World Organisation for Animal Health

Isabella Monne - - ITALY

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:**	Newcastle disease
***Address of laboratory:**	WOAH Reference Laboratory for Newcastle disease Istituto Zooprofilattico Sperimentale delle Venezie (IZSVe) Viale dell'Università 10 – 35020 Legnaro (PD) - Italy
***Tel:**	+39-049 808 4381
***E-mail address:**	imonne@izsvenezie.it
Website:	www.izsvenezie.it
***Name (including Title) of Head of Laboratory (Responsible Official):**	Calogero Terregino, Director of the Research and Development Department, Director of the Specialized Virology and Experimental Research, Acting Director of the Virology Department (IZSVe)
***Name (including Title and Position) of WOAH Reference Expert:**	Isabella Monne, DVM PhD, Head of the Viral genomics and transcriptomics Laboratory, Division of Research and Innovation
***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
Haemoagglutination inhibition (HI)	Yes	542	1
Direct diagnostic tests		Nationally	Internationally
Isolation	Yes	11	

			1
RRT/RT-PCR	Yes	617	881
Sequencing (cleavage site)	Yes	192	280
ICPI - Intracerebral Pathogenicity Index	Yes	1	0
NGS (next generation sequencing)	Yes	2	37

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
Virus antigen (inactivated)	HA, HI, AGID	1170/154 mL	54 mL	100 mL	14	ALGERIA, BURKINA FASO, CYPRUS, CZECH REPUBLIC, FINLAND, IRELAND, ITALY, MALI, MOLDOVA, ROMANIA, SIERRA LEONE, THAILAND, TURKEY, UKRAINE,
Serum	HI, AGID, ELISA, SN	6450/814 mL	543 mL	270 mL	19	ALGERIA, BURKINA FASO, CYPRUS, CZECH REPUBLIC, DENMARK, FINLAND, FRANCE, IRELAND, ITALY, MALI, MOLDOVA, NIGERIA, POLAND, ROMANIA, SIERRA LEONE, SWITZERLAND, THAILAND, TURKEY, UKRAINE,
Virus antigen (inactivated)	RT-qPCR, RT-PCR	402/8 mL	8 mL	0	1	ITALY,
Virus isolate (live)	Various	259/5 mL	5 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?

No

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

No

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?

Yes

Name of WOAH 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
BENIN	2024-06-27	Real Time PCR	0	6
BULGARIA	2024-05-10	Real Time PCR RT PCR	0	4
BURKINA FASO	2024-04-19	Real Time PCR	0	1
GUINEA	2024-06-04	Real Time PCR RT PCR Sequencing	0	10
MALTA	2024-10-25	Real Time PCR	0	44
NIGERIA	2024-05-20	Real Time PCR	0	2
NIGERIA	2024-07-08	Real Time PCR Sequencing	0	1116
POLAND	2024-11-18	Real Time PCR Isolation HI	0	2

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
BELGIUM	Provided declaration of validation and related procedures regarding SOPs 1002 ' Detection and pathotyping of Avian Orthoavulavirus type 1 (AOAV-1) by one-step RT-PCR and Sanger sequencing of the fusion protein	Remote assistance (email)

	cleavage site (Kant et al., 1997) and related procedures	
FINLAND	Provided information on methods for preparation of antigens to be used in APMV1 HI test	Remote assistance (email)
HUNGARY	Provided validation documents for SOP VIR 063 (Detection and pathotyping of Avian Orthoavulavirus type 1 (AOAV-1) by one-step RT-PCR and Sanger sequencing of the fusion protein cleavage site (De Battisti et al., 2013)	Remote assistance (email)
IRELAND	The RL provided information on detecting ND vaccine strains or low virulent strains in brain	Remote assistance (email)
LUXEMBOURG	Provided details about SOP VIR 1000 "Sample preparation and nucleic acids isolation for the detection and typing of Avian influenza virus and Avian Orthoavulavirus type 1 by molecular methods"	Remote assistance (email)
BULGARIA NIGERIA POLAND	The RL provided support in performing genetic characterization and in the process of interpreting results	Remote assistance
PORTUGAL	Provided information on appropriate number of birds allowed in pooled samples to test for AIV/APMV-1 by RT-qPCR	Remote assistance (email)

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
Memorandum of Understanding	2022-2027	Collaborative studies and implementation of projects on animal health, zoonotic diseases and food safety.	The National Research Center for Tropical and Transboundary Diseases - Libya	LIBYA

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H2020 PROJECT European Virus Archive - EVAg. Grant Agreement number 871029 - EVA-GLOBAL. https://www.european-virus-archive.com/	2020-2024	A non-profit global network sharing expertise in virology and aimed to preserve, produce and distribute viruses and derived products.	CSIRO (Australia); ANSES, CIRAD and the Institute Pasteur (France); the Friedrich-Loeffler-Institute (Germany); Erasmus MC (The Netherlands).	AUSTRALIA FRANCE GERMANY THE NETHERLANDS
LIDISKI Project: Improving the livelihoods of smallholder livestock farmers in Nigeria https://www.lidiski.org/	2020-2024	Improving surveillance and control of Peste des petits ruminants (PPR) and Newcastle Disease (ND), the two main diseases affecting the livestock of smallholder farmers in North of Nigeria	1. Centre de coopération Internationale en Recherche Agronomique pour le Développement – CIRAD (France), 2. Istituto Zooprofilattico Sperimentale delle Venezie (IZSVe) (Italy), 3. Ikore (Nigeria) 4. National Veterinary Institute (Nigeria), National Agricultural Extension and Research Liaison Services -NAERLS (Nigeria), 5. The Federal Ministry of Agriculture and Rural Development – FMARD (Nigeria), 6. International Livestock Research Institute – ILRI (Kenya), 7. WOAH-World Organisation for Animal Health	FRANCE ITALY KENYA NIGERIA
Research: Molecular characterization of Newcastle disease virus (AOAV-1) obtained from Western region of Libya https://pubmed.ncbi.nlm.nih.gov/39553761/	2024	The Study aims to discuss the challenge of virulent ND in poultry in Libya, focusing on recent outbreaks investigated in the western region of	1. National Research Center for Tropical and Transboundary Diseases (NRCTTD),Alzintan, Libya. 2. Department of Poultry and Fish Diseases, Faculty of Veterinary Medicine, University of Tripoli, Tripoli, Libya. 3. Libyan Academy for	LIBYA

		Libya.	Postgraduate Studies, Tripoli, Libya. 4. Faculty of Science, Alzintan University, Alzintan, Libya.	

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:

1. Collection and analysis of the information generated by surveillance in domestic and wild birds in Italy
2. Collection and analysis of the information generated by surveillance in rural poultry in Nigeria
3. Collection and analysis of the information generated by genetic surveillance in poultry in the EU

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:

National Information Systems: regular reporting of epidemiological data to the Ministry of Health and the European Commission.
Reporting results of molecular, epidemiological and diagnostic analyses to EU NRLs by email and/or through Mattermost, a flexible, open source platform that enables secure team collaboration and enhances an active collaboration between veterinary/public health laboratories and scientists from the EU. This allows rapid dissemination of Newcastle disease updates when possible.

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
Kammon A, Rammah E, Giweli A, Monne I. (2024) Molecular characterization of Newcastle disease virus (AOAV-1) obtained from Western region of Libya. Open Vet J. 2024 Sep;14(9):2453-2462. doi: 10.5455/OVJ.2024.v14.i9.34. Epub 2024 Sep 30. PMID: 39553761; PMCID: PMC11563623

b) International conferences:

0

c) National conferences:

2
Fortin A., Laconi A., Monne I., Cecchinato M., Crimaudo M., Valastro V., D'Amico V., Bortolami A. Gastaldelli A., Varotto M., Terregino C., Panzarin V. (2024) Sviluppo e validazione di un array di real-time RT-PCR per la rapida patotipizzazione del paramyxovirus aviario di tipo I (APMV-1). IX Simposio Scientifico SIPA, Lodi, 12-13/09/2024

Fortin A., Laconi A., Monne I., Zohari S., Andersson K., Grund C., Cecchinato M., Crimaudo M., Valastro V., D'Amico V., Bortolami A., Gastaldelli M., Varotto M., Abdelrahman A., Amarin N., Abubakar M.B., Belayneh R., Cyprien Y.B., Christodoulou V., Chvala I., Dodovski A., Ghafouri S.A., Giasuddin M., Hassan M., Kammon A., Shittu I., Snoeck C.J., Steensels M., Suarez D., Torchetti M.K., Tshipambe S.M., Ouermi Zerbo L.H., Terregino C., Panzarin V. (2024). Design and validation of a qRT-PCR array to discriminate virulent and avirulent APMV-1. (Poster) EAVLD 2024, 21-23/10/2024, Padova (Italy)

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

8
EURL team at IZSVe (n° 1 presentation on a total of 23)
Presentations from the 29th Annual Meeting of the National Reference Laboratories for Avian Influenza and Newcastle Disease of European Union Member States (October 2023)
https://www.izsvenezie.com/reference-laboratories/avian-influenza-newcastle-disease/workshops/

Presentation as invited speaker (1 international meeting on Newcastle disease)
Monne I. (2024) LIDISKI Project final Meeting - Abuja, Nigeria 11-16/11/2024 . In the frame of the Livestock Disease Surveillance Knowledge Integration (LIDISKI) projet
https://ikore.org/lidiski-project-to-host-closeout-event-in-abuja-celebrating-five-years-of-success-in-strengthening-livestock-disease-surveillance-and-control-in-nigeria/

National Training course organised by IZSVe (1 courses, 1 presentation on NDV)
1. IZSVE's research Activities funded by the Ministry of Health: Projects concluded in 2023.
https://www.izsvenezie.it/documenti//formazione/corsi-convegni/2024/2024-FAD-ricerca-corrente-izsve/programma.pdf
Links from IZSVe's website (n°5):
WOAH & FAO activities
https://www.izsvenezie.com/reference-laboratories/avian-influenza-newcastle-disease/woah-fao-activities/

European Union Reference Laboratory (EURL) for Avian Influenza and Newcastle Disease
http://www.izsvenezie.com/reference-laboratories/avian-influenza-and-newcastle-disease/

Diagnostic protocols
https://www.izsvenezie.com/reference-laboratories/avian-influenza-newcastle-disease/diagnostic-protocols/

EVA-GLOBAL Biobank
https://www.izsvenezie.com/izsve-veterinary-biobank-and-the-oie-collaborating-centre-for-veterinary-biological-biobank/
https://www.european-virus-archive.com/

Other links (1)
Lidiski project - Improving the livelihoods of smallholder livestock farmers in Nigeria
http://www.lidiski.org/
https://www.youtube.com/watch?v=Gp1aa03u4nY&feature=emb_logo

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 : 0

b) Seminars : 0

c) Hands-on training courses: 3

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
C	LIBYA	2
C	NIGERIA	1

TOR8: QUALITY ASSURANCE

18. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)	
UNI CEI EN ISO/IEC 17025:2018	Certificate of Accreditation	17025.pdf
UNI CEI EN ISO/IEC 17043:2010	Certificate of Accreditation	17043.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
Detection of antibodies to Newcastle disease virus (NDV) by haemagglutination inhibition test	ACCREDIA – Italian Accreditation System
Isolation and characterization of Newcastle disease viruses using SPF embryonated chicken eggs and haemagglutination inhibition test	ACCREDIA – Italian Accreditation System
APMV-1 virus (Avian Paramyxovirus Type 1) sequence analysis	ACCREDIA – Italian Accreditation System
Detection of APMV-1 virus (Avian Paramyxovirus Type 1) by RT-PCR	ACCREDIA – Italian Accreditation System
Detection of APMV-1 virus (Avian Paramyxovirus Type 1) by real time RT-PCR	ACCREDIA – Italian Accreditation System
Proficiency testing provider	ACCREDIA – Italian Accreditation System

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

Yes

The RL implements biorisk management actions to prevent diseases among personnel and to protect the community from harm caused by potentially infectious pathogens. Particular attention is also paid to the safe transport management of infectious substances according to IATA guidelines and UN classification system. Agents (pathogenic or infectious organisms, including Newcastle disease viruses) posing moderate hazards to personnel and the environment are handled under BSL-2 conditions. At IZSVe, since 2013, there exists a Biosafety Committee (of which the Head of the RL is a permanent member) responsible for the following tasks: - Evaluation of the safety risks for workers and for the environment connected to the activities to be performed under BSL3 conditions that involves the use of microorganisms, animals and Genetically Modified Microorganisms MOGM; - Evaluation of the emergency procedures - Evaluation of all the management and operative procedures to be applied inside the BSL-3 laboratory and animal facilities including potential biosecurity issues. All Standard Operative Procedures (SOPs) and handling of pathogens are written and performed accordingly to the WHO Laboratory Biosafety Manual (4th Ed.). TheBSL-3 laboratory and animal facilities are maintained regularly to ensure biocontainment during an annual suspension of activities for plant and equipment maintenance following decontamination of the premises. All the BSL-3 facilities are equipped with self-closing set of locking doors with access away from general building corridors and access is restricted and controlled at all times as part of the internal biosecurity measures.

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?

Yes

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

Yes

NETWORK/DISEASE	ROLE OF YOUR LABORATORY (PARTICIPANT, ORGANISER, ETC)	NO. PARTICIPANTS	PARTICIPATING WOAH REF. LABS
Newcastle disease Alert/ Newcastle disease Diagnostic support	Regular exchange of results of molecular, epidemiological and diagnostic analyses by email and/or through Mattermost, a flexible, open source platform that enables active collaboration with the other European Laboratories	1	1. Friedrich Loeffler Institute, Federal Research Institute for Animal Health (Germany)

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
European Proficiency Test on Avian influenza and Newcastle disease Serological, Virological and Molecular tests (2024) https://www.izsvenezie.com/reference-laboratories/avian-influenza-newcastle-disease/proficiency-testing/	Organiser	thirty-nine (39) laboratories : twenty-six (26) EU National reference Laboratories (NRLs) and twelve (13) Non-EU NRLs (including four (3) from EFTA countries)	• Friedrich Loeffler Institute, Federal Research Institute for Animal Health Institute of Diagnostic Virology (Germany); • Animal and Plant Health Agency Weybridge (UK) (detailed Information and Final coded report available at the IZSVe)
European Proficiency Test on Avian influenza and Newcastle disease Serological, Virological and Molecular tests (2023) https://www.izsvenezie.com/reference-laboratories/avian-influenza-newcastle-disease/proficiency-testing/	Organiser	Forty-one (41) laboratories : twenty-six (26) EU National reference Laboratories (NRLs) and twelve (15) Non-EU NRLs (including four (4) from EFTA countries)	• Friedrich Loeffler Institute, Federal Research Institute for Animal Health Institute of Diagnostic Virology (Germany); • Animal and Plant Health Agency Weybridge (UK) (detailed Information and Final coded report • available at the IZSVe)
APHA Proficiency Test on Newcastle disease: Molecular, Serological and Virological tests (2023)	Participant	Information available from the organiser	The Animal and Plant Health Agency (APHA) Surrey, UK;

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
Use of bioinformatic tools to predict antigenic distance among NDV strains	Development of a bioinformatic tool to predict the antigenic distance between strains using the sequences of the F and HN genes and inferred amino acid feature Co-leaded by University of Padova and IZSVe	-National Reference Laboratory for Avian Influenza and Newcastle Disease, Federal Centre for Animal Health (FGBI "ARRIAH"), Yur'evets Vladimir, Russia; - Department of Agriculture National Veterinary Services Laboratories, Ames, IA, USA;
NDV in Columbiformes	Improved control of NDV in Columbiformes	-Laboratório Federal de Defesa Agropecuária – LFDA/SP – CGAL, Campinas

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
National Proficiency test for "Virology, serology and molecular biology diagnosis of avian influenza and Newcastle disease" 2024	organiser	21	AQUA IN 2024 https://www.izsvenezie.com/activities-services/interlaboratory-proficiency-testing/	ITALY,
National Proficiency test for "Virology, serology and molecular biology diagnosis of avian influenza and Newcastle disease" 2023	organiser	20	AQUA IN 2023 https://www.izsvenezie.com/activities-services/interlaboratory-proficiency-testing/	ITALY,

TOR12: EXPERT CONSULTANTS

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

No

29. Additional comments regarding your report:

No