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**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

SN/T 5335-2020

**Technical Specification for Biosafety Operation of African
Swine Fever Testing Laboratory**

非洲猪瘟检测实验室生物安全操作技术规范
(English Translation)

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Foreword

This document was drafted in accordance with the rules given in GB/T 1.1-2020.

This document was proposed and managed by the General Administration of Customs of the People's Republic of China.

Drafting organizations of this document. Gongbei Customs of the People's Republic of China, Qingdao Customs of the People's Republic of China, Shanghai of the People's Republic of China Customs, Beijing Customs of the People's Republic of China, Dalian Customs of the People's Republic of China, Changchun Customs of the People's Republic of China, People's Republic of China Shenzhen Customs of the country, Guangzhou Customs of the People's Republic of China, Changsha Customs of the People's Republic of China, and Chongqing Customs of the People's Republic of China.

1 Scope

This document specifies the basic biological safety requirements of African swine fever testing laboratories, including sample reception and management, sample processing,

sample Testing, the harmless treatment of waste and residual samples, the disinfection of facilities and the environment, and the delivery of positive samples for preliminary screening.

This document is applicable to related activities of African swine fever testing laboratories.

2 Normative references

The contents of the following documents constitute the indispensable clauses of this document through normative references in the text. Among them, dated quotations Only the version corresponding to that date is applicable to this document; for undated references, the latest version (including all amendments) is applicable Used in this document.

GB/T 18088 Entry and Exit Animal Quarantine Sampling GB/T 18648 African swine fever diagnostic technology GB 19489 Laboratory Biosafety General Requirements GB/T 27401 Laboratory Quality Control Specification Animal Quarantine SN/T 1559 Technical Specification for African Swine Fever Quarantine Regulations on Biosafety Management of Pathogenic Microorganism Laboratories (Order No. 424 of the State Council) Transport and packaging specifications for highly pathogenic animal pathogenic microorganisms (virus) species or samples (Announcement No. 503 of the Ministry of Agriculture) World Organization for Animal Health (OIE) Terrestrial Animal Diagnostic Test and Vaccine Manual (2019 Edition) the Food and Agriculture Organization of the United Nations (FAO) Animal Production and Health Manual (2018 Edition)

3 Terms and definitions

There are no terms and definitions that need to be defined in this document.

4 Basic requirements for laboratory biosafety

4.1

African swine fever virus is a highly pathogenic animal microorganism. For related information, see Appendix A. According to Article 30 of Order No. 424 of the State Council it is determined that those engaged in the isolation of highly pathogenic microorganisms and related experimental activities on animals should be carried out in a biosafety level 3 or above laboratory.

4.2

For laboratories that carry out the detection of African swine fever virus nucleic acid and antibodies, their facilities and equipment should comply with the level of biosafety level 2 in GB 19489.

(BSL-2) and above laboratory requirements. The experimental activities before the sample inactivation should be operated in a biological safety cabinet, waste and tested samples it

should be sterilized by high-pressure steam.

4.3

The management, technology, process control and result quality control of laboratories that carry out the detection of African swine fever virus nucleic acid and antibody shall be consistent with Meet the requirements of GB/T 27401.

4.4

For laboratories that carry out the detection of African swine fever virus nucleic acid and antibodies, the types of testing activities they are engaged in should reach the corresponding level of biological Safety laboratory protection requirements, and obtain the approval of the competent authority. Laboratories that have not obtained authorization or testing qualifications should not carry out African swine fever testing.

5 Sample reception and management

5.1

The packaging and transportation of the samples should meet the requirements of the Ministry of Agriculture Announcement No. 503, using sealed three-layer packaging, with a biohazard sticker on the outer packaging.

The risk identification will be delivered to the laboratory by a dedicated person.

5.2

The samples used for African swine fever detection should be refrigerated and transported at 2 °C ~ 8 °C, and delivered to the laboratory as soon as possible (within 24 hours). For viral nucleic acid or the samples for serum antibody testing should be stored temporarily (within 24 hours) at 2 °C ~ 8 °C, and stored at -20 °C or -70 °C for a longer period of time. Need to separate serum of non-anticoagulated blood, the serum was collected after 12 hours to 24 hours at room temperature. The blood used for PCR and other viral nucleic acid detection should be anticoagulated with EDTA.

Organize samples to be collected and submitted for inspection in accordance with the requirements of the Ministry of Agriculture Announcement No. 503. The amount of samples sent should meet the requirements of initial screening test and confirmation of sample delivery.

Meet the requirements of GB/T 18088.

5.3

When the laboratory receives samples, the sampling personnel should check whether the outer packaging is damaged, and confirm that the samples are transported to the laboratory under refrigerated and sealed conditions.

room. If the package is found to be damaged, a sealed package should be added to the outer layer, and the sample delivery personnel should be notified immediately to assess the risk of virus exposure and deal with it.

5.4

After confirming that the outer packaging of the sample is not damaged, open the outer packaging in the sample room and check that the inner packaging of the sample is free of leakage and pollution.

Check that the sample type and quantity are correct, and affix the sample logo.

5.5

A strict management system should be implemented for the African swine fever test samples, and the laboratory should have a special freezer or refrigerator for the African swine fever test samples.

The preservation of products is strictly managed by "double locks". If it is necessary to obtain test samples, it shall be approved by the person in charge of the laboratory, and Sample manager records.

5.6

The sample identification shall include but not limited to the following information. sample number, name, quantity, and test items.

5.7

The samples used for the detection of African swine fever shall not be retained. After the test task is completed, the samples with negative test results should be autoclaved Steam disinfection (121°C, 30 min) or other harmless measures should be used for treatment, and the treatment records should be made. Samples with a positive initial screening result are required If the diagnosis is confirmed, it shall be packaged and sent to the diagnosis laboratory designated by the competent authority.

6.1 Sample preparation

The inspector is responsible for processing and testing the samples. Take out the sample, after the sample is thawed, send it to the biosafety laboratory in a sealed state Sample preparation is carried out in the whole cabinet.

6.2 Sample preparation requirements

Before opening the sample package in the biological safety cabinet, an effective disinfectant should be used for surface disinfection, and then aseptic sampling treatment should be carried out.