WOAH Reference Laboratory Reports Activities 2023
Activities in 2023
This report has been submitted: 24 avril 2024 12:39

Laboratory Information

Name of disease (or topic) for which you are a designated WOAH Reference Laboratory: Leishmaniosis

Address of laboratory: Istituto Zooprofilattico Sperimentale della Sicilia (IZSSi), National Reference Centre for Leishmaniasis (C.Re.Na.L.), via Gino Marinuzzi 3, 90129, Palermo

Tel.: 39-091 656.53.68

E-mail address: fabrizio.vitale@izssicilia.it

Website: https://crenal.izssicilia.it/

Name (including Title of Head of Laboratory (Responsible Official)): Dr. Salvatore Seminara, Official Manager

Name (including Title and Position) of WOAH Reference Expert: Dr. Fabrizio Vitale, Molecular Biology Dept. Director, National Reference Center for Leishmaniasis (C.Re.Na.L.).

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>Immunofluorescence Test (IFAT)</td>
<td>NATIONALLY: 4405</td>
<td>INTERNATIONALLY: 483</td>
</tr>
<tr>
<td>Elisa Test</td>
<td>NATIONALLY: 0</td>
<td>INTERNATIONALLY: 60</td>
</tr>
</tbody>
</table>

Direct diagnostic tests

<table>
<thead>
<tr>
<th>Diagnostic Test</th>
<th>Nationally</th>
<th>Internationally</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leishmania culture</td>
<td>354</td>
<td>0</td>
</tr>
<tr>
<td>Real Time PCR</td>
<td>1284</td>
<td>0</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 (nonWOAH-approved) and/or other diagnostic reagents to WOAH Members?

Yes

<table>
<thead>
<tr>
<th>TYPE OF REAGENT AVAILABLE</th>
<th>RELATED DIAGNOSTIC TEST</th>
<th>PRODUCED/ PROVIDE</th>
<th>AMOUNT SUPPLIED NATIONALLY (ML, MG)</th>
<th>AMOUNT SUPPLIED INTERNATIONALLY (ML, MG)</th>
<th>NO. OF RECIPIENT WOAH MEMBER COUNTRIES</th>
<th>COUNTRY OF RECIPIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>positive dog control serum</td>
<td>IFAT</td>
<td>PRODUCED</td>
<td>70.32 ml</td>
<td>0.54 ml</td>
<td>5</td>
<td>GREECE, ITALY, NORTH MACEDONIA (REP. OF), SOUTH AFRICA, SPAIN,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ITALY, NORTH</td>
</tr>
</tbody>
</table>

Negative dog control
serum IFAT PRODUCED 70.32 ml 0.54 ml 5 MACEDONIA (REP. OF), SOUTH AFRICA, SPAIN,
positive dog control serum ELISA PRODUCED 0 6.75 2 ITALY, SPAIN,
NEGATIVE dog control serum ELISA PRODUCED 0 6.75 2 ITALY, SPAIN,
Slide antigens KIT IFAT PRODUCED 2344 18 5 GREECE, ITALY, NORTH MACEDONIA (REP. OF), SOUTH AFRICA, SPAIN,
immunofluorescent dog conjugate IFAT PROVIDE 93 ml 1 ml 5 GREECE, ITALY, NORTH MACEDONIA (REP. OF), SOUTH AFRICA, SPAIN,
positive cat control serum IFAT PRODUCED 4.02 ml 0 1 ITALY,
negative cat control serum IFAT PRODUCED 4.02 ml 0 1 ITALY,
immunofluorescent cat conjugate IFAT PROVIDE 5.36 ml 0 1 ITALY,
Leishmania infantum DNA Real time pcr PRODUCED 0.65 ml 0 1 ITALY,
Real time Reagent probe Real time pcr PROVIDE 0.1 ml 0 1 ITALY,
Real time Reagent primers Real time pcr PROVIDE 0.16 ml 0 1 ITALY,
Leishmania culture culture PRODUCED 14 ml 0 1 ITALY,

4. Did your laboratory produce vaccines?
No

5. Did your laboratory supply vaccines to WOAH Members?
Not applicable

**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>
</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?
Yes

<table>
<thead>
<tr>
<th>NAME OF WOAH MEMBER COUNTRY SEEKING ASSISTANCE</th>
<th>DATE</th>
<th>WHICH DIAGNOSTIC TEST USED</th>
<th>NO. SAMPLES RECEIVED FOR PROVISION OF DIAGNOSTIC SUPPORT</th>
<th>NO. SAMPLES RECEIVED FOR PROVISION OF CONFIRMATORY DIAGNOSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORTH MACEDONIA (REP. OF)</td>
<td>2023-01-31</td>
<td>IFAT</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>SPAIN</td>
<td>2023-02-07</td>
<td>IFAT</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>SPAIN</td>
<td>2023-02-07</td>
<td>IFAT</td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>
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>SPAIN</td>
<td>Quality assurance</td>
<td>IFAT Proficiency test and Reference Material</td>
</tr>
<tr>
<td>SPAIN</td>
<td>Quality assurance</td>
<td>IFAT Proficiency test and Reference Material</td>
</tr>
<tr>
<td>GREECE</td>
<td>Quality assurance</td>
<td>IFAT Proficiency test and Reference Material</td>
</tr>
<tr>
<td>GREECE</td>
<td>Quality assurance</td>
<td>IFAT Proficiency test and Reference Material</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>Quality assurance</td>
<td>IFAT Proficiency test and Reference Material</td>
</tr>
<tr>
<td>ITALY</td>
<td>Quality assurance</td>
<td>IFAT Proficiency test and Reference Material</td>
</tr>
<tr>
<td>BELGIUM</td>
<td>Quality assurance</td>
<td>remote Leishmania ELISA technical opinion request</td>
</tr>
<tr>
<td>ITALY</td>
<td>Quality assurance</td>
<td>remote molecular Leishmania technical opinion request</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:** In section 3.1.11 on Leishmania in the WOAH manual, it would be appropriate to include the Cat diagnostic algorithm

**Relevance for WOAH** Disease Control,

**Relevance for the Codes or Manual** Manual,

**Field** Diagnostics,

**Animal Category** Terrestrial,

**Disease:** Leishmaniosis

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

**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:** 3.1.11 on Leishmania

**Notes:**

Answer: In section 3.1.11 on Leishmania in the WOAH manual, it would be appropriate to include the Cat diagnostic algorithm

**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:**

national epizootiological report 2023 provided to the ministry of health of Italy
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:

November 2023

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

b) International conferences:

3
CONVEGNO ISWAVLD 2023 - 29 June - 1 July 2023 - Lyon, France
P-79 - New phytatherapeutic approaches in the treatment of canine leishmaniasis: leishmanicidal and immunomodulatory activity of phytocomplexes in in vitro models of Leishmania infantum
XII European Congress of Entomology (ECE 2023), in Heraklion, Crete, on 16-20 October 2023
OC270. Climate change and adaptations: presence and trophism of sandflies on winter in Sicily
“BVD’s One Health perspective: focus on Leishmaniasis” che si è tenuto giorno 04 Maggio 2023 on line “Awareness-raising workshop on Vector Borne Diseases. One Health perspective” nella sezione One Health drugs against parasitic vector borne diseases in Europe and beyond OneHealthdrugs Cost Action CA21111

c) National conferences:

3
CONVEGNO: 76° Convegno SISVET Bari, 21-23 giugno 2023
Titolo: IN VITRO EVALUATION OF COMPATIBILITY OF FELINE TYPE-B BLOOD WITH CANINE AND FELINE BLOOD OF DIFFERENT BLOOD TYPE
“LA LEISHMANIOSI IN OTTICA ONE-HEALTH” organizzato dalla regione Emilia Romagna che si è tenuto presso la Sala XX maggio - Terza Torre, sede della regione Emilia Romagna - BOLOGNA, Viale della Fiera, 8 il 23 maggio 2023
“LEISHMANIOSI ANIMALE E UMANA ESEMPIO DI ONE HEALTH - IL CONTROLLO ENTOMOLOGICO DEI VETTORI AMBIENTALI ED I PIANI DI SORVEGLIANZA SANITARIA” che si è tenuto il 16-17 maggio 2023 presso l’ Istituto Zooprofilattico Sperimentale Sicilia, nella sezione di Catania;

d) 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 : 1
b) Seminars : 0
c) Hands-on training courses: 4
d) Internships (>1 month) 7

<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>A</td>
<td>ITALY</td>
<td>1</td>
</tr>
<tr>
<td>C</td>
<td>ITALY</td>
<td>1</td>
</tr>
</tbody>
</table>
**TOR8: QUALITY ASSURANCE**

18. Does your laboratory have a Quality Management System?
   
   Yes
   
   Quality management system adopted | Certificate scan (PDF, JPG, PNG format)
   ---- | ----
   UNI CEI EN ISO/IEC 17025 2018 | PDF
   
   Certificate of Accreditation n. 0246L.pdf

19. Is your quality management system accredited?

   Yes

   Test for which your laboratory is accredited | Accreditation body
   ---- | ----
   IFAT TEST | IFAT TEST
   REAL TIME PCR | REAL TIME PCR
   LEISHMANIA ISOLATION | LEISHMANIA ISOLATION

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

   Yes

   See Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Chapter 1.1.4

**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

<table>
<thead>
<tr>
<th>Title of event</th>
<th>Date (mm/yy)</th>
<th>Location</th>
<th>Role (speaker, presenting poster, short communications)</th>
<th>Title of the work presented</th>
</tr>
</thead>
<tbody>
<tr>
<td>“BVD’s One Health perspective: focus on Leishmaniasis”</td>
<td>2023-05-01</td>
<td>On line</td>
<td>SPEAKER</td>
<td>“Awareness-raising workshop on Vector Borne Diseases. One Health perspective”</td>
</tr>
</tbody>
</table>

**TOR10: NETWORK WITH WOAH REFERENCE LABORATORIES**

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

   Not applicable (only WOAH Reference Laboratory designated for the disease)

24. Do you network (collaborate or share information) with other WOAH Reference Laboratories designated for the same pathogen?

   Not applicable (Only WOAH Reference Laboratory designated for the disease)

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

   Not applicable (Only WOAH Reference Laboratory designated for the disease)

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?

   Not applicable (Only WOAH Reference Laboratory designated for the disease)

**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>IFAT Test for the leishmaniasis</td>
<td>GREECE, ITALY, NORTH MACEDONIA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IFAT</td>
<td>ORGANIZER</td>
<td>9</td>
<td>IFAT Test for Leishmaniasis diagnosis</td>
<td>GREECE, ITALY, NORTH MACEDONIA (REP OF), SOUTH AFRICA, SPAIN,</td>
</tr>
<tr>
<td>------</td>
<td>-----------</td>
<td>---</td>
<td>-------------------------------------</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>ELISA</td>
<td>ORGANIZER</td>
<td>1</td>
<td>ELISA Test for the leishmaniasis diagnosis</td>
<td>SPAIN,</td>
</tr>
<tr>
<td>REAL TIME PCR</td>
<td>ORGANIZER</td>
<td>3</td>
<td>Real time pcr test for Leishmania diagnosis</td>
<td>ITALY,</td>
</tr>
</tbody>
</table>

**TOR12: EXPERT CONSULTANTS**

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

Yes

<table>
<thead>
<tr>
<th>KIND OF CONSULTANCY</th>
<th>Location</th>
<th>SUBJECT (FACULTATIVE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leishmania diagnosis</td>
<td>Belgium</td>
<td>Lilo Vanstallen, Federaal Agentschap voor de Veiligheid van de Voedselketen, Directoraat Generaal Laboratoria, Externe Laboratoria, AC – Kruidtuin, Food Safety Center, Kruidtuinlaan 55, 1000 Brussel</td>
</tr>
<tr>
<td>Leishmania technical opinion request</td>
<td>Italy</td>
<td>Dr Trentina Di Muccio Istituto Superiore di Sanità Viale Regina Elena 299, 00161 Roma, Italia</td>
</tr>
<tr>
<td>Leishmania diagnosis</td>
<td>Belgium</td>
<td>Mieke Verschatse Medisch Labo Bruyland</td>
</tr>
<tr>
<td>Development of regional surveillance plan for leishmania</td>
<td>Italy</td>
<td>sicily region health department</td>
</tr>
<tr>
<td>Leishmania diagnosis</td>
<td>Belgium</td>
<td>sicily region health department Ghislain Desnoeck - Kirsten De Buyser – Jolien Ingelbeen Dierenartsenpraktijk Desnoeck Oppuursdorp 64B 2890 Puurs-Sint-Amands</td>
</tr>
</tbody>
</table>

29. Additional comments regarding your report:

No