World Organisation for Animal Health

Vinayagamurthy Balamurugan - -

WOAH Reference Laboratory Reports Activities 2024

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LABORATORY INFORMATION

***Name of disease (or topic) for which you are a designated WOAH Reference Laboratory:**	Leptospirosis
***Address of laboratory:**	ICAR-National Institute of Veterinary Epidemiology and Disease Informatics (ICAR-NIVEDI), Yelahanka, Bengaluru, 560119, INDIA
***Tel:**	+918023093136; 23093111
***E-mail address:**	b.vinayagamurthy@icar.gov.in ; director.nivedi@icar.gov.in
Website:	https://www.nivedi.res.in/
***Name (including Title) of Head of Laboratory (Responsible Official):**	Dr. Baldev Raj Gulati, Director, Head of the Institute
***Name (including Title and Position) of WOAH Reference Expert:**	Dr. Balamurugan Vinayagamurthy, Principal Scientist, Designated Expert, ICAR-NIVEDI
***Which of the following defines your laboratory? Check all that apply:**	Governmental Research agency Academic institution

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	
Indirect diagnostic tests		Nationally	Internationally
Microscopic Agglutination Test (MAT)	Yes	2456	0
Direct diagnostic tests		Nationally	Internationally
PCR (LipL32)	Yes	19	0

Bacterial culture	Yes	164	0

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
Leptospira serovars	MAT	PROVIDED	26 cultures (1ml each)	0	1	INDIA,
Anti-Leptospira sera	MAT	PRODUCED	1ml	0	1	INDIA,
Bovine LeptoLAT KIT (in house developed)	Rapid Test -Latex Agglutination Test	PRODUCED	3 Kits-each one for 3 laboratories	0	1	INDIA,
Leptospira reference serovar DNA	PCR	PROVIDED	50µl of DNA each for 3 laboratories	0	1	INDIA,

4. Did your laboratory produce vaccines?

No

5. Did your laboratory supply vaccines to WOAH Members?

No

TOR3: NEW PROCEDURES

6. Did your laboratory develop new diagnostic methods for the designated pathogen or disease?

Yes

7. Did your laboratory validate diagnostic methods according to WOAH Standards for the designated pathogen or disease?

Yes

Name of the new test or diagnostic method developed	Description and References (Publication, website, etc.)
Bovine LeptoLAT kit as rapid screening test for the detection of Leptospira specific antibodies in the serum samples of cattle and buffaloes	Latex Agglutination Test is an agglutination immunoassay for the detection of Leptopsira specific antibodies. The coloured latex beads are sensitized with the broadly reactive and specific antigen (recombinant antigen(s)) from leptospire and suspended in storage buffer. When the specimen is mixed with suspended latex, antibodies present in the specimen interact with the antigen that is coated on the surface of the latex particles leading to the formation of fine and clearly visible granular agglutination Each kit can test 100 serum samples Cost of kit ; NIVEDI web page PDF: https://nivedi.res.in/pdf/2023/rates/NIVEDI%20Rate%20List%20for%20Services_20_11_2024-REVISED_updated.pdf

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?

No

11. Did your laboratory provide expert advice in technical consultancies on the request of an WOAH Member?

Yes

Name of the WOAH Member Country receiving a technical consultancy	Purpose	How the advice was provided
NEPAL	To outline the collaboration/test request made by Dr. Roshan, Research Scholar from the Central Department of Microbiology, Tribhuvan University, Nepal, to ICAR-NIVEDI for confirming the diagnosis of leptospirosis using the MAT method, as Nepal lacks the required facilities.	Through email communication with the concerned parties, Dr. V. Balamurugan provided advice and support for screening samples for leptospirosis using the MAT method for diagnosis. He also shared guidelines for the proper transport and processing of serum samples to facilitate effective testing/collaboration. However, as the samples are plasma, we are working on the best method to transport them without spoilage during transit. Additionally, he was advised to follow international guidelines and procedures.

TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES

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

Yes

Title of the study	Duration	Purpose of the study	Partners (Institutions)	WOAH Member Countries involved other than your country
Evaluation of the USDA ELISA method as a potential substitute for the traditional hamster-based potency test	Initiated/In process	This collaboration aligns with WOAH's goals of promoting animal welfare and advancing quality standards in leptospirosis vaccine development	INTA/SENASA, Argentina	ARGENTINA

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

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:
Seroprevalence and Serogroup Mapping: Epidemiological studies involved data collection on host factors (species, age, sex, breed), as well as other farm-level parameters (population density, history of abortions or reproductive disorders, purchase and introduction of new animals, feed and fodder management, health status, breeding methods, hygiene status, herd characteristics, presence of other animals on the farm such as dogs, rodents, or other livestock, type of farm—individual or mixed farms, farm location, and GPS-based geographic distribution) to understand serogroup prevalence and identify risk factors for leptospirosis. Outbreak Investigation: the collection of clinical samples from animals/fetuses, rodent samples, water and soil samples in the farms, attack rate, mortality, mortality, CFR, and susceptible population, vaccination records, method of feeding, source feed and fodder materials, source of purchase of animals, drainage and waste management parameters, breeding practices, etc., Rodent and Environmental Surveillance: Capturing (including Rodent species identification) and screening rodent samples, monitoring rodent movements in farms and households, and screening environmental samples (soil (rat burrowing, water flow moist soil area), water (waste/drainage/stagnant water), household waste drainage water, animal drinking water troughs, stagnated water animal resting places, and cleaning water, etc.,).

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:
A. Publications in peer-reviewed journals B. Institute Annual Reports 1. Prevalence Status of Anti-Leptospiral Antibodies in Buffaloes in Enzootic States of India: 2.Environmental and Rodent Surveillance of Leptospirosis in an Endemic Region: Insights from Mangalore Taluk, Karnataka, India 3. Investigation of Leptospirosis Outbreak in Swine: A Case Study from Mandya District, Karnataka

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:

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1. Kumar KV, Bokade PP, Pal A, Deenadayalan O, SowjanyaKumari S, Bharath V, Shome BR, Balamurugan V (2024) Detection of anti-leptospiral antibodies using recombinant ErpY-like lipoprotein based latex agglutination test for serodiagnosis of animal leptospirosis. Lett Appl Microbiol 77(11):ovae100 doi:10.1093/lambio/ovae100

2. Kumar KV, Swathi M, Bokade PP, Bharath V, SowjanyaKumari S, Sunder J, Hemadri D, Shome BR, Balamurugan V (2024) Emerging and

Changing Patterns in Prevalence of Anti-leptospiral Antibodies Against Different Serogroups in Livestock in Andaman-Islands Ecosystem. Proceedings of the National Academy of Sciences, India Section B: Biological Sciences 94(5):977-983 doi:10.1007/s40011-024-01589-1
3. Kumar KV, Swathi M, Bokade PP, SowjanyaKumari S, Bharath V, Govindaraj G, Hemadri D, Shome BR, Balamurugan V (2024) Mapping serogroup distribution and seroprevalence of leptospirosis in livestock of Assam, Northeastern State of India: Unveiling uncommon Leptospira serogroups. Comparative Immunology, Microbiology and Infectious Diseases 111:102215 doi:10.1016/j.cimid.2024.102215
4. Mevada Y, Kumar KV, Balamurugan V, Snehal C, Kumar J, Palkhade R (2024) Seroprevalence and Risk Factors Associated with Leptospirosis in High-Risk Occupational Groups in the State of Gujarat as Determined by IgM ELISA and MAT Test: A Cross-Sectional Study. Indian Journal of Occupational and Environmental Medicine 28(2):106-114 doi:10.4103/ijoem.ijoem_83_23
5. Kanthala S, Patel DR, Balamurugan V, Kumar KV, Makwana PM, Parasana DK, Chaudhary PS, Kalyani IH (2024) Sero-monitoring of canine leptospirosis by microscopic agglutination test (MAT) in and around Navsari, South Gujarat, India. International Journal of Veterinary Sciences and Animal Husbandry 9(2):510-514
6. Veena RK, Vinod Kumar K, Swathi M, Bokade PP, Pal A, SowjanyaKumari S, Arun YP, Devaraj S, Jagadeesha K, Padma MR, Jayashankar M, ChethanKumar HB, Shome BR, Gulati BR, Balamurugan V (2024) Epidemiological analysis of leptospirosis, dengue, and Co-infection rates among febrile illness cases in Dakshina Kannada, Karnataka. Indian Journal of Medical Microbiology 51:100698 doi:10.1016/j.ijmmb.2024.100698

b) International conferences:

0

c) National conferences:

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1. Dr. V. Balamurugan participated and delivered an invited expert lecture on "Experiences in Accreditation and Designation of WOAH Reference Laboratory for Leptospirosis. In: VIBCON – 2024, XXIX Annual Convention of ISVIB and National Conference on Challenges in Animal Health and Production Amidst Climate Change: Innovative, Sustainable Solutions and Their Translations, September 26-28, 2024, Chennai, Tamil Nadu Veterinary and Animal Sciences University. pp. 124.
2. V. Balamurugan participated and delivered an invited expert lecture on Bridging Boundaries: A Comprehensive Public Health Strategy for Leptospirosis - Diagnosis and One Health Integration in Zoonosis Management. In: XX Annual Conference of the Indian Association of Veterinary Public Health Specialists (IAVPHS) and National Symposium on Integrating One Health: Bridging the Gap at Human-Animal-Environmental Interfaces, Krantisinh Nana Patil College of Veterinary Science, Shirwal, Dist. Satara (MAFSU, Nagpur), November 14-15, 2024, Shirwal, Dist. Satara, Maharashtra. pp. 131-136.
3. Dr. Arun Y P participated and delivered oral presentation on "Metabolic profiling of Biofilm Formation in pathogenic and intermediate Leptospira: Insights into adaptive strategies (K. Vinod Kumar, Arun Y P, P. P. Bokade, Archana Pal, V. Balamurugan): XX Annual conference of IAVPHS and a national symposium on "Integrating One Health: Bridging the gap at the Human-Animal-Environment Interfaces. 14th-15th November 2024. pp. 87.
4. Ms. Prajakta.P Bokade participated and delivered oral presentation on "First evidence on seroprevalence and serovar distribution of leptospirosis in Mithun (Bos frontalis from Nagaland Arun Y P, P. P. Bokade, V Bharath, K Vinod Kumar, R Vikarm, H. B. Chethan Kumar, S, Girish Patil and V. Balamurugan, India XX Annual conference of IAVPHS and national symposium on "Integrating One Health: Bridging the gap at the Human-Animal-Environment Interfaces. 14th-15th November 2024 pp. 86-87
5. Ms. Prajakta.P Bokade participated and presented poster presentation on Sero-epidemiology of leptospirosis in Buffaloes: insights from Enzootic states of Andhra Pradesh and Odisha, India P. P. Bokade, Apsana. R, Arun Y P, V Bharath, K Vinod Kumar, D. Hemadri, V. Balamurugan, XX Annual conference of IAVPHS and a national symposium on "Integrating One Health: Bridging the gap at the Human-Animal-Environment Interfaces. 14th -15th November 2024, pp. 98-99
6. Ms. Archana Pal participated and presented poster presentation on Investigation of Leptospirosis Outbreak in Swine: A Case Study from Mandya District, Karnataka. Pal A, Kumar KV, Bokade PP, Apsana R, P. AY, Swathi M, Ojha R, Ramamoorthy R, Kemashi J, Karthik KV, Chethan Kumar HB, Shivasharanappa N, Patil SS, Gulati BR, Hiremath J, Balamurugan V (2024) In: VIBCON – 2024, XXIX Annual

convention of ISVIB and National Conference on "Challenges in Animal Health and Production amidst Climate Change: Innovative, Sustainable Solutions and their Translations" 26-28 September, 2024, Chennai, Tamil Nadu. Tamil Nadu Veterinary and Animal Sciences University, p 124
7. Dr. V. Balamurugan participated in the National Public Health India Conference (NPHICON-2024) conducted by National Centre for Disease Control, Delhi from 23rd to 25th February 2024 at NCDC campus, Delhi

d) Other (Provide website address or link to appropriate information):

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1. Chethan Kumar H.B, Siju Susan Jacob, Vinod Kumar K, Arun Y.P and Balamurugan V (2024). Training Manual: Hands-on Training on Geospatial Epidemiology for Zoonotic Disease Surveillance and Mapping. First Edition, Pages xv+69, ICAR-National Institute of Veterinary Epidemiology and Disease Informatics (NIVEDI), Bengaluru, India.

2. V. Balamurugan, Vinod Kumar, Arun Y P, Swathi M,, Prajakta P. Bokade, M. Nagalingam, H. B. Chethan Kumar, K. (2024). Training Manual: Laboratory Diagnosis of Leptospirosis. First Edition, Pages 105, Publisher - ICAR-National Institute of Veterinary Epidemiology and Disease Informatics, Bengaluru-560064, India – ISBN -978-93-6013-1067

3. Kumar KV, Bokade PP, Pal A, Swathi M, Arun YP, Balamurugan V (2024) Leptospirosis in India: The Role of Animal Carriers and Reservoir in Disease Dynamics. In: Sharma DK, Singathia R (eds) Realization of One health concept through new age Research Technologies. Yash Publishing House, Rajasthan, India, , pp 114-127. ISBN No.: 978-81-86882-51-0

4. Vinod Kumar K, Bokade PP, Arun YP, Nagalingam M, Chethan Kumar HB, Balamurugan V (2024) Pocket Guide on Leptospirosis in Animals for Veterinarians. ICAR-National Institute of Veterinary Epidemiology and Disease Informatics, Bengaluru, India- ISBN- 978-933-4104-233

5. Arun YP, Kumar KV, Bokade PP, Balamurugan V (2024) Leptospirosis in Agriculture: Confronting the Farmer ' s Foe. Farm Chronicle – An Agriculture Newsletter 03:38-42 (website: @thefarmchronicles)

TOR7: SCIENTIFIC AND TECHNICAL TRAINING

17. Did your laboratory provide scientific and technical training to laboratory personnel from other WOAH Members?

No

TOR8: QUALITY ASSURANCE

18. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)	
ISO 17025:2017	PDF	ICAR-NIVEDI_NABL+SCOPE Certificate.pdf
ISO 9001:2015	PDF	IRCCLASS CERTIFICATE EXP2026.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
Detection of Leptospira antibodies by MAT (Microscopic Agglutination Test)	National Accreditation Board for Testing and Calibration Laboratories (NABL), India
Detection of Leptospira DNA by PCR	National Accreditation Board for Testing and Calibration Laboratories (NABL), India
Detection of Leptospira DNA by Realtime PCR	National Accreditation Board for Testing and Calibration Laboratories (NABL), India

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

Yes

ICAR-NIVEDI’s facilities are NABL accredited to store and handle selected agents, including Leptospira. All laboratory activities are carried out in the facility at BSL-2 biocontainment.

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?

No

TOR10: NETWORK WITH WOAH REFERENCE LABORATORIES

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

No

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

No

25. Did you organise or participate in inter-laboratory proficiency tests with WOAH Reference Laboratories designated for the same pathogen during the past 2 years?

Yes

Purpose of the proficiency test:	Role of your Reference Laboratory (organiser/ participant)	No. participating Laboratories	Participating WOAH Ref. Labs/ organising WOAH Ref Lab
Performance of MAT (Reference serovars) and Leptospirosis diagnosis by MAT	Participant	77	International Proficiency Testing Scheme for the Leptospirosis MAT

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?

Yes

Title of the project or contract	Scope	Name(s) of relevant WOAH Reference Laboratories
Evaluation of the USDA ELISA method as a potential substitute for the traditional	This collaboration aligns with WOAH's goals of promoting animal welfare and advancing	INTA/SENASA, Argentina, led by Dr. Luis

hamster-based potency test	quality standards in leptospirosis vaccine development	Samartino and Ms. Jessica Petrakovsky

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 during the past 2 years?

Yes

Purpose for inter-laboratory test comparisons1	Role of your reference laboratory (organizer/participant)	No. participating laboratories	Name of the test	WOAH Member Countries
Performance of Leptospirosis diagnosis by PCR	Participant	50	Leptospirosis Molecular LEPN 435	AUSTRALIA, THE NETHERLANDS,

TOR12: EXPERT CONSULTANTS

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

No

29. Additional comments regarding your report:

Yes

1. The ICAR-NIVEDI's WOAH Reference Laboratory for Leptospirosis was officially inaugurated on 2nd January 2025 by Dr. Himanshu Pathak, Director General, ICAR, and Secretary DARE, GoI.
2. As a newly designated WOAH Reference Laboratory for Leptospirosis, we are ready to undertake sample screening for both WOAH member and non-member countries. We kindly request FAO's or WOAH's facilitation to streamline and support this initiative to receive samples at ICAR-NIVEDI from ASIAN/SAARC and other region countries.
3. We are also keen to organize international training programs—both virtual and hands-on—for WOAH member and non-member countries in the upcoming reporting year (2025). We request FAO's or WOAH's assistance in facilitating these trainings, including organizational and financial supports.
4. Furthermore, we express our interest in initiating the WOAH Reference Laboratory Network for Leptospirosis, aimed at connecting the WOAH Leptospira working group and their laboratories around the globe. This initiative will enhance our knowledge, foster effective collaboration, and allow us to share our expertise with the global community, including the development of uniform protocols, genomic data analysis, and other relevant aspects.
5. ICAR-NIVEDI's WOAH Reference Laboratory actively participates in online meetings, seminars, and conferences organized by FAO and WOAH at various times, as and when required, to acquire knowledge, enhance expertise, collaborate effectively, and share our expertise with global communities.