

# OIE Reference Laboratory Reports Activities

## *Activities in 2021*

**This report has been submitted : 2022-01-03 12:36:30**

<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
Immunofluorescence test (IFAT)	Yes	5338	150
Direct diagnostic tests		Nationally	Internationally
Leishmania culture	Yes	10	1
Real Time RT-PCR	Yes	679	0

**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	86,510	0,2	6	<input checked="" 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	81,790	0,2	6	<input checked="" 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	1,742	0,05	6	<input checked="" 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	36,720	0,2	6	<input checked="" 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	0,260	0	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	0,260	0	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	0,340	0	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	3,850	0	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	34,000	0	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 donovani strain	Culture	Produced	6,000	0	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 aethiopica strain	Culture	Produced	6,000	0	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 guyanensis strain	Culture	Produced	4,000	0	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	2,000	0	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	6,000	4,000	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
Leishmania amazonensis strain	Culture	Produced	2,000	0	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	30	30
SPAIN	November	30	30
SOUTH AFRICA	October	30	30
NORTH MACEDONIA (REP. OF)	March	30	30
PORTUGAL	December	30	30

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
SOUTH AFRICA	quality assurance	IFAT proficiency test and Reference Material
GREECE	quality assurance	IFAT proficiency test and Reference Material
NORTH MACEDONIA (REP. OF)	quality assurance	IFAT proficiency test and Reference Material
PORTUGAL	quality assurance	IFAT proficiency test and Reference Material
SPAIN	quality assurance	IFAT proficiency test and Reference Material
ITALY	quality assurance	IFAT proficiency test and 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 IZS 04/21: Sequenziamento de novo del genoma di Leishmania infantum isolato da cane: nuovo ceppo di riferimento nel bacino del Mediterraneo. Analisi filogenetica e studi epidemiologici. (NGS/MCAN)	2 years	De novo genome sequencing of Leishmania infantum isolated from dog: new reference strain in the Mediterranean basin. Phylogenetic analysis and epidemiological studies.	Dr. Luca Galluzzi Università degli studi di Urbino Dipartimento di Scienze Biomolecolari, Sezione di Biotecnologie, sede distaccata di Fano	ITALY
RICERCA CORRENTE IZS 04/21: Sequenziamento de novo del genoma di Leishmania infantum isolato da cane: nuovo ceppo di riferimento nel bacino del Mediterraneo. Analisi filogenetica e studi epidemiologici. (NGS/MCAN)	2 years	De novo genome sequencing of Leishmania infantum isolated from dog: new reference strain in the Mediterranean basin. Phylogenetic analysis and epidemiological studies.	Dr Gianluca Rugna Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna	ITALY
Ricerca Finalizzata Giovani ricercatori: Leishmaniasis in Agrigento, Caltanissetta and Palermo provinces: human outbreaks and animal reservoirs GR-2019-12369134	3 years	Leishmaniasis in Agrigento, Caltanissetta and Palermo provinces: human outbreaks and animal reservoirs	Dr Maurelli Maria Paola Department of Veterinary Medicine and Animal Production University of Naples Federico II	ITALY
Ricerca Finalizzata Giovani ricercatori: Leishmaniasis in Agrigento, Caltanissetta and Palermo provinces: human outbreaks and animal reservoirs GR-2019-12369134	3 years	Leishmaniasis in Agrigento, Caltanissetta and Palermo provinces: human outbreaks and animal reservoirs	Dr Restivo Vincenzo Department of Urgency Emergency University Hospital P.Giaccone of Palermo	ITALY



Ricerca corrente Studio degli aspetti clinici ed epidemiologici, relativi fattori di rischio, prevenzione, sistemi di sorveglianza ed early detection delle malattie trasmissibili, con particolare riguardo alle zoonosi ed alle malattie trasmesse da vettori.	2 years	Study of clinical and epidemiological aspects, related risk factors, prevention risk factors, prevention, surveillance systems and early detection of communicable diseases, with particular regard to zoonoses and vector-borne diseases	Dr.ssa Loredana Baldi Direttore Dipartimento OREB - Osservatori Regionali Epidemiologia e Biostatistica.	ITALY
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; R. Elena Carra, IZS Lombardia, Emilia Romagna	TUNISIA
DISCONTTOOLS expert group for Leishmania	2 years	Leishmaniasis Network	prof. Jose de la Fluente (SaBio istituto de investigation en recursos cinegeticos, IREC); 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; Dr. Carla Maia (Medical Parasitology Unit) Global Health and Tropical Medicine Istituto de Higiene e Medical Tropical); Dr. Laia Solano Gallego (universidad Autonoma de Barcelona; prof. Gaetano Oliva University of Napoli	PORTUGAL
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; dr. Mehmet Erman , University of Istanbul	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
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**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 2021 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:
November 2021

**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. André Pereira, Ricardo Parreira, José Manuel Cristóvão, Fabrizio Vitale, Patrick Bastien, Lenea Campino, Carla Maia, Leishmania infantum strains from cats are similar in biological properties to canine and human strains, Veterinary Parasitology, Volume 298, 2021, 109531, ISSN 0304-4017, <https://doi.org/10.1016/j.vetpar.2021.109531>
2. Maida CM, Tramuto F, Di Naro D, Randazzo G, Stefanelli P, Marotta C, Reale S, Cernigliaro A, Barone T, Cesari C, Pulvirenti C, Angeloni U, Di Martino A, Rezza G, Vitale F, Mazzucco W; SAMI-Surv Collaboration, Alba D, Amodio E, Ascitutto R, Candura R, Cascio F, Casuccio A, Costantino C, D'Agostino N, D'Amato S, Di Quarto L, Fruscione S, Graziano G, La Milia D, Lucchese M, Mangano G, Messina M, Migliorisi C, Mistretta G, Palmeri G, Pecoraro L, Restivo V, Rizzo AP, Savatteri A, Scibetta S, Scondotto S, Sparaco A, Spoto V, Stabile D, Tagliavia AM, Vitale F, Zappia M, Zichichi S. First detection of SARS-CoV-2 A.23.1 sub-lineage in migrants arriving to Italy via the Mediterranean Sea and public health implications. Travel Med Infect Dis. 2021 Sep-Oct;43:102142. doi: 10.1016/j.tmaid.2021.102142. Epub 2021 Jul 16. PMID: 34280534; PMCID: PMC8284064
3. 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, 10, 865. <https://doi.org/10.3390/pathogens1007086>
4. Cosco D, Bruno F, Castelli G, Puleio R, Bonacci S, Procopio A, Britti D, Fresta M, Vitale F, Paolino D. Meglumine Antimoniate-Loaded Aqueous-Core PLA Nanocapsules: Old Drug, New Formulation against Leishmania-Related Diseases. Macromol Biosci. 2021 Jul;21(7):e2100046. doi: 10.1002/mabi.202100046. Epub 2021 Jun 12. PMID: 34117834
5. Tramuto F, Reale S, Lo Presti A, Vitale F, Pulvirenti C, Rezza G, Vitale F, Purpari G, Maida CM, Zichichi S, Scibetta S, Mazzucco W, Stefanelli P. Genomic Analysis and Lineage Identification of SARS-CoV-2 Strains in Migrants Accessing Europe Through the Libyan Route. Front Public Health. 2021 Apr 15;9:632645. doi:

10.3389/fpubh.2021.632645. PMID: 33937168; PMCID: PMC8082074

6. Spada E, Vitale F, Bruno F, Castelli G, Reale S, Perego R, Baggiani L, Proverbio D. A pre- and during Pandemic Survey of Sars-Cov-2 Infection in Stray Colony and Shelter Cats from a High Endemic Area of Northern Italy. *Viruses*. 2021 Apr 3;13(4):618. doi: 10.3390/v13040618. PMID: 33916759; PMCID: PMC8066308.

7. Bruno, F.; Castelli, G.; Vitale, F.; Catanzaro, S.; Badaco, V.V.; Roberti, M.; Colomba, C.; Cascio, A.; Tolomeo, M. Antiparasitic Effect of Stilbene and Terphenyl Compounds against *Trypanosoma cruzi* Parasites. *Pharmaceuticals* 2021, 14, 1199. <https://doi.org/10.3390/ph14111199>

b) International conferences: 0

c) National conferences: 3

1. I risultati dell'attività di ricerca dell'IZS Sicilia" che si è svolto via telematica 11/06/2021 presso IZS Sicilia. Relatore : Dr.ssa Federica Bruno

Titolo della presentazione: Sorveglianza epidemiologica della Leishmaniosi Canina, genotipizzazione degli isolati (Next Generation Sequencing), mappe delle densità flebotomine e rischio sanitario in relazione alla Leishmania e Flebovirus in territorio strategico e borderline del Mediterraneo: Isola di Pantelleria".

2. "BIOTECNOLOGIE NELLA DIAGNOSTICA VETERINARIA A SOSTEGNO DEL MEDICO VETERINARIO AZIENDALE" che si è svolto il 9/11/2021 presso IZS Sicilia, sede territoriale di Ragusa. Relatore: Dr Fabrizio Vitale

3. LA LEISHMANIOSI ANIMALE E UMANA:

SORVEGLIANZA E CONTROLLO». Il 05 Ottobre 2021 presso la sede territoriale di Ragusa al fine di fornire tutti gli aggiornamenti e le novità sulla Leishmaniosi animale, presente nel bacino del Mediterraneo, per consentire il corretto controllo della zoonosi. Relatori:

Dr. Fabrizio Vitale

Dr.ssa Bruno Federica

Dr. Castelli Germano

Dr.ssa Eugenia Oliveri

d) Other:

(Provide website address or link to appropriate information) 3

<https://emop2021.digitalevents.rs/eposter-gallery/>

### **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 1725	Certificato di Accreditamento n. 0246.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 Leishmania 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)	18	<input checked="" type="checkbox"/> Africa <input type="checkbox"/> Americas <input type="checkbox"/> Asia and Pacific <input checked="" type="checkbox"/> Europe <input type="checkbox"/> Middle East
organise proficiency test (RT-PCR)	3	<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)
diagnosis, screening of animals for leishmaniosis and surveillance	Italy	• Guido FERRARI - Veterinary Services Manager Ceva Salute Animale SpA
Leishmania strain, diagnosis	France	• Alessio Giannelli DVM, PhD, Dipl. EVPC Project Manager Veterinary Vaccines
diagnosis, screening of animals for leishmaniosis and surveillance	Italy	• Laboratorio BioGene

25. Additional comments regarding your report: