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 WOAH 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 WOAH 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

<table>
<thead>
<tr>
<th>Diagnostic Test</th>
<th>Indicated in WOAH Manual (Yes/No)</th>
<th>Total number of test performed last year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indirect diagnostic tests</td>
<td></td>
<td></td>
</tr>
<tr>
<td>commercial ELISA</td>
<td>Yes</td>
<td>2171171</td>
</tr>
<tr>
<td>Direct diagnostic tests</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cultural test</td>
<td>Yes</td>
<td>97</td>
</tr>
<tr>
<td>qPCR-IS9000 test</td>
<td>Yes</td>
<td>2490</td>
</tr>
</tbody>
</table>

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 (non-WOAH-approved) and/or other diagnostic reagents to WOAH Members?
   No
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?
Yes

<table>
<thead>
<tr>
<th>NAME OF THE NEW TEST OR DIAGNOSTIC METHOD DEVELOPED</th>
<th>DESCRIPTION AND REFERENCES (PUBLICATION, WEBSITE, ETC.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>cultural Double method incubation assay from bovine faeces</td>
<td>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: 030245251; Email: <a href="mailto:saq.doc@izsler.it">saq.doc@izsler.it</a></td>
</tr>
</tbody>
</table>

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?
No

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

<table>
<thead>
<tr>
<th>NAME OF THE WOAH MEMBER COUNTRY RECEIVING A TECHNICAL CONSULTANCY</th>
<th>PURPOSE</th>
<th>HOW THE ADVICE WAS PROVIDED</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITALY</td>
<td>Information about the EU regulation 426 relative to the paratuberculosis. The requests come from other official laboratories or other official authorities.</td>
<td>By phone</td>
</tr>
<tr>
<td>ITALY</td>
<td>Technical information about the methods. The requests come from other official laboratories part of the Italian Nation Health System</td>
<td>By phone</td>
</tr>
</tbody>
</table>

**TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES**

12. Did your laboratory participate in international scientific studies in collaboration with WOAH Members other than the own?
No

13. In exercising your activities, have you identified any regulatory research needs* relevant for WOAH?
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 WOAH Standard Setting,
Relevance for the Codes or Manual Manual,
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 example these papers:


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)

- Articles published in peer-reviewed journals:

  3


- International conferences:

  2


- National conferences:

  3

  1) IX Congresso nazionale sulla paratubercolosi”, in collaboration with Milan University, Department of Veterinary Medicine and Animal Sciences, date 27.01.2023 in Lodr, 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 caprina), Viterbo, 22-23 febbraio 2023, with the following oral communications:

3) XXIII Congresso di Laboratorio di Laboratorio Veterinario "SIDILV", Brescia, 11-13 ottobre 2023, with the following poster contribution:

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

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: 0
   b) Seminars: 1
   c) Hands-on training courses: 0
   d) Internships (>1 month) 0

<table>
<thead>
<tr>
<th>Type of technical training provided (a, b, c or d)</th>
<th>Country of origin of the expert(s) provided with training</th>
<th>No. participants from the corresponding country</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>KOSOVO</td>
<td>4</td>
</tr>
</tbody>
</table>

TOR8: QUALITY ASSURANCE

18. Does your laboratory have a Quality Management System?
   Yes

<table>
<thead>
<tr>
<th>Quality management system adopted</th>
<th>Certificate scan (PDF, JPG, PNG format)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO17025</td>
<td>508908.pdf</td>
</tr>
</tbody>
</table>

19. Is your quality management system accredited?
   Yes

<table>
<thead>
<tr>
<th>Test for which your laboratory is accredited</th>
<th>Accreditation body</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELISA test from blood, sera and milk</td>
<td>ACCREDIA</td>
</tr>
<tr>
<td>qPCR-15900 from faeces, milk and tissues</td>
<td>ACCREDIA</td>
</tr>
<tr>
<td>Culture from faeces</td>
<td>ACCREDIA</td>
</tr>
<tr>
<td>Culture from milk</td>
<td>ACCREDIA</td>
</tr>
</tbody>
</table>

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 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 your laboratory organise or participate in inter-laboratory proficiency tests with WOAH Reference Laboratories designated for the same pathogen?

No

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?

Yes

<table>
<thead>
<tr>
<th>TITLE OF THE PROJECT OR CONTRACT</th>
<th>SCOPE</th>
<th>NAME(S) OF RELEVANT WOAH REFERENCE LABORATORIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material transfer agreements signed with the other two experts of the reference laboratories for paratuberculosis</td>
<td>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</td>
<td>Dr. Virginie Poisson from ANSES (France) Dr. Bernardo Alonso from SENASA (Argentina)</td>
</tr>
</tbody>
</table>

**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?

Yes

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

**Participants:**
- HUNGARY,
- IRELAND,
- ISRAEL,
- ITALY,
- POLAND,
- SOUTH AFRICA,
- SPAIN,
- SWEDEN,
- SWITZERLAND,
- THE NETHERLANDS,
- UNITED KINGDOM,

**ELISA test for milk**

**TOR12: EXPERT CONSULTANTS**

28. Did your laboratory place expert consultants at the disposal of WOAH?
   No

29. Additional comments regarding your report:
   No