World Organisation for Animal Health

Katsuhiko Fukai - - JAPAN

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:**	Classical swine fever
***Address of laboratory:**	6-20-1 Josui-Honcho Kodaira Tokyo 187-0022
***Tel:**	+81-42 321 14 40
***E-mail address:**	fukai@affrc.go.jp
Website:	https://www.naro.go.jp/laboratory/niah/index.html
***Name (including Title) of Head of Laboratory (Responsible Official):**	Ken Katsuda, Director
***Name (including Title and Position) of WOAH Reference Expert:**	Katsuhiko Fukai, D.V.M., Ph.D., Manager, Division of Transboundary Animal Disease Research
***Which of the following defines your laboratory? Check all that apply:**	Research agency

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
Neutralization test	Yes	0	0

ELISA	Yes	0	0
Direct diagnostic tests		Nationally	Internationally
Virus isolation	Yes	19	0
real-time RT-PCR	Yes	5	0
Sequencing	Yes	48	0
conventional RT-PCR	Yes	18	0

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
DNA as positive control	Conventional RT-PCR for CSFV RNA detection (Vilcek et al., 1994, Arch. Virol., 136, 309–323)	Produced and provided	37 laboratories	0	1	JAPAN,
CPK-NS cells	Virus neutralization test (Sakoda et al., 1998, J Virol Methods, 75, 59–68)	Produced and provided	5 laboratories	0	1	JAPAN,

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

Name of the new test or diagnostic method developed	Description and References (Publication, website, etc.)
Tissue Direct Solution E	Reagent for simplified extraction of viral nucleic acids from ear pinna sections and organs https://catalog.takara-bio.co.jp/product/basic_info.php?unitid=U100009568

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?

No

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
THAILAND	Methods for evaluating the efficacy of attenuated CSF vaccines	Face-to-face
UGANDA	WOAH-recommended diagnostic procedures for CSF	Face-to-face

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
The collaboration of the development of the agriculture and food industry in Japan and Taiwan	2020-2025	To strategically cooperate for fostering the development of agricultural and food science and technology	Veterinary Research Institute, Council of Agriculture	CHINESE TAIPEI

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:

Developing new vaccine strategies, conducting efficacy trials against CSF, and advancing CSFV diagnostic methods—including rapid, sensitive, and cost-effective tests—alongside standardized reference material distribution

15. Did your laboratory disseminate epidemiological data that had been processed and analysed?

No

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:

0

b) International conferences:

2

Nishi T. 2024. Establishment of a direct PCR assay for simultaneous differential diagnosis of African swine fever and classical swine fever using diverse clinical samples. The Cutting Edge of African Swine Fever Research Symposium. Tsukuba, Japan, October 18, 2024, Oral presentation.

Kitamura T. 2024. Research for the control of African swine fever and classical swine fever. The 4th Joint Meeting of Veterinary Science in East Asia. Obihoro, Japan, September 8, 2024, Oral presentation.

c) National conferences:

1

Fukai K. 2024. Transboundary livestock infectious diseases. The 79th Kyushu-Yamaguchi Conference on Pathological Appraisal. Kagoshima, Japan, July 11, 2024, Oral presentation.

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

0

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: 2

d) Internships (>1 month) 1

Type of technical training provided (a, b, c or	Country of origin of the expert(s) provided	No. participants from the corresponding

d)	with training	country
C	THAILAND	2
D	UGANDA	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	PDF	ISO17025_certificate.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
CSFV RT-PCR	Japan Accreditation Board

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

Yes

Our high-containment facility is compliant with the containment level for group 4 pathogens described in the WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2024.

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
WOAH-Terrestrial Manual , Chapter CSF	Update of the vaccine part and justification for the listed diagnostic methods in the chapter CSF of the WOAH Terrestrial Manual	8	China, Japan, UK, Germany, Spain, Chinese Taipei, Poland, Canada

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
Validation of diagnostic protocols: Realtime RT-PCR, Conventional RT-PCR, Antigen ELISA, Virus isolation, Sequencing, Virus Neutralization assay, Antibody ELISA	Participant	N/A	Germany
Validation of diagnostic protocols: Realtime RT-PCR, Conventional RT-PCR, Sequencing, Virus Neutralization assay, Antibody ELISA	Participant	N/A	Canada

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?

No

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?

Yes

Kind of consultancy	Location	Subject (facultative)
Revision and update the WOAH Terrestrial_Manual, Classical swine_fever virus (infection with classical swine fever virus)	Remote	Revision and update

29. Additional comments regarding your report:

No

N/A