WOAH Reference Laboratory Reports Activities 2023

Activities in 2023

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Laboratory Information

Name of disease (or topic) for which you are a designated WOAH Reference Laboratory:	Babesiosis
Address of laboratory:	Via Gino Marinuzzi, 3
Tel.:	0039 3291374911
E-mail address:	valeria.blanda@izssicilia.it
Website:	
Name (including Title) of Head of Laboratory (Responsible Official):	Dr. Annalisa Guercio
Name (including Title and Position) of WOAH Reference Expert:	Dr. Valeria Blanda, researcher
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	
Indirect diagnostic tests		Nationally	Internationally
Babesia caballi IFI		88	105
Babesia caballi ELISA		58	105
Babesia canis IFI		129	0
Babesia bovis IFI		19	0
Canine Babesia ELISA		55	0
Direct diagnostic tests		Nationally	Internationally
Babesia spp. PCR		291	156
Babesia caballi (BC48) PCR		27	105
Babesia bovis (rap1) PCR		15	0
Babesia bigemina (spel_Avel) PCR		14	0
Babesia spp. Real Time PCR		260	0
Babesia ovis PCR		7	0
Babesia caballi isolation		0	1

TOR2: REFERENCE MATERIAL

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No

3. Did your laboratory supply standard reference reagents (nonWOAH-approved) and/or other diagnostic reagents to WOAH Members?

Yes	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
Babesia caballi field strain	Babesia caballi isolation	Provided	0	1 mL	1	THE NETHERLANDS,
Babesia caballi positive blood	PCR/Real Time PCR	Provided	0	6 mL	1	THE NETHERLANDS,
Babesia caballi negative blood	PCR/Real Time PCR	Provided	0	6 mL	1	THE NETHERLANDS,
Babesia caballi positive serum	IFAT	Provided	0	10 mL	1	THE NETHERLANDS,
Babesia caballi negative serum	IFAT	Provided	0	10 mL	1	THE NETHERLANDS,
Babesia caballi positive serum	ELISA	Provided	0	10 mL	1	THE NETHERLANDS,
Babesia caballi negative serum	ELISA	Provided	0	10 mL	1	THE NETHERLANDS,
Babesia bigemina positive control DNA (plasmid)	PCR/Real Tme PCR	Produced and provided	0,200 mL	0	1	ITALY,
Babesia bovis positive control DNA (plasmid)	PCR/Real Tme PCR	Produced and provided	0,200 mL	0	1	ITALY,

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.)
Immunochromatographic test for the detection of antibodies to Theileria equi and Babesia caballi	An Interlaboratory evaluation of the diagnostic performance of a rapid immunochromatographic test for the simultaneous detection of antibodies to Theileria equi and Babesia caballi in horses and donkeys. https://pubmed.ncbi.nlm.nih.gov/38549117/
Reverse Line Blot for simultaneous detection of Tick-Borne Pathogens in equines.	Development of a Reverse Line Blot for simultaneous detection of Tick-Borne Pathogens in equines. Manuscript yet to be submitted https://www.soipa.it/wp-content/uploads/2021/06/Atti-XXXI-Congresso- SoIPa-2021-ESDA-Event-1.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

Yes

TOR4: DIAGNOSTIC TESTING FACILITIES

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

NAME OF WOAH MEMBER COUNTRY SEEKING ASSISTANCE	DATE	WHICH DIAGNOSTIC TEST USED		PROVISION OF CONFIRMATORY
COUNTRY SEEKING ASSISTANCE			SUPPORT	DIAGNOSES

THE NETHERLANDS	2023-01-26	Babesia caballi IFAT	20	0
THE NETHERLANDS	2023-02-16	Babesia caballi ELISA	20	0
THE NETHERLANDS	2023-07-18	Babesia caballi PCR	36	0
ROMANIA	2023-02-23	Babesia spp. PCR	156	0
THE NETHERLANDS	2023-07-13	Babesia caballi IFAT	36	0
THE NETHERLANDS	2023-07-13	Babesia caballi ELISA	36	0
THE NETHERLANDS	2023-12-22	Babesia caballi PCR	25	0
THE NETHERLANDS	2023-12-22	Babesia caballi IFAT	25	0

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

Yes

65		
NAME OF THE WOAH MEMBER COUNTRY RECEIVING A TECHNICAL CONSULTANCY	PURPOSE	HOW THE ADVICE WAS PROVIDED
BELGIUM	Issues regarding serological detection of antibodies against Babesia gibsoni	Electronic consultation
SOUTH AFRICA	Request for information regarding diagnostic tests to export dogs to South Africa	Information provided by e-mail
SOUTH AFRICA	Methodology information for molecular detection of tick borne pathogens and for obtaining reference material	On-line consultation
BELGIUM	lssues regarding serological tests for Babesia gibsoni	Advice provided via e-mail
BELGIUM	Request for information regarding diagnostic tests to export dogs to South Africa	Information provided by e-mail
UNITED KINGDOM	Request of organization of B. gibsoni proficiency test	Electronic consultation and organization of a proficiency test
BELGIUM	Request for information regarding diagnostic tests for Babesia gibsoni	Advice provided via e-mail
THE NETHERLANDS	Support for an international valiation of a rapid immunochromatographic test	In person, study design and work organization
SOUTH AFRICA	Support for an international valiation of a rapid immunochromatographic test	In person, study design and work organization

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
Molecular survey of vector-borne diseases in sheltered dogs from Romania.	2 year	To carry out a molecular survey of vector-borne pathogens in sheltered dogs from Romania.	Departement of Parasitology and Parasitic Disease, University of Agricultural and Veterinary Medicine, Romania	ROMANIA
Diagnostic performance of a rapid immunochromatographic test for the simultaneous detection of antibodies to Theileria equi and Babesia caballi in horses and donkeys.	3 years	To evaluate the diagnostic performance of a rapid immunochromatographic test for the simultaneous detection of antibodies to Theileria equi and Babesia caballi in horses and donkeys.	Vectors and Vector-Borne Diseases Research Programme, Department of Vet- erinary Tropical Diseases, Faculty of Veterinary Science, University of Pretoria 2 State Key Lab- oratory for Animal Disease Control and Prevention, Harbin Veterinary Research Institute, Chinese Academy of Agricultural Sciences, Harbin Laboratory of Parasitology and Parasitic Diseases, School of Veterinary Medicine, Aristotle University of Thessaloniki, University Campus, Thessaloniki, Greece	CHINA (PEOPLE'S REP. OF) GREECE ISRAEL SOUTH AFRICA THE NETHERLANDS

			Koret School of Veterinary Medicine, The Hebrew University of Jerusalem, 7610001 Rehovot 6 TBD International BV, BioScience Center, Wagenin- gen University & Research, Runderweg 6, 8219 PK Lelystad	
18 th Workshop of the National Reference Laboratories for Parasites	2 days	Experices and activities of national Reference Centers on parasites	National Reference Laboratories for Parasites	BELGIUM BULGARIA CROATIA CYPRUS CZECH REPUBLIC DENMARK ESTONIA FINLAND FRANCE GERMANY GREECE ICELAND IRELAND ITALY LATVIA LITHUANIA NORWAY PORTUGAL ROMANIA SPAIN SWEDEN THE NETHERLANDS

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

Yes

-Research need : 1— Please type the Research need: From several countries, I receive requests for the execution of IFAT to detect Babesia gibsoni antibodies to allow the dogs to enter certain countries, such as South Africa. However, lately the execution of this test has become increasingly complex because the kit is difficult to find as many manufacturers have suspended its production. It may be useful to consider different tests to allow entry of dogs in countries with these restrictions for Babesia gibsoni Relevance for WOAH Disease Control. Relevance for the Codes or Manual Field Diagnostics, Animal Category Terrestrial, Disease: Babesia spp. Kind of disease (Zoonosis, Transboundary diseases) Transboundary diseases, If any, please specify relevance for Codes or Manual, chapter and title (e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture) Answer: Notes:

Answer:

TOR6: EPIZOOLOGICAL DATA

14. Did your Laboratory collect epidemiological data relevant to international disease control?

Yes 1. MOLECULAR SURVEY OF VECTOR-BORNE DISEASES IN SHELTERED DOGS FROM ROMANIA 2. Study population of Theileria equi and Babesia caballi antibodies 3. Pilot application in epidemiological field of a biomolecular test for the simultaneous determination of Equine Tick Borne Pathogens.

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

1. The study has been conducted in a cohort of 156 dogs (67 male and 89 female) whit a mean age of 40,34 ±42,5 months (range:3-192 months), hosted in 4 shelters in Romania. Overall, 2.56% of the dogs were positive for Rickettsia spp., none resulted positive for Babesia spp. https://www.sisvet.it/new/wp-content/uploads/2023/09/Book_Integrale_def_SISVET_76.pdf

2. Blood samples for serum or samples drawn into EDTA were collected from 255 horses and donkeys.

Using the rapid test, 137 samples (53.7%) tested positive for T. equi, and 23 (9.0%) samples tested positive for B. caballi. The overall coincidence rate between the rapid test and the cELISA for T. equi was 93% based on 129 positive and 108 negative samples out of 255. The overall coincidence rate between both tests for B.caballi was 92.9% based on nine positive and 228 negative horses out of 255.

https://pubmed.ncbi.nlm.nih.gov/38549117/

3. In total, 148 DNA samples extracted from whole blood or ticks were analyzed. Overall, 97 samples among those examined tested positive for at least one of the tested Tick Borne Pathogens (A. phagocytophilum, T. equi, B. caballi, Rickettsia spp.)

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:

1

- Jongejan F, Du C, Papadopoulos E, Blanda V, Di Bella S, Cannella V, Guercio A, Vicari D, Tirosh-Levy S, Steinman A, Baneth G, van Keulen S, Hulsebos I, Berger L, Wang X. Diagnostic performance of a rapid immunochromatographic test for the simultaneous detection of antibodies to Theileria equi and Babesia caballi in horses and donkeys. Parasit Vectors. Manuscipt prepared in 2023; publushed 2024;17(1):160. doi: 10.1186/s13071-024-06253-1. PMID: 38549117; PMCID: PMC10979598.

b) International conferences:

1

- Di Bella S., Gucciardi F., Giacchino I., Blanda V., Cannella V., D'Agostino R., Alfano M., Cascino M., Di Paola L., La Russa F., Purpari G., Grippi F., Guercio A. A biomolecular survey on the presence of zoonotic bacteria in troglophile bats in Sicily (Southern Italy). Presentato alla "5th Edition of World Congress on Infectious Diseases (WCID2023)", Joint Event on Vaccines and Infectious Diseases. 23-25 Oct, 2023 Boston, Massachusetts, Usa and Virtually.

c) National conferences:

1

- Napoli E., Palazzolo V., Di Bella S., Blanda V., Guercio A., D'Amico G., Gabrielli S., Brianti E. Molecular survey of vector-borne diseases in sheltered dogs from Romania. Presentato al 76° Convegno SISVET, Bari, 21-23 giugno 2023

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

1

- Training event Continuing Medical Education "Pathogens transmitted by ticks in small ruminants: research activities and experiences from the territory", held on 24/10/2023, Istituto Zooprofilattico Sperimentale della Sicilia, Palermo (Italy) Event number 397940

TOR7: SCIENTIFIC AND TECHNICAL TRAINING

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

Yes

a) Technical visit : 4

b) Seminars : 1

c) Hands-on training courses: 2

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
A	THE NETHERLANDS	1

c	INDIA	2
D	GERMANY	3
В	ITALY	100

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	Accreditation certificate	Certificato di Accreditamento n. 0246L.pdf

19. Is your quality management system accredited?

Yes	
Test for which your laboratory is accredited	Accreditation body
Babesia bovis IFI	Accredia
Babesia caballi IFI	Accredia
Babesia canis IFI	Accredia
Babesia bigemina (Spel-Aval) PCR	Accredia
Babesia bovis (rap1) PCR	Accredia
Babesia caballi (BC48) PCR	Accredia

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

Yes

Our Centre follows regulations to ensure the analyses and experiments are carried out safely. Molecular and serological studies on these pathogens are performed in a BSL2 laboratory, consisting of different separated lab spaces. IFAT and ELISA tests are performed in the lab spaces dedicated to serology. For the molecular tests a clean DNA/RNA free room and separated lab spaces for DNA/RNA extraction, amplification and post PCR activities are available. At the Istituto Zooprofilattico Sperimentale della Sicilia, BSL3 facilities are also available. Reference materials are stored at the Mediaterranean Biobank, located at our Institute, which is accredited ISO 9001. It is equipped with technological systems for the long-term conservation of biological samples at temperatures of -20, -80, -196 °C, in order to guarantee total safety for operators and environments. It is supplied with the SINTESY.eagle.cryo software, a SCADA (Supervisory Control and Data Acquisition) system dedicated to the automation of the devices storing biological samples in Cryobanks.

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?

Yes

Title of event	Date (mm/yy)	Location	Role (speaker, presenting poster, short communications)	Title of the work presented
Training event Continuing Medical Education "Pathogens transmitted by ticks in small ruminants: research activities and experiences from the territory"	2023-10-24	lstituto Zooprofilattico Sperimentale della Sicilia, Palermo (Italy)	Speaker	Babesia spp. in small ruminants

TOR10: NETWORK WITH WOAH REFERENCE LABORATORIES

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

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

Yes

ROLE OF YOUR LABORATORY

NETWORK/DISEASE	(PARTICIPANT, ORGANISER, ETC)	NO. PARTICIPANTS	PARTICIPATING WOAH REF. LABS
Babesiosis	Sharing information on common projects (Babesia bovis, Babesia canis) to establish collaborations; sharing information about the possibility of getting B.vogeli IFAT slides; about the testing of a recombinant ELISA for Babesia bovis and Babesia bigemina	2	Juan Mosqueda, Babesiosis Reference Laboratories in Mexico
Babesiosis	Sharing information about the organization of an inter-laboratory proficiency test for equine piroplasmosis; about a new methodology for the detection of zoonotic Babesia species DNA; about the sharing IFAT slides for Theileria equi and Babesia caballi.	2	Naoaki Yokoyama, Bovine babesiosis Reference Laboratory in Japan

25. Did you organise or participate in inter-laboratory proficiency tests with WOAH Reference Laboratories designated for the same pathogen? No

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
Testing a new Babesia ELISA method	Entente of testing an ELISA for the serodiagnosis of Babesia bovis and Babesia bigemina	WOAH Babesiosis Reference Laboratories in Mexico, Centro Nacional de Servicios de Constatación en Salud Animal (CENAPA)
Training Course Veterinary Entomology: Controlling Vector-Borne Diseases	Organization of a Training Course	Scientific and Technical Office of REMESA (Réseau Méditerranéen de Santé Animale)

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? Yes

Purpose for inter-laboratory test comparisons1	Role of your reference laboratory (organizer/participant)	No. participating laboratories	Name of the Test	WOAH Member Countries
Detection of Babesia gibsoni DNA by PCR/Real Time PCR	Organizer	2	Babesia gibsoni PCR/Real Time PCR	UNITED KINGDOM,
Detection of anti-Babesia caballi antibodies	Organizer	2	Babesia caballi IFAT/ELISA	THE NETHERLANDS,
Detection of Babesia caballi DNA	Organizer	2	Babesia caballi PCR/Real Time PCR	THE NETHERLANDS,

TOR12: EXPERT CONSULTANTS

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

KIND OF CONSULTANCY	Location	SUBJECT (FACULTATIVE)	
BSC Reference Laboratory Questionnaire	ON-LINE SURVEY	Questionnaire on the Reference Laboratory system and	
	ON-LINE SORVET	processes	

29. Additional comments regarding your report:

Yes

Yes

Our WOAH Centre for Babesiosis has worked for years in close collaboration with the WOAH Theileriosis Reference Laboratory, which is located at the same Institute, and it has maintained this connection even after the WOAH expert for Theileriosis retired.