World Organisation for Animal Health

Timm C. Harder - - GERMANY

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:**	Avian influenza
***Address of laboratory:**	Südufer 10, D-17493 GreifswaldInsel Riems
***Tel:**	+49-38351 7 1546
***E-mail address:**	timm.harder@fli.de
Website:	www.fli.de
***Name (including Title) of Head of Laboratory (Responsible Official):**	Prof Dr Martin Beer
***Name (including Title and Position) of WOAH Reference Expert:**	Dr Timm Harder
***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
Hemaggltuination inhibition assay	Yes	470	0
ELISA	Yes	720	0
Direct diagnostic tests		Nationally	Internationally
RT-qPCR	Yes	5980	56
Nucleotide sequencing	Yes	185	24

Virus isolation	Yes	84	12

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
RNA	RT-qPCR	28	26	2	1	BANGLADESH,
Inactivated viral antigen	HI	56	56	0	1	GERMANY,
Hyperimmune serum	ELISA, HI	24	23	1	1	UNITED KINGDOM,

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?

Yes

Name of the new test or diagnostic method developed	Description and References (Publication, website, etc.)
H5 ELISA	Commercial H5 ELISA for bovine sera

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	No. samples received for provision of confirmatory

			support	diagnoses
ICELAND	2024-01-01	RT.qPCR, Nucleotide sequencing	24	24
BANGLADESH	2024-05-01	RT-qPCR, Nucleotide sequencing	12	12

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

No

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
Kappaflu	4 years	Avian influenza epidemiology, pathogenesis and economic aspects	Broad consortium featuring various European labs	ITALY SWEDEN THE NETHERLANDS UNITED KINGDOM
Constanze-2	2 years	Active avian influenza surveillance at Lake Constance	National reference labs of Switzerland, Austria, Germany, various ornithological institutions	AUSTRIA SWITZERLAND

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

Yes

Research need : 1

Please type the Research need: Defining surveillance needs in poultry populations vaccinated against HPAIV

Relevance for WOAH Disease Control,

Relevance for the Code or Manual Code,

Field Epidemiology and Surveillance, Diagnostics, Vaccines,

Animal Category Terrestrial,

Disease:

Avian influenza

Kind of disease (Zoonosis, Transboundary diseases) Zoonosis, 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

If the answer is yes, please provide details of the data collected:
Design, supervision, participation and analyses of national surveillance programs in wild bird, mammalas and poultry in Germany

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:
Various phylogenetic analyses based on nucleotide sequencing (Iceland, Bangladesh, Germany)

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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Ahrens AK, Jónsson SR, Svansson V, Brugger B, Beer M, Harder TC, Pohlmann A. Iceland: an underestimated hub for the spread of high-pathogenicity avian influenza viruses in the North Atlantic. J Gen Virol. 2024; 105. doi: 10.1099/jgv.0.001985

Ahrens AK, Pohlmann A, Grund C, Harder T, Beer M. Novel Genotypes of Highly Pathogenic Avian Influenza H5N1 Clade 2.3.4.4b Viruses, Germany, November 2023. Emerg Infect Dis. 2024 Aug;30(8):1737-1739. doi: 10.3201/eid3008.240103

Ahrens AK, Pohlmann A, Grund C, Beer M, Harder TC. Out of the blue: detection of a unique highly pathogenic avian influenza virus of subtype H7N5 in Germany. Emerg Microbes Infect. 2024 Dec;13(1):2420723. doi: 10.1080/22221751.2024.2420723. Epub 2024 Nov 8. PMID: 39435698

Bregnballe T, Herrmann C, Globig A, Pohlmann A, Günther A, Staubach C, Neumann Heise J, Harder T, Beer M, Knief U, Heinicke T, Leivits M, Lundström K, Nurmoja I, Liang Y, Larsen LE, Hjulsager CK, Fox AD. Outbreaks of highly pathogenic avian influenza (HPAI) epidemics in Baltic Great Cormorant Phalacrocorax carbo colonies in 2021 and 2022. Birds 6, NNMM (2024); in press.

EFSA Panel on Animal Health and Animal Welfare (AHAW); European Union Reference Laboratory for Avian Influenza; Nielsen SS, Alvarez J, Bicout DJ, Calistri P, Canali E, Drewe JA, Garin-Bastuji B, Gortázar C, Herskin MS, Michel V, Miranda Chueca MÁ, Padalino B, Roberts HC, Spoolder H, Stahl K, Velarde A, Viltrop A, Winckler C, Bortolami A, Guinat C, Harder T, Stegeman A, Terregino C, Lanfranchi B, Preite L, Aznar I, Broglia A, Baldinelli F, Gonzales Rojas JL. Vaccination of poultry against highly pathogenic avian influenza - Part 2. Surveillance and mitigation measures. EFSA J. 2024 Apr 18;22(4):e8755. doi: 10.2903/j.efsa.2024.8755

Fusaro A, Zecchin B, Giussani E, Palumbo E, Agüero-García M, Bachofen C, Bálint Á, Banihashem F, Banyard AC, Beerens N, Bourg M, Briand FX, Bröjer C, Brown IH, Brugger B, Byrne AMP, Cana A, Christodoulou V, Dirbakova Z, Fagulha T, Fouchier RAM, Garza-Cuartero L, Georgiades G, Gjerset B, Grasland B, Groza O, Harder T, Henriques AM, Hjulsager CK, Ivanova E, Janeliunas Z, Krivko L, Lemon K, Liang Y, Lika A, Malik P, McMenamy MJ, Nagy A, Nurmoja I, Onita I, Pohlmann A, Revilla-Fernández S, Sánchez-Sánchez A, Savic V, Slavec B, Smietanka K, Snoeck CJ, Steensels M, Svansson V, Swieton E, Tammiranta N, Tinak M, Van Borm S, Zohari S, Adlhoch C, Baldinelli F, Terregino C, Monne I. High pathogenic avian influenza A(H5) viruses of clade 2.3.4.4b in Europe-Why trends of virus evolution are more difficult to predict. Virus Evol. 2024 Apr 6;10(1):veae027. doi: 10.1093/ve/veae027

Graaf-Rau A, Schmies K, Breithaupt A, Ciminski K, Zimmer G, Summerfield A, Sehl-Ewert J, Lillie-Jaschniski K, Helmer C, Bielenberg W, grosse Beilage E, Schwemmle M, Beer M, Harder T. Reassortment incompetent live attenuated and replicon influenza vaccines provide improved protection against influenza in piglets. npj Vaccines 9, 127 (2024). https://doi.org/10.1038/s41541-024-00916-x

Grau, K., Lillie-Jaschniski, K., Graaf-Rau, A., Harder, T.C., Eddicks, M., Zöls, S., Zablotski, Y., Ritzmann, M., Stadler, J., 2024. Effect of stabilizers on the detection of swine influenza A virus (swIAV) in spiked oral fluids over time: [Preprint]. Research Square. https://doi.org/10.21203/rs.3.rs-4486513/v1

King J, Pohlmann A, Bange A, Horn E, Hälterlein B, Breithaupt A, Globig A, Günther A, Kelm A, Wiedemann C, Grund C, Haecker K, Garthe S, Harder T, Beer M, Schwemmer P. Red knots in Europe: a dead end host species or a new niche for highly pathogenic avian influenza? J Gen Virol. 2024l; 105. doi: 10.1099/jgv.0.002003

Nooruzzaman M, Mumu TT, Hossain I, Kabiraj CK, Begum JA, Rahman MM, Ali MZ, Giasuddin M, King J, Diel DG, Chowdhury EH, Harder T, Islam MR, Parvin R. Continuing evolution of H5N1 highly pathogenic avian influenza viruses of clade 2.3.2.1a G2 genotype in domestic poultry of Bangladesh during 2018-2021. Avian Pathol. 2024, 9:1-14. doi: 10.1080/03079457.2024.2403427

Occhibove F, Knauf S, Sauter-Louis C, Staubach C, Allendorf V, Anton A, Barron S, Bergmann H, Bröjer C, Buzan E, Cerny J, Denzin N, Gethöffer F, Globig A, Gethmann J, Gonzálvez M, García-Bocanegra I, Harder T, Jori F, Keuling O, Neimanis A, Neumann Heise J, Pastori I, Parreira Perin P, Rijks J, Schulz K, Trogu T, Plis K, Vada R, Vercher G, Wischnewski N, Zanet S, Ferroglio E. The role of mammals in Avian Influenza: a review. EFSA Supporting Publications. EFSA J 2024, 21, 8692E. https://doi.org/10.2903/sp.efsa.2024.EN-8692

Schmies K, Hennig C, Rose N, Fablet C, Harder T, Grosse Beilage E, Graaf-Rau A. Dynamic of swine influenza virus infection in weaned piglets in five enzootically infected herds in Germany, a cohort study. Porcine Health Manag. 2024 Oct 1;10(1):36. doi: 10.1186/s40813-024-00390-w.

Stadler J, Zwickl S, Gumbert S, Ritzmann M, Lillie-Jaschnicki K, Harder T, Graaf-Rau A, Skampardonis V, Eddicks M. Influenza surveillance in pigs: balancing act between broad diagnostic coverage and specific virus characterization. Porc Health Manag 10, 19 (2024). https://doi.org/10.1186/s40813-024-00367-9

Swayne DE, Sims LD, Brown I, Harder T, Stegeman A, Abolnik C, Delgado M, Awada L, Pavade G, Torres G. Strategic challenges in the global control of high pathogenicity avian influenza. Rev Sci Tech. 2024; Special Edition: 89-102. doi: 10.20506/rst.SE.3563. PMID: 39713829.

b) International conferences:

3
FAO headquarter, Rome: Avian Influenza Conference

IABS, Paris: Conference on Vaccination in poultry against HPAIV

European AIV Reference Laboratory, Venice: Annual Conference on AIV and NDV (zoom)

c) National conferences:

10
Various regional and national presentations at symposia of disease control entities, farmers associations, consumers association

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

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	Document of accreditation	Akkreditierungsurkunde_2024.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
All assays mentioned in question 1	DAKKS

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

Yes

Work at FLI comprises biosafety levels 1-4. All procedure are layed down in written SOPs and management handbooks. Changes are to be approved by a biosecurity committee at FLI. The system is supervised internally by biorisk department and externally by independent officers of the state veterinary services. A separate ethics committee at FLI disucsses and eventually decides about work that is in the field of GoF/DURC.

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
Kappaflu	European research project on AIV	30	Various WOAH and FAO reference labs/centres from Europae in monthly discussions

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
AIV diagnostic capabilities: RT-qPCR, HI, HA,	Participant	45	EU-RL, Italy, organizer
AIV diagnostic capabilities: RT-qPCR, HI, HA,	Participant	35	APHA, UK, organizer
AIV diagnostic capabilities: RT-qPCR, HI, HA,	Participant	20	CSIRO, Australia, organizer
AIV diagnostic capabilities: RT-qPCR, HI, ELISA	Participant	60	GD Deventer, Netherlands, organizer

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
Kappaflu	AIV epidemiology, pathogenesis, economics	EU-RL Italy; APHA, UK; The Crick Institute, UK; Erasmus, NL

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?

No

n.a.

TOR12: EXPERT CONSULTANTS

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

No

29. Additional comments regarding your report:

No