

# OIE Reference Laboratory Reports Activities

## *Activities in 2020*

**This report has been submitted : 2021-01-05 12:31:43**

<b>Name of disease (or topic) for which you are a designated OIE Reference Laboratory:</b>	Leishmaniosis
<b>Address of laboratory:</b>	Istituto Zooprofilattico Sperimentale della Sicilia (IZSSi), National Reference Centre for Leishmaniasis (C.Re.Na.L.), via Gino Marinuzzi 3, 90129, Palermo ITALY
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<b>Name (including Title) of Head of Laboratory (Responsible Official):</b>	Dr. Salvatore Seminara, official manager
<b>Name (including Title and Position) of OIE Reference Expert:</b>	Dr. Fabrizio Vitale, Molecular Biology Dept. Director, National Reference Center for Leishmaniasis (C.Re.Na.L.).
<b>Which of the following defines your laboratory? Check all that apply:</b>	Governmental

**ToR 1: To use, promote and disseminate diagnostic methods validated according to OIE Standards**

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 OIE Manual (Yes/No)	Total number of test performed last year	
		Nationally	Internationally
Indirect diagnostic tests		Nationally	Internationally
Indirect immunofluorescence test (IFAT)	Yes	3489	10
Direct diagnostic tests		Nationally	Internationally
Leishmania culture	Yes	27	none
Real Time RT-PCR	Yes	470	none

**ToR 2: To develop reference material in accordance with OIE requirements, and implement and promote the application of OIE Standards.  
To store and distribute to national laboratories biological reference products and any other reagents used in the diagnosis and control of the designated pathogens or disease.**

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

No

3. Did your laboratory supply standard reference reagents (non OIE-approved) and/or other diagnostic reagents to OIE Member Countries?

Yes

Type of reagent available	Related diagnostic test	Produced/ provide	Amount supplied nationally (ml, mg)	Amount supplied internationally (ml, mg)	No. of recipient OIE Member Countries	Region of recipients
Positive dog control serum	indirect immunofluorescent test	produced	38	0.3	2	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
Negative dog control serum	indirect immunofluorescent test	produced	38	0.3	2	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
Slide antigens (kit)	indirect immunofluorescent test	produced	1555	10	2	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
immunofluorescent dog conjugate	indirect immunofluorescent test	provide	16.8	0.3	2	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
Positive cat control serum	indirect immunofluorescent test	produced	0.09	none	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East

Negative cat control serum	indirect immunofluorescent test	produced	0.09	none	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
immunofluorescent cat conjugate	indirect immunofluorescent test	provide	0.09	none	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
Leishmania infantum DNA	Real Time PCR	produced	0.7	none	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
Leishmania infantum RNA	Real Time PCR	produced	1.4	none	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
Leishmania tropica RNA	Real Time PCR	produced	1.4	none	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
Leishmania braziliensis RNA	Real Time PCR	produced	1.4	none	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East

Leishmania infantum strain	Culture	produced	5.6	none	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
Leishmania tropica strain	culture	produced	5	none	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
Leishmania braziliensis strain	culture	produced	5	none	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americ as <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East

4. Did your laboratory produce vaccines?

No

5. Did your laboratory supply vaccines to OIE Member Countries?

No

***ToR 3: To develop, standardise and validate, according to OIE Standards, new procedures for diagnosis and control of the designated pathogens or diseases***

6. Did your laboratory develop new diagnostic methods validated according to OIE Standards for the designated pathogen or disease?

No

7. Did your laboratory develop new vaccines according to OIE Standards for the designated pathogen or disease?

No

**ToR 4: To provide diagnostic testing facilities, and, where appropriate, scientific and technical advice on disease control measures to OIE Member Countries**

8. Did your laboratory carry out diagnostic testing for other OIE Member Countries?

Yes

Name of OIE Member Country seeking assistance	Date (month)	No. samples received for provision of diagnostic support	No. samples received for provision of confirmatory diagnoses
GREECE	october	10	10

9. Did your laboratory provide expert advice in technical consultancies on the request of an OIE Member Country?

Yes

Name of the OIE Member Country receiving a technical consultancy	Purpose	How the advice was provided
GREECE	quality assurance	IFAT proficiency test
GREECE	quality assurance	Reference Material
ITALY	quality assurance	IFAT proficiency test
ITALY	quality assurance	Reference Material

**ToR 5: To carry out and/or coordinate scientific and technical studies in collaboration with other laboratories, centres or organisations**

10. Did your laboratory participate in international scientific studies in collaboration with OIE Member Countries other than the own?

Yes

Title of the study	Duration	Purpose of the study	Partners (Institutions)	OIE Member Countries involved other than your country
RICERCA CORRENTE iza si 01/19: Studio degli aspetti epidemiologici e fattori di rischio della Leishmaniosi nel bacino del Mediterraneo: sistema di sorveglianza Italia-Tunisia.	2 years	monitoring dog leishmania infection in tunisia	Dr. Karim Aoun, Istituto Pasteur di Tunisi- Department of Parasitology	TUNISIA
RICERCA CORRENTE iza si 01/19: Studio degli aspetti epidemiologici e fattori di rischio della Leishmaniosi nel bacino del Mediterraneo: sistema di sorveglianza Italia-Tunisia.	2 years	monitoring dog leishmania infection in tunisia	R. Elena Carra, IZS Lombardia, Emilia Romagna	ITALY
Ricerca Corrente IZS SI 08/20 : La Leishmaniosi viscerale zoonotica nel gatto: epidemiologia comparata nei territori Milano-Latina-Palermo-Istanbul. Valutazione sistemica della sintomatologia, diagnosi e patogenesi.	2 years	epidemiological study of Feline Leishmaniosi in Mediterranean	Prof Daniela proverbio, University of Milano. Dr.ssa Migliazzo ASL Latina	ITALY
Ricerca Corrente IZS SI 08/20 : La Leishmaniosi viscerale zoonotica nel gatto: epidemiologia comparata nei territori Milano-Latina-Palermo-Istanbul. Valutazione sistemica della sintomatologia, diagnosi e patogenesi.	2 years	pidemiological study of Feline Leishmaniosi in Mediterranean	dr. Mehmet Erman , University of Istanbul	TURKEY
DISCONTTOOLS expert group for Leishmania	2 years	Leishmaniasis Network	prof. Jose de la Fluente (SaBio instituto de investigation en recursos cinegeticos, IREC)	SPAIN
DISCONTTOOLS expert group for Leishmania	2 years	Leishmaniasis Network	Dr. Sofia Boutsini DVM, MSc, PhD Veterinary Centre of Athens Head of Parasitology - Parasitic Diseases, Entomology and Bee Pathology Department 25 , Neapoleos str., Ag.Paraskevi ATHENS 15310 GREECE	GREECE
DISCONTTOOLS expert group for Leishmania	2 years	Leishmaniasis Network	Dr. Carla Maia (Medical Parasitology Unit-Global Health and Tropical Medicine Instituto de Higiene e Medical Tropical)	PORTUGAL

DISCONTTOOLS expert group for Leishmania	2 years	Leishmaniasis Network	Dr. Laia Solano-Gallego (universidad Autonoma de Barcelona)	SPAIN
DISCONTTOOLS expert group for Leishmania	2 years	Leishmaniasis Network	prof. Gaetano Oliva University of Napoli	ITALY
Piano di monitoraggio per la LEISHMANIOSI nel territorio della Regione Siciliana	2 years	monitoring dog Leishmania infection in Sicily Region (Italy)	government of the sicily region	ITALY

**ToR 6: To collect, process, analyse, publish and disseminate epizootiological data relevant to the designated pathogens or diseases**

11. Did your Laboratory collect epizootiological data relevant to international disease control?

Yes

If the answer is yes, please provide details of the data collected:
National epizootiological report 2020 provided to the ministry of health of Italy

12. Did your laboratory disseminate epizootiological data that had been processed and analysed?

Yes

If the answer is yes, please provide details of the data collected:
National epizootiological report 2020 provided to the ministry of health of Italy

**13. What method of dissemination of information is most often used by your laboratory? (Indicate in the appropriate box the number by category)**

a) Articles published in peer-reviewed journals: 7

- 1) Di Pietro S., Crinò C., Falcone A., Crupi R., Francaviglia F., Vitale F., Giudice E. Parasitemia and its daily variation in canine leishmaniasis,2020, Parasitology Research,119,10,"3541","3548","10.1007/s00436-020-06845-7".
- 2) Castelli G., Bruno F., Caputo V., Fiorella S., Sammarco I., Lupo T., Migliazzo A., Vitale F., Reale S.,2020,PLoS Neglected Tropical Diseases,14,7, e0008465,"1","16","10.1371/journal.pntd.0008465.
- 3)Spada E., Perego R., Vitale F., Bruno F., Castelli G., Tarantola G., Baggiani L., Magistrelli S., Proverbio D., 2020, Animals,10,5, 817, 10.3390/ani10050817.
- 4) Pereira A., Parreira R., Cristóvão J.M., Castelli G., Bruno F., Vitale F., Campino L., Maia C.,2020,Infection, Genetics and Evolution,77, 104069,10.1016/j.meegid.2019.104069.
- 5) Maurelli M.P., Bosco A., Manzillo V.F., Vitale F., Giaquinto D., Ciuca L., Molinaro G., Cringoli G., Oliva G., Rinaldi L., Gizzarelli M.,2020,"Veterinary Sciences",7,2, 43, 10.3390/vetsci7020043
- 6) Fabrizio Vitale\*, Federica Bruno, Antonella Migliazzo, Antonella Galante, Angela Vullo, Raffaele Graziano,



Salvatore D'Avola, Valentina Caputo and Germano Castelli, Cross-sectional survey of canine leishmaniasis in Pantelleria island in Sicily, Veterinaria Italiana 2020, 56 (2), xxx-xxx. doi: 10.12834/VetIt.2059.10976.3  
 7) Ceccarelli M, Buffi G, Diotallevi A, Andreoni F, Bencardino D, Vitale F, Castelli G, Bruno F, Magnani M, Galluzzi L. Evaluation of a kDNA-Based qPCR Assay for the Detection and Quantification of Old World Leishmania Species. Microorganisms. 2020 Dec 16;8(12):2006. doi:

b) International conferences: 0

c) National conferences: 1

"I risultati dell'attività di ricerca dell'IZS sicilia" 14/09/ 2020 presso IZS Sicilia. Palermo. Relatore : Dr. Germano Castelli

d) Other:

(Provide website address or link to appropriate information) 0

**ToR 7: To provide scientific and technical training for personnel from OIE Member Countries**

**To recommend the prescribed and alternative tests or vaccines as OIE Standards**

14. Did your laboratory provide scientific and technical training to laboratory personnel from other OIE Member Countries?

Yes

a) Technical visits: 6

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	Italy	6

**ToR 8: To maintain a system of quality assurance, biosafety and biosecurity relevant for the pathogen and the disease concerned**

15. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)
ISO 17025	accreditation Certificate 2020.pdf

16. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
screening e titolazione sierologica mediante immunofluorescenza indiretta per la leishmaniosi	ACCREDIA
isolamento Leishmania da materiale biologico di specie recettive	ACCREDIA
Analisi Quantitativa mediante PCR Real Time della Leishmana infantum	ACCREDIA

17. 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*)

### **ToR 9: To organise and participate in scientific meetings on behalf of the OIE**

18. Did your laboratory organise scientific meetings on behalf of the OIE?

No

19. Did your laboratory participate in scientific meetings on behalf of the OIE?

No

### **ToR 10: To establish and maintain a network with other OIE Reference Laboratories designated for the same pathogen or disease and organise regular inter-laboratory proficiency testing to ensure comparability of results**

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

Not applicable (Only OIE Reference Lab. designated for disease)

21. Was your laboratory involved in maintaining a network with OIE Reference Laboratories designated for the same pathogen or disease by organising or participating in proficiency tests?

Not applicable (Only OIE Reference Lab. designated for disease)

22. Did your laboratory collaborate with other OIE Reference Laboratories for the same disease on scientific research projects for the diagnosis or control of the pathogen of interest?

Not applicable (Only OIE Reference Lab. designated for disease)

**ToR 11: To organise inter-laboratory proficiency testing with laboratories other than OIE Reference Laboratories for the same pathogens and diseases to ensure equivalence of results**

23. Did your laboratory organise or participate in inter-laboratory proficiency tests with laboratories other than OIE Reference Laboratories for the same disease?

Yes

Note: See Interlaboratory test comparisons in: Laboratory Proficiency Testing at: <http://www.oie.int/en/our-scientific-expertise/reference-laboratories/proficiency-testing> see point 1.3

Purpose for inter-laboratory test comparisons <sup>1</sup>	No. participating laboratories	Region(s) of participating OIE Member Countries
organise proficiency test (IFAT)	9	<input type="checkbox"/> Africa <input type="checkbox"/> Americas <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East

**ToR 12: To place expert consultants at the disposal of the OIE**

24. Did your laboratory place expert consultants at the disposal of the OIE?

Yes

Kind of consultancy	Location	Subject (facultative)
draft case definition for leishmaniosis	web meeting	lilia Zribi, Laia Maria Solano Gallego, Fabrizio Vitale, Gregorio Torres, Jenny Hutchison, Elizabeth Marier, Antonio Caminiti.

25. Additional comments regarding your report: