

WOAH Reference Laboratory Reports Activities 2025

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LABORATORY INFORMATION

*Name of disease (or topic) for which you are a designated WOA Reference Laboratory:	Bluetongue
*Address of laboratory:	Istituto Zooprofilattico Sperimentale dell' Abruzzo e del Molise, via Campo Boario,64100, Teramo, Italy
*Tel:	+39-0861 33 24 40
*E-mail address:	g.savini@izs.it
Website:	www.izs.it
*Name (including Title) of Head of Laboratory (Responsible Official):	Nicola D'Alterio, DVM, General Director, Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise
*Name (including Title and Position) of WOA Reference Expert:	Giovanni Savini , DVM, PhD, head of the Animal Health Department, Istituto Zooprofilattico Sperimentale dell' Abruzzo e del Molise
*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 WOA Manual (Yes/No)	Total number of test performed last year	
		Nationally	Internationally
Indirect diagnostic tests			
C-ELISA (serogroup specific) for Ab vs BTV	Yes	5436	0
VN (serotype specific) for Ab vs BTV	Yes	18656	405
C-ELISA (serogroup specific) for Ab vs EHDV	Yes	430	0
VN (serotype specific) for Ab vs EHDV	Yes	73	0
ELISA (serogroup specific based on VP7) for Ab vs AHSV	Yes	33	0
Direct diagnostic tests			
Serogroup specific Real-time RTPCR for BTV and EHDV	Yes	6928	65
Serotype specific PCR real time for BTV	Yes	19824	290
Serogroup specific Real-time RTPCR for AHSV	Yes	6	0
Isolation on cell culture	Yes	301	19
Microscopic examination Culicoides imicola identification	No	2009	0
Microscopic examination Culicoides spp.	No	2015	

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TOR2: REFERENCE MATERIAL

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

No

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

Yes

Type of reagent available	Related diagnostic test	Produced/ provide	Amount supplied nationally (ml, mg)	Amount supplied internationally (ml, mg)	No. of recipient WOA?H Member Countries	Country of recipients
BTV Antibody Test Kit c- ELISA rec VP7	c- ELISA	Produced	310 packages	0	1	ITALY,
BTV Antibody Test Kit c- ELISA rec VP7	c- ELISA	Provide	302 packages	0	1	ITALY,
c-ELISA BTV antigen for 310 tests	c- ELISA	Produced	17,5 ml	0	1	ITALY,
BTV VP7 monoclonal antibody	c- ELISA	Produced	6000 ml	0	1	ITALY,
BTV inactivated reference strain	RT Real Time PCR	Produced	401 ml	0	1	ITALY,
BTV inactivated reference strain	RT Real Time PCR	Provide	63 ml	8 ml	3	FRANCE, ITALY, PORTUGAL,
c-ELISA EHDV antigen	c- ELISA	Produced	12 ml	0	1	ITALY,
EHDV VP7 monoclonal antibody	c- ELISA	Produced	3000 ml	0	1	ITALY,
EHDV inactivated reference strain	RT Real Time PCR	Produced	72 ml	0	1	ITALY,
EHDV inactivated reference strain	RT Real Time PCR	Provide	16 ml	3 ml	1	FRANCE, ITALY, PORTUGAL,
c-ELISA AHSV antigen	c- ELISA	Produced	2.8 ml	0	1	ITALY,

4. Did your laboratory produce vaccines?

No

5. Did your laboratory supply vaccines to WOA?H Members?

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 WOA?H Standards for the designated pathogen or disease?

Yes

Name of the new test or diagnostic method developed	Description and References (Publication, website, etc.)
Serotype specific PCR Real Time for BTV3	www.izs.it
Serotype specific PCR Real Time for BTV5	www.izs.it
Serotype specific PCR Real Time for BTV12	www.izs.it

8. Did your laboratory develop new vaccines for the designated pathogen or disease?

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

TOR4: DIAGNOSTIC TESTING FACILITIES

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

Yes

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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
MALTA	2025-03-01	RT real Time PCR	0	3
MALTA	2025-03-01	VNT	0	3
MALTA	2025-04-01	RT real Time PCR	0	2
MALTA	2025-04-01	VNT	0	2
MALTA	2025-05-01	RT real Time PCR	0	2
MALTA	2025-10-01	RT real Time PCR	0	24
MALTA	2025-10-01	VNT	0	24
TUNISIA	2025-11-01	RT real Time PCR	0	34
ALBANIA	2025-11-01	VNT	0	16

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
MALTA	Diagnostic assistance	Remote
ALBANIA	Diagnostic assistance	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?

Yes

Title of the study	Duration	Purpose of the study	Partners (Institutions)	WOAH Member Countries involved other than your country
Ecology of Wild-life, Livestock, huMan and Infectious Diseases in changing environments — WiLiMan-ID	5 years (2024-2028)	The main objective of WiLiMan-ID is to identify key factors allowing five animal infectious diseases to spread and persist, in changing environments. The five diseases are: Avian influenza African swine fever West-Nile fever African horse sickness Chronic wasting disease	Austria-Biofaction Belgium-Sciensano Denmark-The University of Copenhagen France- ANSES France-Ecole Nationale Vétérinaire (ENVN) France-INRAE France-National Research Institute for Agriculture, Food and Environment (INRAE) Germany- Friedrich-Loeffler-Institut (FLI) Morocco-The Hassan II Agronomic and Veterinary Institute (IAV) Norway-The Norwegian Veterinary Institute (vetinst) Spain-The Central Veterinary Laboratory of the Spanish Ministry of Agriculture, Fisheries and Food. Sweden-Swedish Veterinary Agency (SVA) The Netherlands-Wageningen University & Research (WUR)	AUSTRIA BELGIUM DENMARK FRANCE GERMANY MOROCCO NORWAY SPAIN SWEDEN THE NETHERLANDS

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:

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Data related to the BTV3-BTV4- BTV5 and BTV8 serotypes outbreaks occurring in Italy in 2025

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:

Sequencing of BTV5 strain circulating in Italy in 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:

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1. Ahmed KA, Karawita A, Klein MJ, Mincarelli LF, Secondini B, Satta G, Ancora M, Foxi C, Di Domenico M, Quaglia M, Goffredo M, Lorusso A, Cammà C, Court L, Rane RV, Walsh TK, Paradkar PN, Eagles D, Pandey G, Hardy CM. Complete mitochondrial genomes of *Culicoides brevitarsis* and *Culicoides imicola* biting midge vectors of Bluetongue Virus. *Mitochondrial DNA B Resour.* 2025 Jan 3;10(1):67-71. doi: 10.1080/23802359.2024.2447750. PMID: 39776561; PMCID: PMC11703489
2. Martínez R, De Los Ángeles Riscalde M, Cano-Terriza D, Lorusso A, Spedicato M. From Africa to Europe: the rise of epizootic haemorrhagic disease virus serotype 8. *Vet Ital.* 2025 Sep 4;61(4). doi: 10.12834/VetIt.3793.35560.1. PMID: 40904031
3. Ishaq M, Jamal SM, Ali S, Teodori L, Leone A, Bonfini B, Spedicato M, Savini G. Serological Evidence of Bluetongue Virus Serotypes Circulating in Pakistan. *Intervirology.* 2025;68(1):57-66. doi: 10.1159/000546965. Epub 2025 Jun 24. PMID: 40555218; PMCID: PMC12334142
4. Ishaq M, Jamal SM, Teodori L, Leone A, Bonfini B, Spedicato M, Savini G. Serological evidence of epizootic hemorrhagic disease and serotypes of epizootic hemorrhagic disease virus in Pakistan. *Acta Trop.* 2025 Jul;267:107675. doi: 10.1016/j.actatropica.2025.107675. Epub 2025 May 25. PMID: 40425081.
5. O. Portanti, E.Ciarrocchi, R. Irelli, A.Palombieri, R. Salini, I. Melegari, M.Pisciella, S.Pulsoni, D. Di Sabatino, M.Spedicato, G. Savini, A.Lorusso. Validation of a molecular multiplex assay for the simultaneous detection and differentiation of bluetongue virus and epizootic haemorrhagic disease virus in biological samples. PMID: 39542043 DOI: 10.1016/j.jviromet.2024.115064

b) International conferences:

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1. Conference Inf-Act 2025, Naples, April, 3rd -5th, 2025
2. British Society of Veterinary Pathology (BSVP) – Spring Meeting 2025. Webinar. June 7th, 2025
3. "Seminar for the countries in the Eurasian Economic Union on the topic "WOAH standards and recommendations on bluetongue (sheep catarrhal fever). Methods of control and prevention, distribution trends. Current epidemiological situation on Foot-and-Mouth Disease in Europe" (WOAH-EEC)" Webinar. June 30th, 2025
4. 13th International Congress for Veterinary Virology Including an EPIZONE Session. Portorož, Slovenia. September, 2nd-5th, 2025
5. 69th IAEA General Conference. Vienna (Austria) September, 15th -19th, 2025
6. EU National References Lab. Annual Meeting 2025 -African Horse Sickness and Bluetongue Virus. Alcalá De Henares (Spain). October, 28th -29th, 2025
7. Microbiology & Infection", V edition. Francavilla (Teramo_Italy). November 6th, 2025

c) National conferences:

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1. Immunità Dei Piccoli Ruminanti: Tra Emergenze E Nuovi Potenziali Biomarkers. Webinar. March 21st, 2025
2. Annual Meeting Dei Dottorandi all'Università Degli Studi Di Teramo.. Teramo, Italy. September, 24th, 2025
3. Annual meeting SivasZoo 2025 "Medicina Veterinaria Forense E Tecniche Di Diagnostica Negli Animali Da Zoo E Selvatici". Naples, October, 4th -5th, 2025

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

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- a public web site (www.izs.it) disseminating information and data on Bluetongue is continuously updated in order to have:
- the latest on the Italian and European Regulations issued by the Italian Ministry of Health;
 - the current (2025) and past epidemiological situations in Italy;

- weekly updated maps on entomological and serological surveillance activities (bluetongue national information system);
- the current epidemiological situations in the Mediterranean Basin;
- rules and regulations
- scientific documents

TOR7: SCIENTIFIC AND TECHNICAL TRAINING

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

Yes

a) Technical visit : 0

b) Seminars : 0

c) Hands-on training courses: 0

d) Internships (>1 month) 1

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
D	GEORGIA	1

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	ACCREDIA_IZSAM	ACCREDIA_IZSAM.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
C-ELISA (serogroup specific) for Ab vs BTV	ACCREDIA
VN (serotype specific) for Ab vs BTV	ACCREDIA
C-ELISA (serogroup specific) for Ab vs EHDV	ACCREDIA
VN (serotype specific) for Ab vs EHDV	ACCREDIA
ELISA (serogroup specific based on VP7) for Ab vs AHSV	ACCREDIA
Serogroup specific Real-time RT- PCR for BTV and EHDV	ACCREDIA
Serotype specific PCR real time for BTV	ACCREDIA
Serotype specific PCR real time for EHDV	ACCREDIA

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

Yes

The biosecurity policy integrates aspects related to safety, security and environmental protection. Risks associated with all activities are assessed and managed to ensure the safety of workers and the protection of the environment, in accordance with international standards. In particular, IZSAM has developed its biosecurity manual in accordance with World Health Organization (WHO) standards, specifically the WHO Laboratory Biosafety Manual, 4th edition (2020), as well as specific procedures for the safe handling and containment of infectious microorganisms and hazardous biological materials. Furthermore, in order to reduce or eliminate environmental exposure (air, water and soil) to potentially infectious or hazardous agents, IZSAM has obtained ISO 14001 certification. A rigorous management system for biological materials, chemicals and related waste is in place, together with regular information and training activities for personnel. To ensure the safe handling and transport of goods, IZS Teramo has developed protocols and procedures in accordance with WHO guidance (Guidance on regulations for the transport of infectious substances 2019–2020; WHO/WHE/CPI/2019.20). The laboratory is officially authorised by the Italian Ministry of Health to import biological materials and reagents of any origin through the airports of Rome (Fiumicino) and Milan (Malpensa and Linate). Air transport of biological materials classified as infectious substances is carried out in accordance with the IATA Dangerous Goods Regulations (DGR). IZS Teramo also complies with ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road) and Directive 2008/68/EC to guarantee the safe road transportation of dangerous goods, and operates vehicles specifically equipped for this purpose. Traceability of biological materials for research purposes is ensured through the use of Material Transfer Agreements (MTAs), while dispatch and receipt are regulated by dedicated

Standard Operating Procedures.

TOR9: SCIENTIFIC MEETINGS

21. Did your laboratory organise scientific meetings related to the pathogen in question on behalf of WOAHP?

Yes

National/ International	Title of event	Co-organiser	Date	location	No. Participants
National	Giornata di studio sulla Bluetongue	Italian Ministry of Health	2025-12-02	Teramo (Italy)	67

22. Did your laboratory participate in scientific meetings related to the pathogen in question on behalf of WOAHP?

Yes

Title of event	Date	location	Role (speaker, presenting poster, short communications)	Title of the work presented
Conference Inf-Act 2025	2025-04-02	Naples (Italy)	Poster	Complete mitochondrial genomes of <i>Culicoides brevitarsis</i> and <i>Culicoides imicola</i> biting midge vectors of Bluetongue Virus
British Society of Veterinary Pathology (BSVP) – Spring Meeting 2025	2025-06-06	Online	Speaker	Bluetongue: An Unpredictable Disease That Continually Surprises
Seminar for the countries in the Eurasian Economic Union on the topic "WOAH standards and recommendations on bluetongue (sheep catarrhal fever). Methods of control and prevention, distribution trends. Current epidemiological situation on Foot-and-Mouth Disease in Europe" (WOAH-EEC)	2025-06-29	Online	Speaker	European Vectors of Bluetongue: Insights from Italy
13th International Congress for Veterinary Virology Including an EPIZONE Session	2025-09-01	Portorož (Slovenia)	Poster	A VP2 subunit vaccine confers complete protection from EHDV-8 infection in calves
69th IAEA General Conference	2025-09-14	Vienna (Austria)	Speaker	Zoonotic and Vector-Borne Disease
EU National References Lab. Annual Meeting 2025 -African Horse Sickness and Bluetongue Virus	2025-10-27	Alcalá De Henares (Spain)	Speaker	BTv-5 Joins the Party: Genomic Constellations of Recent Italian Strains; Short presentations on BTv diagnostic activities
Microbiology & Infection", V edition	2025-11-05	Francavilla (Teramo_Italy)	Speaker	Ecologia degli insetti vettori di malattie infettive in Italia

TOR10: NETWORK WITH WOAHP REFERENCE LABORATORIES

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

Yes

24. Are you a member of a network of WOAHP Reference Laboratories designated for the same pathogen?

Yes

NETWORK/DISEASE	ROLE OF YOUR LABORATORY (PARTICIPANT, ORGANISER, ETC)	NO. PARTICIPANTS	PARTICIPATING WOAHP REF. LABS
WOAHP Bluetongue reference laboratories network (WOAHPBTNet)	Organiser	1	All the WOAHP BT reference laboratories
VectorNet	PARTICIPANT	14	Expert from EU member states

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25. Did you organise or participate in inter-laboratory proficiency tests with WOA 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 WOA Ref. Labs/ organising WOA Ref Lab
Detection of BTV and serotyping in blood samples (Real Time RT-PCR)	Participant	0	Information not available at the moment
Detection of BTV antibody in serum samples (c-ELISA)	Participant	0	Information not available at the moment
Detection of AHSV in blood samples (Real Time RT-PCR)	Participant	0	Information not available at the moment
Detection of AHSV antibody in serum samples (c-ELISA)	Participant	0	Information not available at the moment
Detection of EHDV in blood samples (Real Time RT-PCR)	Participant	0	Information not available at the moment
Detection of EHDV antibody in serum samples (c-ELISA)	Participant	0	Information not available at the moment

26. Did your laboratory collaborate with other WOA 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 WOA Reference Laboratories
Please see ToR 5	Please see ToR 5	All the WOA BT reference laboratories

TOR11: OTHER INTERLABORATORY PROFICIENCY TESTING

27. Did your laboratory organise or participate in inter-laboratory proficiency tests with laboratories other than WOA 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
Detection of BTV and EHDV in blood samples (Real Time RT-PCR)	Organizer	18	Circuito inter-laboratorio Bluetongue RT-PCR ed EHDV RT-PCR. Distribuzione 1/2025	AUSTRALIA, ITALY, PORTUGAL,
Detection of BTV antibody in serum samples (c-ELISA)	Organizer	24	CIRCUITO INTERLABORATORIO PER LA RILEVAZIONE DEGLI ANTICORPI NEI CONFRONTI DEL VIRUS DELLA BLUETONGUE MEDIANTE ELISA. Distribuzione 1/2025	ALBANIA, ITALY,
Detection of EHDV antibody in serum samples (c-ELISA)	Organizer	13	CIRCUITO INTERLABORATORIO PER LA RILEVAZIONE DEGLI ANTICORPI NEI CONFRONTI DEL VIRUS DELLA MALATTIA EMORRAGICA EPIZOOTICA (EHD) MEDIANTE ELISA. Distribuzione 1/2025	ITALY, PORTUGAL,

TOR12: EXPERT CONSULTANTS

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

Yes

Kind of consultancy	Location	Subject (facultative)
BTV vaccination plan consultant	online	/
ad hoc group meeting	Rome (Italy)	Ministry of Health

29. Additional comments regarding your report:

No