

WOAH Reference Laboratory Reports Activities 2025

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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):	Prof. Francesca Di Gaudio, 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

Diagnostic Test	Indicated in WOAH Manual (Yes/No)	Total number of test performed last year	
		Nationally	Internationally
Indirect diagnostic tests			
Immunofluorescence test (IFAT)	Yes	6009	160
Elisa Test	Yes	90	60
Direct diagnostic tests			
Leishmania culture	Yes	21	0
Real Time RT-PCR	Yes	1344	1

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

Type of reagent available	Related diagnostic test	Produced/ provide	Amount supplied nationally (ml, mg)	Amount supplied internationally (ml, mg)	No. of recipient WOAH Member Countries	Country of recipients
positive dog control serum	IFAT	PRODUCED	99,18 ml	5,7 ml	5	ALGERIA, GREECE, ITALY, PORTUGAL, SPAIN,

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Negative dog control serum	IFAT	PRODUCED	93,89 ml	5,5 ml	5	ALGERIA, GREECE, ITALY, PORTUGAL, SPAIN,
positive dog control serum	ELISA	PRODUCED	4,5 ml	3 ml	3	ITALY, PORTUGAL, SPAIN,
Negative dog control serum	ELISA	PRODUCED	4,5 ml	3 ml	3	ITALY, PORTUGAL, SPAIN,
Slide antigens KIT	IFAT	PRODUCED	20610 slides	200 slides	3	GREECE, ITALY, SPAIN,
immunofluorescent dog conjugate	IFAT	PROVIDE	0,06 ml	0	1	ITALY,
immunofluorescent cat conjugate	IFAT	PROVIDE	1,260 ml	0	1	ITALY,
immunofluorescent human conjugate	IFAT	PROVIDE	0,4 ml	0	1	ITALY,
positive cat control serum	IFAT	PRODUCED	0	0,05	1	SPAIN,
Leishmania infantum DNA	Real time pcr	PRODUCED	0,5	1,95	3	FRANCE, ITALY, SPAIN,
NEGATIVE dog control DNA	Real time pcr	PRODUCED	0,8	0,2	2	ITALY, SPAIN,
Positive dog control DNA	Real time pcr	PRODUCED	0,8	0,2	2	ITALY, SPAIN,
Leishmania culture medium	culture	produced	4 ML	0	1	ITALY,
Leishmania infantum RNA	Real time pcr	produced	0	10 ML	1	FRANCE,

4. Did your laboratory produce vaccines?

No

5. Did your laboratory supply vaccines to WOA Members?

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?

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

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
PORTUGAL	2025-09-16	ELISA	30	30
SPAIN	2025-11-18	real time pcr	20	20

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GREECE	2025-12-02	IFAT	30	30
SPAIN	2025-12-02	IFAT	30	30
SPAIN	2025-12-02	ELISA	30	30
BELGIUM	2025-09-12	REAL TIME PCR	1	1
BELGIUM	2025-02-26	IFAT	5	5
AUSTRALIA	2025-12-10	IFAT	1	1
FRANCE	2025-12-16	IFAT	94	94

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	ELISA Proficiency test and Reference Material remote
ITALY	Quality assurance	LEISHMANIA CULTURE ISOLATION PROTOCOL
ITALY	Quality assurance	IFAT Proficiency test and Reference Material remote
ITALY	Quality assurance	remote molecular Leishmania technical opinion request
SPAIN	Quality assurance	remote molecular Leishmania technical opinion request
GREECE	Quality assurance	IFAT Proficiency test and Reference Material remote

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 2025 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:

11/2025

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

doi: 10.1186/s13071-025-07105-2.

<https://doi.org/10.1186/512917-025-04544.y>

DOI: 10.3390/pathogens14121194

b) International conferences:

0

c) National conferences:

4

P089 Infezioni parassitarie nella martora (Martes Martes) in Sicilia: uno studio preliminare M. Cometa , E. Oliveri , M.L. Di Pasquale , F. La Russa , G. Castelli , F. Bruno , S. Scibetta , S. Reale , F. Vitale

P191 Epidemiologia della Leishmaniosi Canina in Sicilia (2021–2024): L'impatto della Pianificazione Sanitaria sulla qualità della Sorveglianza F. Bruno , G. Castelli , E. Oliveri , A. Galante , F. La Russa , M.L. Di Pasquale , C. Bongiorno , S. Meli , R. Hamel , F. Vitale

P202 Ruolo dei cavalli nella trasmissione della leishmaniosi: risultati di uno studio sierologico in Sicilia V. Biondi , G. Castelli , F. Bruno , R. Hamel , F. Facciponte , S. Giardina , E. Oliveri , M. Cometa , F. Vitale

ORAL COMUNICATION - Germano Castelli

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 WOAHO Members?

Yes

a) Technical visit : 2

b) Seminars : 3

c) Hands-on training courses: 5

d) Internships (>1 month) 3

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
C	ITALY	8
A	ALGERIA	2
D	ITALY	3
B	TUNISIA	3

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.00220 T.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
IFAT TEST	IFAT TEST

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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?H?

Yes

National/ International	Title of event	Co-organiser	Date	location	No. Participants
International	WOAH-IAEA Meeting	IAEA, IZS SICILIA, PASTEUR TUNISI, UNIVERSITY OF NAPLES	2025-11-10	PALERMO	20
National	Leishmaniosi animale e umana: esempio di One Health – I Meeting Nazionale dei Laboratori IIZZSS Leishmani	IIZZSS, ITALIAN MINISTRY OF HEALTH	2025-05-28	ROMA	50

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
COST Action CA21111 – One Health Drugs Against Parasitic Vector-Borne Diseases (OHD)	2025-07-06	Brussels	short communications	THE ROLE OF Experimental Zooprophyllactic Institute of Sicily, Palermo - Italy

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. Are you a member of a network of 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	WOAH Member Countries
IFAT	ORGANIZER	13	IFAT	GREECE, ITALY, SPAIN,

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ELISA	ORGANIZER	5	ELISA	ITALY, PORTUGAL, SPAIN,
REAL TIME PCR	ORGANIZER	5	REAL TIME PCR	ITALY, SPAIN,

TOR12: EXPERT CONSULTANTS

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

Yes

Kind of consultancy	Location	Subject (facultative)
Development of regional surveillance plan for leishmania	Italy	with sicily region health department
SEROLOGICAL DATA TUSCANY REGION	REMOTE	TUSCANY REGION
SEROLOGICAL DATA CAMPANIA REGION	REMOTE	FOR IZS MEZZOGIORNO
VALIDATION RAPID KIT	PALERMO	SEAMATIC SRL
DISCONTOOLS: update Leishmaniasis	REMOTE	Johannes Charlier Project Manager DISCONTOOLS
OPINION DECREE ART 1 COMMA 2 DLG 136/22	REMOTE	ITALIAN HEALTH MINISTRY

29. Additional comments regarding your report:

No