World Organisation for Animal Health

María del Carmen Gallardo Frontaura - - SPAIN

# WOAH Reference Laboratory Reports Activities 2025

**This report has been submitted: 20 janvier 2026 15:10**

## LABORATORY INFORMATION

| | |
|---|---|
| ***Name of disease (or topic) for which you are a designated WOAH Reference Laboratory:** | African swine fever |
| ***Address of laboratory:** | Carretera de Algete el Casar s/n |
| ***Tel:** | +34916202300 |
| ***E-mail address:** | gallardo@inia.csic.es |
| **Website:** | |
| ***Name (including Title) of Head of Laboratory (Responsible Official):** | Prof. Noemí Sevilla Hidalgo |
| ***Name (including Title and Position) of WOAH Reference Expert:** | Dr. María del Carmen Gallardo Frontaura |
| ***Which of the following defines your laboratory? Check all that apply:** | Governmental 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 |
| INgezim ASF-BLOCKING ELISA R.11.PPA.K.3/5 | No | 0 | 18 |
| Indirect immunoperoxidase technique (IPT) | Yes | 0 | 269 |
| Immunoblotting (IB) | Yes | 0 | 2 |
| Direct diagnostic tests | | Nationally | Internationally |
| Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) | Yes | 0 | 899 |
| Virus isolation and Haemadsorption test (HAD) | Yes | 0 | 237 |

## 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 |
|---|---|---|---|---|---|---|
| ASF semipurified | WOAH indirect ELISA | PRODUCED | 16,000 DOSES | 0 | 1 | SPAIN, |

| | | | | | | |
|---|---|---|---|---|---|---|
| antigen (ASF-Ag) | | | | | | |
| ASF positive reference sera (ASF-PC) | WOAH indirect ELISA WOAH IPT WOAH IB | PRODUCED | 0 | 6.2 ML | 5 | BELGIUM, CROATIA, ESTONIA, POLAND, UKRAINE, |
| ASF negative reference sera (ASF-NC) | WOAH indirect ELISA WOAH IPT WOAH IB | PRODUCED | 0 | 2.2 ML | 4 | CROATIA, ESTONIA, POLAND, UKRAINE, |
| ASF limit reference sera (ASF-LC) | WOAH indirect ELISA WOAH IPT WOAH IB | PRODUCED | 0 | 3,2 ML | 5 | BELGIUM, CROATIA, ESTONIA, POLAND, UKRAINE, |
| ASFV ISOLATES | PCR and virus isolation | PRODUCED | 0 | 17 ML | 3 | BELGIUM, ITALY, SLOVENIA, |
| IMMUNOBLOTTING STRIPS | WOAH IB | PRODUCED | 0 | 173 STRIPS | 3 | BELGIUM, SLOVAKIA, SLOVENIA, |
| Fixed ASFV monkey stable cells 96- wells immuno-plates (ASF-IPT) | WOAH-IPT | PRODUCED | 0 | 13 plates (1200 determinations) | 4 | CROATIA, ESTONIA, NORWAY, SLOVENIA, |
| Secondary antibody protein-A peroxidase (HRP-Protein A) | WOAH indirect ELISA WOAH IPT WOAH IB | IMPORTED | 0 | 2 MG | 2 | CROATIA, ESTONIA, |
| ASF-REF1 ASF reference panel of serum samples | For the evaluation, validation and internal verification of ASF antibody detection techniques | PRODUCED | 0 | 10 ml | 1 | POLAND, |
| ASF-REF2 ASF reference panel of serum and tissue samples | For the evaluation, validation and internal verification of DNA extraction methods | PRODUCED | 0 | 16 ml | 1 | POLAND, |
| ASF-REF3 ASF reference panel of DNAs | For the validation and internal verification of ASF-PCR techniques | PRODUCED | 0 | 21 | 1 | POLAND, |

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?

Yes

| Name of the new test or diagnostic method developed | Description and References (Publication, website, etc.) |
|---|---|
| GPS Genetic PCR Solutions | Report title: Evaluation of the GPS Genetic PCR commercial kit / experimental kit for the virological diagnosis of African swine fever (*) Date of publication: 10 March 2025 DIGITAL.CSIC, Spanish National Research Council (Spain) |
| KleverVet ASFV PCR Kit | Report title: Evaluation of the KleverVet ASFV PCR Kit commercial kit / experimental kit for the virological diagnosis of African swine fever (*) Date of publication: 27 January 2025 DIGITAL.CSIC, Spanish National Research Council (Spain) |

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

**María del Carmen Gallardo Frontaura - - SPAIN**

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 |
|---|---|---|---|---|
| CROATIA | 2025-04-10 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) | 0 | 12 |
| LATVIA | 2025-04-16 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) | 0 | 92 |
| BULGARIA | 2025-04-25 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) | 0 | 20 |
| CZECH REPUBLIC | 2025-05-08 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) - Commerical ELISA: INgezim ASF-BLOCKING ELISA R.11.PPA.K.3/5 - WOAH- Immunoblotting (IB) | 0 | 10 |
| MOLDOVA | 2025-05-20 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) - Commerical ELISA: INgezim ASF-BLOCKING ELISA R.11.PPA.K.3/5 - WOAH- Immunoblotting (IB) | 0 | 15 |
| ROMANIA | 2025-05-29 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) | 0 | 26 |
| ESTONIA | 2025-05-29 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) - Commerical ELISA: INgezim ASF-BLOCKING ELISA R.11.PPA.K.3/5 - WOAH- Immunoblotting (IB) | 0 | 26 |
| GREECE | 2025-06-10 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and | 0 | 10 |

| | | | | |
|---|---|---|---|---|
| | | HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) | | |
| NORTH MACEDONIA (REP. OF) | 2025-07-18 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) | 0 | 22 |
| ESTONIA | 2025-08-11 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) | 0 | 14 |
| ESTONIA | 2025-09-24 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) - Commerical ELISA: INgezim ASF-BLOCKING ELISA R.11.PPA.K.3/5 - WOAH- Immunoblotting (IB) | 0 | 10 |
| CROATIA | 2025-10-17 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) - Commerical ELISA: INgezim ASF-BLOCKING ELISA R.11.PPA.K.3/5 - WOAH- Immunoblotting (IB) | 0 | 20 |
| SPAIN | 2025-12-01 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) | 0 | 2 |
| SPAIN | 2025-12-09 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) - Commerical ELISA: INgezim ASF-BLOCKING ELISA R.11.PPA.K.3/5 - WOAH- Immunoblotting (IB) | 0 | 12 |
| ROMANIA | 2025-12-18 | - WOAH-Real-time PCR procedure 2 (Fernández-Pinero et al., 2013) - Virus isolation and HAD test - WOAH-indirect Immunoperoxidase test (IPT) (Gallardo et al., 2022) | 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 |
|---|---|---|
| | Expert technical advice on ASFV molecular epidemiology and multigene genotyping, specifically regarding the interpretation and classification of MGF | |

| | | |
|---|---|---|
| KOREA (REP. OF) | variants (MGF-1 to MGF-8) within genotype II ASFV, including clarification of criteria used to distinguish MGF subtypes and their relevance within the multigene genotyping framework developed and validated at eh EURL and WOAH reference lab. | Remote technical consultancy (scientific correspondence and expert clarification). |
| JAMAICA | Expert technical advice on ASFV molecular diagnostics, specifically on the selection and implementation of internal extraction and amplification controls for real-time PCR assays in a country with a naïve ASFV population and restrictions on the importation of ASFV biological material. | Remote technical consultancy (scientific correspondence and expert guidance). |
| UNITED STATES OF AMERICA | 1. Expert technical advice on ASF diagnostic sampling strategies, specifically regarding sample pooling (blood and spleen swabs) for ASFV real-time PCR detection, including clarification of recommended pooling ratios, study design, and Ct value ranges evaluated across different stages of infection, to support diagnostic assay validation activities. 2. Expert technical advice on ASFV inactivation procedures and biosafety, including guidance on validated inactivation approaches including verification by virus isolation. Provision of the standard operating procedures (SOPs) related to virus isolation and handling, to support work under appropriate containment conditions. | Remote technical consultancy, including sharing of SOPs and technical guidance via scientific correspondence. |
| NEPAL | Expert technical advice to support the establishment of ASF laboratory diagnostic capacity, including access to EU Reference Laboratory (EURL) and WOAH–recommended diagnostic protocols and related technical guidance, following difficulties with previously implemented methods. | Remote technical consultancy, including provision of access to EURL ASF diagnostic protocols and scientific correspondence. |
| ARGENTINA | Expert technical advice on ASF serological diagnosis, specifically regarding confirmatory methods beyond ELISA, including guidance on the availability and use of immunoperoxidase test (IPT) and immunofluorescence assay (IFA) for ASF diagnosis and their applicability in routine laboratory settings. | Remote technical consultancy (scientific correspondence and technical guidance). |
| CROATIA | Expert technical advice on ASF serology and virus characterization, including interpretation of antibody-positive results compatible with chronic ASF infection in wild boar, clarification of the ASFV serotype concept and its relevance in Europe, and guidance on the feasibility and limitations of ASF antibody serotyping in relation to circulating genotype II viruses. | Remote technical consultancy (scientific correspondence and expert guidance). |

| | | |
|---|---|---|
| SLOVENIA | Expert technical advice supporting laboratory accreditation of ASF serological diagnostics, specifically addressing ELISA (Ingenasa 1.1.K3) incubation temperature settings, validation of WOAH and EURL-recommended conditions (37 °C ± 2 °C) versus manufacturer instructions, and interpretation of these parameters in the context of external audit and quality management requirements. | Remote technical consultancy (scientific correspondence and technical guidance). |
| FRANCE | Expert technical advice on ASF virus isolation procedures, specifically regarding the use of blood samples collected in EDTA versus heparin tubes for ASFV isolation on porcine macrophages, in line with WOAH Manual recommendations and EURL standard operating procedures, to support the optimisation and simplification of laboratory workflows. | Remote technical consultancy (scientific correspondence and technical guidance). |
| HUNGARY | Expert technical advice on ASF virus isolation and molecular characterization, including guidance on sample type and quality (blood/fluids, tonsils), virus isolation on porcine macrophages (PAM/PBMs), interpretation of HAD-positive and HAD-negative strains, selection of genomic regions for diagnosis, genotyping and subtyping (p72 and multigene approach), and advice supporting the design of a PhD research project and collaborative studies on ASFV isolates circulating in Hungary. | Remote technical consultancy (scientific correspondence, protocol guidance and expert recommendations). |
| NORWAY | Expert technical advice on ASF serological diagnosis, specifically regarding the performance of commercial competition ELISA kits for ASF antibody detection (INGEZIM® PPA COMPAC K3 and ID Screen® ASF Competition), including information derived from WOAH and EURL validation studies on sensitivity and specificity, to support laboratory decision-making while maintaining neutrality regarding manufacturers. | Remote technical consultancy (scientific correspondence and expert guidance). |
| THE NETHERLANDS | 1- Expert technical advice on ASF diagnostic workflows for suspicion cases, including guidance on the appropriate use of PCR as frontline testing, the role and timing of serology in suspicion and follow-up investigations, handling of sample matrices (EDTA blood, target organs, serum), and consideration of alternative techniques (e.g. IPT) under specific epidemiological scenarios, while respecting national contingency planning responsibilities. 2. Expert technical advice on ASF sampling | Remote technical consultancy (scientific correspondence and expert guidance). |

| | | |
|---|---|---|
| | strategies and pooling practices, including guidance on tissue selection in experimental vs field conditions, | |
| PORTUGAL | Expert technical advice on ASF serological diagnostics, specifically regarding the performance and validation of the ID.VET competitive ELISA, including interpretation of specificity and sensitivity results under field and experimental conditions, impact of sample matrix effects (e.g. hemolysis in hunted wild boar), and guidance on confirmatory testing strategies (IPT or alternative assays) within surveillance programmes. | Remote technical consultancy (scientific correspondence and expert guidance). |
| ROMANIA | Expert technical advice on ASFV detection in meat and feed samples, including clarification of the regulatory framework, recommended PCR methods, and sample preparation procedures. | Remote technical consultancy (scientific correspondence and protocols). |
| SWITZERLAND | Expert technical advice on ASFV molecular diagnosis, including guidance on the replacement of discontinued UPL probes by a TaqMan probe, confirmation of equivalent diagnostic performance, and provision of the EURL/WOAH real-time PCR protocol and SOPs. | Remote technical consultancy, including sharing of protocols and technical documentation. |

# 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 |
|---|---|---|---|---|
| Multigene molecular characterization of African swine fever virus genotype II circulating in Europe (2007–2025) | 2025 | Comprehensive molecular characterization of ASFV genotype II circulating in Europe using a multigene approach (Gallardo et al., 2023), enabling the identification of 29 genetic groups. The study aimed to improve molecular epidemiology, trace virus spread across countries and hosts, and support surveillance, control and risk assessment strategies at European level. | EU, FAO and WOAH Reference Laboratory for ASF (CISA-INIA/CSIC) in collaboration with National Reference Laboratories (NRLs) of the participating WOAH Member Countries. | BULGARIA CROATIA CZECH REPUBLIC ESTONIA GREECE LATVIA MOLDOVA NORTH MACEDONIA (REP. OF) ROMANIA SPAIN |

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

Yes

Research need : 1

**Please type the Research need:** Harmonisation of molecular characterization strategies for African swine fever virus (ASFV) during outbreak investigations

**Relevance for WOAH** Disease Control, Capacity Building, Standard Setting, Facilitation of international collaboration,

**Relevance for the Code or Manual** Manual,

**Field** Epidemiology and Surveillance, Diagnostics,

**Animal Category** Terrestrial,

**Disease:**

African swine fever

**Kind of disease (Zoonosis, Transboundary diseases)** Transboundary diseases,

**Additional keywords if needed: One keyword per entry**

ASF,Molecular epidemiology,Whole genome sequencing,Multigene genotyping,Outbreak investigation

**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:* WOAH Terrestrial Manual – Chapter on African swine fever (diagnostic methods and molecular characterization)

**Notes:**

*Answer:* The main regulatory gap identified for African swine fever (ASF) concerns the lack of harmonised molecular characterization approaches applied during outbreak investigations. At present, molecular characterization is not performed in a homogeneous manner across affected countries, largely due to the large size and complexity of the ASFV genome, which makes whole genome sequencing (WGS) difficult to implement routinely at National Reference Laboratories (NRLs). There is a clear need to strengthen and standardise WGS activities at international reference laboratories, generating high-quality reference data for ASFV circulating in affected countries. In parallel, it is essential to define and harmonise validated multigene genotyping approaches that can be applied by NRLs lacking WGS capacity. Incorporating both WGS and standardised multigene characterization protocols into the WOAH Terrestrial Manual would significantly enhance molecular epidemiology, improve outbreak tracing, support disease control strategies, and ensure comparability of data between countries.

# 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:

The laboratory collected epidemiological and molecular data on African swine fever virus (ASFV) from samples submitted by WOAH Member Countries, including host species (wild boar/domestic pig), geographical origin, epidemiological context (case/outbreak), and molecular characterization data generated through a multigene genotyping approach and, when applicable, whole genome sequencing. These data support transboundary disease monitoring, outbreak investigation and international disease control.

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:

Processed and analysed molecular epidemiological data were disseminated to National Reference Laboratories, Competent Authorities, WOAH, FAO and the European Commission, including results of multigene characterization, assignment to genetic groups, and interpretation of virus circulation and spread across affected countries. Data were also shared through scientific publications, international meetings and expert networks.

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:

*2*

*1. Torresi C, Biccheri R, Cammà C, Gallardo C, Marcacci M, Zoppi S, Secondini B, Riverso C, Soler A, Casciari C, Pela M, Rossi E, Pellegrini C, Iscaro C, Feliziani F, Giammarioli M. Genome-Wide Approach Identifies Natural Large-Fragment Deletion in ASFV Strains Circulating in Italy During 2023. Pathogens. 2025 Jan 10;14(1):51. doi: 10.3390/pathogens14010051. PMID: 39861012; PMCID: PMC11769418.*

*2. Kamber Taslaman, M.; Prpić, J.; Božiković, M.; Lolić, M.; Barbić, L.; Gallardo, C.; Nieto, R.; Jemeršić, L. Epizootiology of African Swine Fever in the Croatian Wild Boar Population and the Estimation of the Surviving Dynamics (2023–2024). Viruses 2026, 18, 15. https://doi.org/10.3390/v18010015*

b) International conferences:

*4*
*28–29 Apr 2025 – Global African Swine Fever Research Alliance (GARA) Scientific Meeting.*
*Organiser: GARA. Location: Rome, Italy. Type: Oral presentation.*
*Title: African swine fever: leveraging molecular and biological virus knowledge to enhance diagnostics and control.*
*Author: Gallardo C.*

*3 Jun 2025 – Workshop on Laboratory Diagnosis of ASF and CSF.*
*Organiser: EU Reference Laboratories for ASF and CSF with DG SANTE (EC). Location: Madrid, Spain. Type: Oral presentation.*
*Title: Report of the ASF EURL activities in 2024–2025.*
*Author: Gallardo C.*
*Link: https://asf-referencelab.info/annual-meetings/workshop-asfcsf-2025/*

*17–19 Jun 2025 – Global Laboratory and Epidemiology Networking Workshop on Transboundary Animal Diseases (TADs) – ASF Laboratory diagnostics.*
*Organiser: IAEA. Location: Vienna, Austria. Type: Oral presentation.*
*Title: ASF Laboratory diagnostics.*
*Author: Gallardo C.*

*10–12 Dec 2025 – EUVET Mission on African swine fever in Spain.*
*Organiser: European Union Reference Laboratory for ASF. Location: Barcelona, Spain. Type: Oral presentation.*
*Title: Molecular characterization of the ASF Spanish isolate.*
*Authors: Gallardo C., Nieto R.*

c) National conferences:

*0*

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

*1*
*Due to the widespread circulation of genotype II ASFV, high-resolution molecular tools are required for effective outbreak tracing and molecular epidemiology. The WOAH for ASF maintains a dedicated genotype II sequence database, based on a harmonised multigene approach, allowing the discrimination of 28 genetic clusters and supporting outbreak investigations and disease control funding by the EC under the EURL framework.*
*https://asf-referencelab.info/sequence-database-info/*

# 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/IEC 17025 | Spanish Accreditation Service (ENAC) with accreditation number No 969/LE1865 under ISO/IEC 17025 | 969_LE1865.pdf |

19. Is your quality management system accredited?

Yes

| Test for which your laboratory is accredited | Accreditation body |
|---|---|
| ASF antibody detection by commercial blocking ELISA SOP/CISA/PPA/ELISA/2 | ENAC |
| ASF antibody detection by the WOAH indirect ELISA SOP/CISA/PPA/ELISA/1 | ENAC |
| ASF antibody detection by WOAH Immunoblotting (confirmatory test) SOP: SOP/CISA/ASF/IB/1 | ENAC |
| | |

| | |
|---|---|
| ASF virus detection by WOAH conventional PCR SOP: SOP/CISA/ASF/PCR/1 | ENAC |
| ASF virus detection by the WOAH real-time PCR procedure 1 SOP: SOP/CISA/ASF/PCR/2; | ENAC |
| ASF virus detection by the WOAH real-time PCR procedure 2 SOP/CISA/ASF/PCR/3 | ENAC |
| ASF antibody detection by the WOAH Immunoperoxidase test (IPT) SOP: SOP/CISA/ASF/IPT/1 | ENAC |

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

Yes

The activities related to African swine fever (ASF) are carried out at the Centre for Research on Animal Health (CISA-INIA/CSIC), a high-containment biosafety level 3 (BSL-3) facility located in Valdeolmos (Madrid, Spain). CISA was established by Spanish Royal Decree and is integrated within the Spanish National Research Council (CSIC). CISA operates under a comprehensive biorisk management system, with controlled access, trained personnel, validated standard operating procedures, and dedicated infrastructure for the safe handling of high-consequence animal pathogens. The biosafety facility includes BSL-3 laboratories and animal facilities, air-lock systems, sealed infrastructures, decontamination barriers and autoclaves, ensuring full containment and biosecurity. CISA is part of the Network of High Biosafety Laboratories (RLASB) and the Laboratory Network for Biological Alert (RELAB) in Spain. In addition, CISA biosecurity is accredited under UNE-CWA 15793 / ISO 35001, and the institute is designated as a FAO Reference Centre for Biorisk Management, demonstrating internationally recognised expertise in biosafety and biosecurity.

# 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 Centres Network Meeting (Joint WOAH Reference Centre Network Meeting) | 2025-05-21 | Paris, France | Speaker / technical contributor iwth short comunicaction on ASF reference reagents | Availability and sharing of reagents |
| GF-TADs for Africa – Fifth Meeting of the Standing Group of Experts (SGE) on ASF (Topic: ASF vaccines and vaccination) | 2025-10-13 | Lomé, Togo | Speaker (oral presentation) | Update on the global ASFV vaccine situation and guidance for African context |

# 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 |
|---|---|---|---|
| Reference Laboratory Network for African swine Fever | Participant | 7 | - CSIRO Australian Centre for Disease Preparedness — Australia - National Centre for Foreign Animal Disease, Canadian Food Inspection Agency — Canada - National ASF Reference Laboratory, China Animal Health and Epidemiology Center — People's Republic of China - Onderstepoort Veterinary Institute, Agricultural Research Council — South Africa - Centro de Investigación en Sanidad Animal (CISA-INIA/CSIC) — Spain - The Pirbright Institute — United Kingdom - National Veterinary Services |

| | | | |
|---|---|---|---|
| | | | Laboratories (NVSL), USDA-APHIS — United States of America |

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 |
|---|---|---|---|
| 1. EURL-XXI Inter-Laboratory comparison tests for ASF (ILCT-ASF) 2023-2024.Harmonisation of ASF serological and virological diagnostic tests, organised by the EURL for ASF and funded by the European Commission for EU Member States; WOAH non-EU laboratories participated on a self-funded basis. | ORGANIZER | 36 | WOAH Reference Laboratory for ASF – UCM (Madrid), Spain (participant); WOAH Reference Laboratory for ASF – Australia (participant) |
| 2. EURL-XXII Inter-Laboratory comparison tests for ASF (ILCT-ASF) 2024-2025. Harmonisation of ASF serological and virological diagnostic tests, organised by the EURL for ASF and funded by the European Commission for EU Member States; WOAH non-EU laboratories participated on a self-funded basis. | ORGANIZER | 39 | WOAH Reference Laboratory for ASF – UCM (Madrid), Spain (participant); WOAH Reference Laboratory for ASF – Australia (participant) National Centre for Foreign Animal Disease, Canadian Food Inspection Agency — WOAH Reference Laboratory for ASF, Canada (participant) |
| 3. EURL-XXIII Inter-Laboratory comparison tests for ASF (ILCT-ASF) 2025-2026. Harmonisation of ASF serological and virological diagnostic tests, organised by the EURL for ASF and funded by the European Commission for EU Member States; WOAH non-EU laboratories participated on a self-funded basis. | ORGANIZER | 37 | CSIRO Australian Centre for Disease Preparedness — WOAH Reference Laboratory for ASF, Australia (participant) National Centre for Foreign Animal Disease, Canadian Food Inspection Agency — WOAH Reference Laboratory for ASF, Canada (participant) Onderstepoort Veterinary Institute, Agricultural Research Council — WOAH Reference Laboratory for ASF, South Africa (participant) National Veterinary Services Laboratories (NVSL), USDA-APHIS — WOAH Reference Laboratory for ASF, United States of America (participant) Centro de Investigación en Sanidad Animal (CISA-INIA/CSIC) — WOAH Reference Laboratory for ASF, Spain (organiser) |

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?

Yes

| Purpose for inter-laboratory test comparisons1 | Role of your reference laboratory (organizer/participant) | No. participating laboratories | Name of the test | WOAH Member Countries |
|---|---|---|---|---|
| Harmonisation of ASF serological and virological diagnostic capacities in Latin American WOAH | | | | ARGENTINA, COLOMBIA, |

| | | | | |
|---|---|---|---|---|
| Member Countries, through inter-laboratory proficiency testing organised within the WOAH framework, to strengthen diagnostic readiness, comparability of results and regional preparedness for ASF. | ORGANIZER | 8 | II WOAH-ASF ILCT 2025 | COSTA RICA, CUBA, ECUADOR, PARAGUAY, PERU, URUGUAY, |

# TOR12: EXPERT CONSULTANTS

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

Yes

| Kind of consultancy | Location | Subject (facultative) |
|---|---|---|
| Participation in WOAH Reference Centres Network Meeting | Paris, France (22–23 May 2025) | Expert contribution to the WOAH Reference Centres Network, focusing on genomic platforms, point-of-care testing (POCT), inter-laboratory comparison tests (ILCTs), availability and sharing of diagnostic reagents, and harmonisation of ASF diagnostic and surveillance approaches, including collaboration with other WOAH Reference Laboratories. |

29. Additional comments regarding your report:

No