World Organisation for Animal Health

Timm C. Harder - - GERMANY

WOAH Reference Laboratory Reports Activities 2025

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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 Greifswald-Insel Riems
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***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:**	Prof. 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
ELISA	Yes	1145	0
Hemagglutination inhibition	Yes	23	0
Direct diagnostic tests		Nationally	Internationally
PCR	Yes	18560	260
Virus isolation (cells)	Yes	169	5
NGS whole genome sequencing	Yes	177	15

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
Viral RNA	PCR	150/59	47	12	2	DENMARK, ICELAND,
Antisera	ELISA, HI	90/32	32	1	1	DENMARK,

Replication-competent viruses	VI, PCR, HI	25/16	16	1	1	DENMARK,

4. Did your laboratory produce vaccines?

No

5. Did your laboratory supply vaccines to WOAH Members?

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?

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

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
ICELAND	2025-11-10	PCR, NGS sequencing	18	18

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
Kappa-Flu	4 years	Advancement of knowledge on AIV	Various EU member states and the UK	ITALY SWEDEN THE NETHERLANDS UNITED KINGDOM
Molecular epidemiology of HPAIV in Iceland	2 years	Phylgenetic analysis of icelandic HPAIV	Keldur University, Reykjavik	ICELAND

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

Yes

Research need : 1

Please type the Research need: Testing HPAI-vaccinated poultry flocks for freedom from HPAIV infections.

Relevance for WOAH Disease Control,

Relevance for the Code or Manual Manual,

Field Epidemiology and Surveillance, Diagnostics, Vaccines,

Animal Category Terrestrial,

Disease:

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:
Surveillance of wild birds and poultry in Germany for HPAIV.

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:
Passing on sequencing results to the Eurpean Reference Laboratory for Avian Influenza, Italy.

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:

9

Hennig C, Graaf-Rau A, Schmies K, Elling R, Henneke P, Dürrwald R, grosse Beilage E, Schwemmle M, Beer M, Harder T. High serological barriers may contribute to restricted Influenza-A-virus transmission between pigs and humans. One Health 21 (2025) 101214. https://doi.org/10.1016/j.onehlt.2025.101214

Klink J, Alexandra Rieger, Peter Wohlsein, Sophie Aurich, Christiane Hoffmann, Christa Ewers, Marie-Kristin Raulf, Christina Strube, Annette Johne, Pavlo Maksimov, Timm Harder, Dennis Rubbenstroth, Laura Rehburg, Gisa Gerold, Robert Fux, Volker Rickerts, Hermann Ansorge, Ursula Siebert. Pathological findings in raccoon dogs (Nyctereutes procyonoides) in Schleswig-Holstein, Germany. J Comp Pathol, 2025: 219, 59-77; https://doi.org/10.1016/j.jcpa.2025.04.004.

Licheri M, Mwanga M, Licheri MF, Graaf-Rau A, Sägesser C, Bittel P, Harder T, Suter-Riniker F, Kelly JN, Dijkman R. Optimized high-throughput whole-genome sequencing workflow for surveillance of influenza A virus. Genome Med. 2025, 26; 17(1):103. doi: 10.1186/s13073-025-01512-x . PMID: 41013580

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. 2025; 54(2): 198-211. doi: 10.1080/03079457.2024.2403427

Parvin R, Helal SB, Uddin MM, Tasnim S, Hossain MR, Shila RA, Begum JA, Nooruzzaman M, Ahrens AK, Harder T, Chowdhury EH. Emerging Highly Pathogenic Avian Influenza H5N1 Clade 2.3.4.4b Causes Neurological Disease and Mortality in Scavenging Ducks in Bangladesh. Vet Sci. 2025 Jul 23;12(8):689. doi: 10.3390/vetsci12080689

Piesche R, Cazaban C, Frizzo da Silva L, Ramírez-Martínez L, Hufen H, Beer M, Harder T, Grund C. Immunogenicity and protective efficacy of five vaccines against highly pathogenic avian influenza virus H5N1, Clade 2.3.4.4b, in fattening geese.
Vaccines. 2025, 13, 399; doi: 10.3390/vaccines13040399

Sajjadi NC, Abolnik C, Baldinelli F, Brown I, Cameron A, de Wit S, Dhingra M, Espeisse O, Guerin JL, Harder T, Ho J, Chua TH, Hussein K, Lyons N, Monne I, Okamuro Y, Pacheco DT, Pavade G, Poncon N, Prajitno TY, Rojas JG, Swayne D, Stegeman A. Vaccination and surveillance for high pathogenicity avian influenza in poultry-current situation and perspectives. Biologicals. 2025 May 12;91:101840. doi: 10.1016/j.biologicals.2025.

Stadler J, Grau K, Lillie-Jaschniski K, Pesch S, Graaf-Rau A, Harder T, Zoels S, Fux R, Ritzmann M, Eddicks M. Diagnostic performance of ELISA kits and expanded antigen panels for hemagglutination inhibition assays in pig herds enzootically infected with porcine Influenza A viruses. Porcine Health Manag. 2025 Oct 27;11(1):53. doi: 10.1186/s40813-025-00464-3

Westphal L, Vietinghoff V, Moritz T, Nordheim H, Schaarschmidt T, Teifke JP, Wohlsein P, Piroch I, Harder T, König P, Höper D, Benke H, Dähne M. By-Catch of Grey Seals in Fish Traps in the German Baltic Sea—From Incidents to Mitigation and Fisheries Regulation. Aquatic Conservation: Marine and Freshwater Ecosystems, 2025: 35, e70147. https://doi.org/10.1002/aqc.70147

b) International conferences:

3

c) National conferences:

5

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?

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	KENYA	1

TOR8: QUALITY ASSURANCE

18. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)	
DIN EN ISO/IEC 17025:2018	PDF	Akkreditierungsurkunde_2024.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
PCR	DAKKS
ELISA	DAKKS
Virus isolation	DAKKS
NGS sequencing	DAKKS
HI	DAKKS

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

Yes

External and internal hierarchical supervision systems relevant to biosafety hazards and genetically-modified organisms.

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	location	Role (speaker, presenting poster, short communications)	Title of the work presented
WOAH Reference Centre Network Meeting	2025-05-21	Parix	Co-speaker	Data sharing with network activites and databases

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

Yes

NETWORK/DISEASE	ROLE OF YOUR LABORATORY (PARTICIPANT, ORGANISER, ETC)	NO. PARTICIPANTS	PARTICIPATING WOAH REF. LABS
Avian influenza	Participant	9	9 reference lab in the global diagnostic network for animal influenza viruses.

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
PCR, serology, organized by EU-RL, Padova, Italy	participant	>40	Various European countries
PCR organized by ACDP, Geelong, Australia	participant	>10	Global network of FAO/WOAH

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	Various aspects of AIV-related diagnsotic topics	EU-RL, IZSVe Padova, Italy

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
PCR, serology organized by GD Deventer, The Netherlands	participant	40	PCR, ELISA	THE NETHERLANDS,

TOR12: EXPERT CONSULTANTS

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

No

29. Additional comments regarding your report:

No