title) of Head of Laboratory (Responsible Official):</b>	Dr. Varisco Giorgio, General Director
<b>*Name (including Title and Position) of WOAHO Reference Expert:</b>	Dr. Ricchi Matteo, Professional Executive
<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 WOAHO Manual (Yes/No)	Total number of test performed last year	
		Nationally	Internationally
<b>Indirect diagnostic tests</b>			
ELISA test on blood and milk	Yes	194049	21
<b>Direct diagnostic tests</b>			
Culture	Yes	109	0
PCR	Yes	1888	0

## TOR2: REFERENCE MATERIAL

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

No

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

No

4. Did your laboratory produce vaccines?

Not applicable

5. Did your laboratory supply vaccines to WOAHO Members?

## TOR3: NEW PROCEDURES

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

No

Matteo Ricchi - - ITALY

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.)
PCR targeting IS900	Extension of validation of the method to goat and sheep. This extension encompassed both the confirming of LOD for the faeces of goat and sheep and, just for goat, the determination of new diagnostic performances (diagnostic sensitivity and specificity) according to Bayesian approach. Moreover, in order to confirm the specificity of the method, the inclusivity was further tested by an in silico analysis. Briefly, the sequences amplified by the primers and probe of the test method were compared with a dataset containing 495 genomes of MAP field isolates from cattle, goats, deer, sheep, humans and antelopes (saber-horned oryxes) using BLAST. The results returned showed 100% homology within all strains analysed with a value of $e < 10^{-12}$ .
PCR targeting f57	Extension of validation of the method for confirmatory purposes to MAP field isolates globally recovered worldwide from different species, including humans by in silico analyses. Moreover, in order to confirm the specificity of the method, the inclusivity was further tested by an in silico analysis. Briefly, the sequences amplified by the primers and probe of the test method were compared with a dataset containing 495 genomes of MAP field isolates from cattle, goats, deer, sheep, humans and antelopes (saber-horned oryxes) using BLAST, to verify the presence of these sequences in the genomes of these bacteria and to expand the knowledge base on the application of this test method to non-bovine species. The results returned showed 100% homology within all strains analysed with a value of $e < 10^{-50}$ .

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

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

## 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
IRELAND	Request of information about the use of MGIT for the culture of MAP	I received a message from Dr Ramovic of the Bacteriology/Parasitology Division of the Department of Agriculture, Food and the Marine, Ireland. She asked me for information on using a cultural system to isolate MAP field isolates from diagnostic specimens using semi-automatic systems and liquid media. I suggested she contact two colleagues in Europe who are currently using the system she is interested in. I have involved in my reply also the other two WOAHS Paratuberculosis experts, Dr. Poisson and Dr. Alonso.
HUNGARY	Questions about the performance of different ELISA tests for diagnosing Mycobacterium avium subspecies paratuberculosis (MAP). Discussion of doubtful results obtained and potential issues linked to these results.	I received a message from Dr Tóth at the National Food Chain Safety Office, Directorate of Veterinary Diagnostics, Department of Immunology and Sampling, National Reference Laboratory, Hungary, regarding some dubious ELISA results obtained by certain laboratories. The message provided a detailed response and attempted to clarify a few points that could be important for this diagnosis. I have involved in my reply also the other two WOAHS Paratuberculosis experts, Dr. Poisson and Dr.

## TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES

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

No

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

Yes

### Research need : 1

**Please type the Research need:** Developing of reference material for PCR and ELISA assays

**Relevance for WOAHP Standard Setting,**

**Relevance for the Code or Manual Manual,**

**Field Diagnostics,**

**Animal Category** Terrestrial,

**Disease:**

**Kind of disease (Zoonosis, Transboundary diseases)** Transboundary diseases,

**Additional keywords if needed: One keyword per entry**

standards, cultures, PCRs

**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:* Chapter: 3.1.17. Paratuberculosis (Johne's disease)

**Notes:**

*Answer:* I would recommend and suggest to the WOAHP to organise the activity of producing international positive standards (with known load of MAP) for standardisation purposes

## 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 on the prevalence and spread of the disease within the area of responsibility. Modelling of previous data on MAP survival in the cheese-making production process.

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:

Molecular epidemiological data on field isolates recovered during the year. Evaluation of a plan aimed at reducing the prevalence of paratuberculosis in dairy herds.  
Evaluation of the potential risk of MAP transmission through pasture sharing in the interface between domestic and wild ruminants.

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: Bonilauri P, Rosamilia A, Benedetti S, Daminelli P, Losio MN, Moreno A, Ricchi M, Santini N, Varisco G, Vianello S, Merialdi G. Can the Grana Padano and Parmigiano Reggiano production process guarantee a reduction in pathogenic microorganisms equivalent to the pasteurization process? *Ital J Food Saf.* 2025 Dec 16. doi: 10.4081/ijfs.2025.14524.

2: Filippi A, Ventura G, Lamontanara A, Orrù L, Ostanello F, Frontoni R, Mazzera L, Tuccia E, Ricchi M, Garbarino C. The Results After One Year of an Experimental Protocol Aimed at Reducing Paratuberculosis in an Intensive Dairy Herd. *Animals (Basel).* 2025 Sep 15;15(18):2695. doi: 10.3390/ani15182695.

3: Garbarino C, Nava M, Filippi A, Forti A, Russo S, Barsi F, Bianchi A, Filipe J, Arrigoni N, Pedrotti L, Corlatti L, Ricchi M, Luzzago C. Contamination of alpine pastures by *Mycobacterium avium* subsp. *paratuberculosis*: Evaluation of cattle and red deer contribution through environmental fecal samples. *Vet Microbiol.* 2025 Oct;309:110661. doi: 10.1016/j.vetmic.2025.110661.

b) International conferences:

3

1) Paratuberculosis in Italy: where are we? Garbarino C., Cerioli M., Nassuato C., Boldini M., Gradassi M., Ventura G., Rosignoli C., Tonni M., Maisano M. A., Ricchi M., Bellini S., Santi A., Ruocco Li, Lomolino R., Luppi A., Diana P., Tamba M. *European Buiatric Congress 2025, Nantes 15-16 may 2025.*

2) Pasture shared by wild and domestic ruminants: monitoring paratuberculosis in red deer. C. Garbarino, M. Nava, A. Filippi, A. Forti, S. Russo F. Barsi, A. Bianchi, J. Filipe, I. Bertoletti, L. Pedrotti, L. Corlatti, M. Ricchi, C. Luzzago. *Congress of the Mediterranean Federation for Health and Production of Ruminants (Fe.Me.S.P.Rum.), Bologna 4-6 september 2025*

3) Surveillance of paratuberculosis in Alpine red deer (*Cervus elaphus*) at the interface between domestic and wild animals. Filippi A., Nava M., Bianchi A., Corlatti L., Gugiatti A., Pedrotti L., Ricchi M., Bertoletti I., Luzzago C., Garbarino C. *The 5th International Conference on Life Science and Agriculture of Albania 2030 (ICOALS) 3 – 5 November 2025 - Tirana, Albania*

c) National conferences:

4

1) Aggiornamenti su paratubercolosi e tubercolosi animale. University of Parma, Parma, Italy 12sd December 2025. Dr. Ricchi gave a lecture about new method for the quantification of MAP in faeces by dPCR and qPCR, underlying some validation points. Dr. Garbarino gave a lecture dedicated to the Italian control plan for the managing of paratuberculosis. Dr. Filippi showed data about our experience in the control of paratuberculosis in dairy herds.

2) Aggiornamenti e nuove prospettive nella gestione e controllo della Paratubercolosi. 24th October 2025, Sassari, Italy. Dr. Ricchi gave a lecture about the role of MAP as zoonotic agent. Dr. Garbarino gave two lectures: one dedicated to the Italian control plan for the managing of paratuberculosis and the other dedicated to the presence of Paratuberculosis in the wild red deer populating the Stelvio Park, Italy.

3) Paratubercolosi: facciamo il punto. 4th November 2025, Rome, Italy. Dr. Ricchi gave a lecture about the role of MAP as zoonotic agent. Dr. Garbarino gave a lecture dedicated to the Italian control plan for the managing of paratuberculosis

4) Paratubercolosi. La malattia e le Linee guida per l'adozione dei piani di controllo e per l'assegnazione della qualifica sanitaria degli allevamenti. 12sd November 2025, Catanzaro, Italy. Dr. Ricchi gave two lectures: one dedicated to the parthenogenesis of Paratuberculosis and the other one about the role of MAP as zoonotic agent. Dr. Garbarino gave two lectures: one dedicated to the Italian control plan for the managing of paratuberculosis and the other dedicated to the epidemiology and diagnosis of Paratuberculosis in both domestic and wild ruminants.

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

1

Technical meeting with people from other laboratories belonging to different Italian Istituti Zooprofilattici laboratories, to discuss the latest proficiency test organised by the National Reference Centre for Paratuberculosis, and to present the new projects underway at our laboratory.

## 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 : 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	POLAND	1

## 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	pdf	508908.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
ELISA in blood and milk	ACCREDIA
qPCR targeting IS900 sequence in faeces, milk and tissue	ACCREDIA
Cultural assay (double incubation method) in faeces	ACCREDIA
Molecular assay for the identification of Mycobacterium avium subsp. paratuberculosis by field isolates amplifying the F57 sequence	ACCREDIA
Cultural assay for 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. Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities and TO THE 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. Are you a member of a network of 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 during the past 2 years?

Yes

Purpose of the proficiency test:	Role of your Reference Laboratory (organiser/ participant)	No. participating Laboratories	Participating WOAHP Ref. Labs/ organising WOAHP Ref Lab
The aim was to evaluate the ELISA assays currently available at the three laboratories designated by WOAHP for paratuberculosis. A small panel of positive and negative sera derived from a larger panel employed by the Italian National Centre for Paratuberculosis to organise the National Ring Trial was sent to the other two WOAHP laboratories.	Organiser and participant	3	Both the other two experts have participated

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?

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 during the past 2 years?

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
ELISA test on milk	Partecipant	30	2025 International Proficiency Testis Scheme (PTS) for Mycobacterium avium subsp. paratuberculosis antibody detection in milk	BELGIUM, DENMARK, FINLAND, FRANCE, GERMANY, HUNGARY, IRELAND, ISRAEL, ITALY, LITHUANIA, NEW ZEALAND, SOUTH AFRICA, SPAIN, SWEDEN, THE NETHERLANDS, UNITED KINGDOM,
Elisa test on blood and serum	Partecipant	37	2025 International Proficiency Testis Scheme (PTS) for Mycobacterium avium subsp. paratuberculosis antibody detection in serum	BELGIUM, CZECH REPUBLIC, DENMARK, FINLAND, FRANCE, GERMANY, GREECE, IRELAND, ITALY, LITHUANIA, SOUTH AFRICA, SPAIN, SWEDEN, SWITZERLAND, THE NETHERLANDS, UNITED KINGDOM,
Cultural assay	Partecipant	6	16707/BA PT0127: Mycobacterium avium subsp. paratuberculosis (Johnes) culture	ITALY, UNITED KINGDOM,
ELISA test on milk	Partecipant	31	2024 International Proficiency Testis Scheme (PTS) for Mycobacterium avium subsp. paratuberculosis antibody detection in milk	BELGIUM, DENMARK, FRANCE, GERMANY, HUNGARY, IRELAND, ISRAEL, ITALY, SOUTH AFRICA, SPAIN, SWEDEN, SWITZERLAND, THE NETHERLANDS, UNITED KINGDOM,
Elisa test on blood and serum	Partecipant	45	2025 International Proficiency Testis Scheme (PTS) for Mycobacterium avium subsp. paratuberculosis antibody detection in serum	AUSTRIA, BELGIUM, CZECH REPUBLIC, DENMARK, FRANCE, GERMANY, GREECE, HUNGARY, IRELAND, ITALY, NEW CALEDONIA, PORTUGAL, SOUTH AFRICA, SPAIN, SWEDEN, SWITZERLAND, THE NETHERLANDS, UNITED KINGDOM,
ELISA test on serum (cow, goat, buffalo, sheep) and milk (cow)	Organizer	33	PROVA VALUTATIVA (PROFICIENCY TEST) PARATUBERCOLOSI: DIAGNOSI SIEROLOGICA (ELISA) DISTRIBUZIONE (ROUND): 01/2024	ITALY,
Cultural and PCR assays in faeces	Organizer	20	PROVA VALUTATIVA (PROFICIENCY TEST) PARATUBERCOLOSI: DIAGNOSI SIEROLOGICA (COLTURA E/O PCR) DISTRIBUZIONE (ROUND): 01/2025	ITALY,
Cultural assay	Partecipant	7	16590/BA PT0127: Mycobacterium avium subsp. paratuberculosis (Johnes) culture	ITALY, UNITED KINGDOM,
Cultural assay	Partecipant	6	16692/BA PT0127: Mycobacterium avium subsp. paratuberculosis (Johnes) culture	ITALY, UNITED KINGDOM,

## TOR12: EXPERT CONSULTANTS

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

No

29. Additional comments regarding your report:

*This year, together with the other experts, we have revised the paratuberculosis chapter of the WOA?H Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. Moreover, I was appointed to and participated in the commission for Dr Badia Bringué's PhD graduation at the Department of Genetics, Physical Anthropology and Animal Physiology at the University of the Basque Country, Spain.*