

WOAH Reference Laboratory Reports Activities 2024

This report has been submitted: 20 janvier 2025 11:06

LABORATORY INFORMATION

*Name of disease (or topic) for which you are a designated WOA 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):	Prof. Francesca Di Gaudio, Official Manager
*Name (including Title and Position) of WOA 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

Diagnostic Test	Indicated in WOA Manual (Yes/No)	Total number of test performed last year	
Indirect diagnostic tests		Nationally	Internationally
Immunofluorescence test (IFAT)	Yes	4405	283
Elisa Test	Yes	0	60
Direct diagnostic tests		Nationally	Internationally
Leishmania culture	Yes	100	

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			0
Real Time RT-PCR	Yes	1564	2

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
positive dog control serum	IFAT	PRODUCED	110,76 ml	4,4 ml	4	FRANCE, GREECE, ITALY, NORTH MACEDONIA (REP. OF),
Negative dog control serum	IFAT	PRODUCED	115,36 ml	4,1 ml	4	FRANCE, GREECE, ITALY, NORTH MACEDONIA (REP. OF),
suspect titration dog serum	IFAT	PRODUCED	0	1,2 ml	2	FRANCE, NORTH MACEDONIA (REP. OF),
positive dog control serum	ELISA	PRODUCED	1,15 ml	1,15 ml	2	ITALY, SOUTH AFRICA,
NEGATIVE dog control serum	ELISA	PRODUCED	1,15 ml	1,15 ml	2	ITALY, SOUTH AFRICA,
Slide antigens KIT	IFAT	PRODUCED	21360	10	3	GREECE, ITALY, NORTH MACEDONIA (REP. OF),
immunofluorescent dog conjugate	IFAT	PROVIDE	45,380 ml	0,4 ml	3	GREECE, ITALY, NORTH MACEDONIA (REP. OF),
positive cat control serum	IFAT	PRODUCED	3,72 ml	0	1	ITALY,
negative cat control serum	IFAT	PRODUCED	2,42 ml	0	1	ITALY,
immunofluorescent cat conjugate	IFAT	PROVIDE	1,960 ml	0	1	ITALY,
positive human control serum	IFAT	PRODUCED	0,6 ml	0	1	ITALY,
negative human control serum	IFAT	PRODUCED	0,6 ml	0	1	ITALY,

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immunofluorescent human conjugate	IFAT	PROVIDE	0,1 ml	0	1	ITALY,
Leishmania infantum DNA	Real time pcr	PRODUCED	0,25 ml	0,05 ml	3	ITALY, SOUTH AFRICA, SPAIN,
NEGATIVE dog control DNA	Real time pcr	PRODUCED	0,6 ml	0	1	ITALY,
Positive dog control DNA	Real time pcr	PRODUCED	0,6 ml	0	1	ITALY,
Leishmania culture medium	culture	produced	200	0	1	ITALY,

4. Did your laboratory produce vaccines?

No

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

Yes

Name of the new test or diagnostic method developed	Description and References (Publication, website, etc.)
PCR REAL TIME	Castelli G, Bruno F, Reale S, Catanzaro S, Valenza V, Vitale F. Molecular Diagnosis of Leishmaniasis: Quantification of Parasite Load by a Real-Time PCR Assay with High Sensitivity. Pathogens. 2021 Jul 9;10(7):865. doi: 10.3390/pathogens10070865. PMID: 34358015; PMCID: PMC8308825

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

No

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

No

TOR4: DIAGNOSTIC TESTING FACILITIES

10. Did your laboratory carry out diagnostic testing for other WOA Members?

Yes

Name of WOA Member Country seeking assistance	Date	Which diagnostic test used	No. samples received for provision of diagnostic support	No. samples received for provision of confirmatory diagnoses
NORTH MACEDONIA (REP. OF)	2024-01-23	IFAT	30	30
GREECE	2024-03-11	IFAT	30	30
GREECE	2024-10-21	IFAT	30	30

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SOUTH AFRICA	2024-03-10	ELISA	30	30
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11. Did your laboratory provide expert advice in technical consultancies on the request of an WOA Member?

Yes

Name of the WOA Member Country receiving a technical consultancy	Purpose	How the advice was provided
SPAIN	Quality assurance	IFAT Proficiency test and Reference Material remote
SPAIN	Quality assurance	remote molecular Leishmania technical opinion request
GREECE	Quality assurance	IFAT Proficiency test and Reference Material remote
GREECE	Quality assurance	IFAT Proficiency test and Reference Material remote
SOUTH AFRICA	Quality assurance	ELISA Proficiency test and Reference Material remote
ITALY	Quality assurance	IFAT Proficiency test and Reference Material remote
CHINA (PEOPLE'S REP. OF)	Quality assurance	LEISHMANIA CULTURE ISOLATION PROTOCOL remote
ITALY	Quality assurance	remote molecular Leishmania technical opinion request

TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES

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

No

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

No

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 2024 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:

October 2024

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:

4

<https://doi.org/10.1016/j.actatropica.2023.107037>.. <https://doi.org/10.1371/journal.pntd.0012085>
<https://doi.org/10.1128/mbio.00995-24> <https://doi.org/10.1186/s13071-024-06396-1>

b) International conferences:

4

ALIVE, Animal Leishmaniosis International Veterinary Event, in Nice, France, 18-20 April 2024
: ""O-25-R Genomic and epidemiological evidence for the emergence of a putative *L. donovani*/*L. infantum* hybrid with unusual epidemiology in Northern Italy. Bruno F., Castelli G., Li B. Reale S., Carra E., Vitale F., Scibetta S., Calzolari M., Varani S., Ortalli M., Franceschini E., Gennari W., Rugna G. and G.F. Späth
ALIVE, Animal Leishmaniosis International Veterinary Event, in Nice, France, 18-20 April 2024
Titolo: O-40-R In silico evaluation of a MLST panel for typing *Leishmania* spp. field isolates Silvia Scibetta, Carlotta Piazza, Stefano Reale*, Federica Bruno, Germano Castelli, Eugenia Oliveri, Tiziana Lupo, and Fabrizio Vitale.
ALIVE, Animal Leishmaniosis International Veterinary Event, in Nice, France, 18-20 April 2024
O-33-C Acute phase proteins and protein profile in *Leishmania infantum* naturally infected cats Eva Spada, Germano Castelli, Federica Bruno, Fabrizio Vitale, Flavia Facciponte, Susanna Giardina, Vito Biondi, Arianna Ravasi, Antonella Migliazzo, Aurora Rossi, Roberta Perego, Luciana Baggiani, Lora Koenhems, Merve Alan, Mehmet Erman Or, Daniela Proverbio.
ALIVE, Animal Leishmaniosis International Veterinary Event, in Nice, France, 18-20 April 2024
P-03 Seroprevalence and molecular detection of *Leishmania infantum* in cats from Central Italy
Simona Gabrielli*, Caterina Fanì, Sergio Villanueva-Saz, Diana Marteles, Francesca Messina, Carmine Fiorillo, Simone Trichei, Federica Bruno, Germano Castelli, Fabrizio Vitale, Michele Trotta.

c) National conferences:

1

Congresso della Società italiana di Microbiologia (SIM) Pavia 9-11 Settembre 2024, poster dal titolo
"Screening of a chalcone-based library for anti-*Leishmania* activity". S. MORSELLI, M. ORTALLI, T. GRITTI, A. GAROFALO, E. ROGGIOLANI, L. FLORIS, C. L. PIERRI, A. CANNAROZZI, G. CASTELLI, F. BRUNO, F. BELLUTI, S. VARANI

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 WOA Members?

Yes

a) Technical visit : 0

b) Seminars : 7

c) Hands-on training courses: 0

d) Internships (>1 month) 5

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	MALTA	3
B	MOROCCO	1
B	TUNISIA	1
B	PORTUGAL	1
B	MAURITANIA	1
D	ITALY	7

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	Certificato di Accreditamento 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 WOA?

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Yes

National/ International	Title of event	Co-organiser	Date	location	No. Participants
International	Veterinary Entomology: Controlling Vector- Borne Disease	Remesa WOA H IZS SICILIA	2024-06-09	Palermo	7

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
TRANS-MEDITERRANEAN ZOO N O S I S P R E V E N T I O N S U R V E I L L A N C E N E T W O R K	2024-06-02	Stintino	speaker	

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?

Not applicable (only WOA H Reference Laboratory designated for the disease)

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

Not applicable (only WOA H Reference Laboratory designated for the disease)

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?

Not applicable (Only WOA H Reference Laboratory designated for the disease)

there are no other WOA H laboratories for Leishmaniasis

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?

Not applicable (only WOA H 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 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	WOA H Member Countries
IFAT	ORGANIZER	10		GREECE, ITALY,

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ELISA	ORGANIZER	3	ITALY, NORTH MACEDONIA (REP. OF), SOUTH AFRICA,
REAL TIME PCR	ORGANIZER	3	ITALY, SOUTH AFRICA,

TOR12: EXPERT CONSULTANTS

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

Yes

Kind of consultancy	Location	Subject (facultative)
Leishmania diagnosis	FRANCE	Stephane AUDHUY VirbacDiagnostics
WEBINAR	REMOTE	CRENAL has organized a live Webinar on April 8, 2024 for Italian Society of Veterinary Laboratory Diagnostics : "Animal and human leishmaniasis: an example of One Health"
Development of regional surveillance plan for leishmania	Italy	with sicily region health department
validation of their new product, VG2, an immunofluorescence and blood gas analyzer.	Italy	for Seamaty Italia

29. Additional comments regarding your report:

No