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

SN/T 3224-2012

**Protocol for validation of ELISA for the diagnosis of animal
infectious/contagious diseases**

动物传染病ELISA检测技术确认规范

(English Translation)

Issued on: January 1, 1970

Implemented on: January 1, 1970

Issued by: General Administration of Customs

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules.

This revised standard adopts the World Organisation for Animal Health (OIE) "Terrestrial animal diagnostic tests and vaccines Handbook" (2010 edition) 1.1.4/5 "Infectious disease diagnosis to confirm the principles and methods." this standard and OIE "terrestrial animal diagnostic tests and vaccines Handbook" (2010 edition) 1.1.4/5 "Infectious Diseases confirmed the original diagnosis Management and methods, "compared to the main technical differences are as follows.

--- Specifies how the non-standard methods, laboratory design (development) of the method, beyond the standard method of its intended scope, expanding Charge and modified standard methods to confirm the method does not involve building process;

--- Does not involve the diagnostic sensitivity and specificity of diagnosis;

How to get international recognition after --- not involve confirmation.

This standard is proposed and managed by the National Certification and Accreditation Administration Committee.

This standard was drafted. People's Republic of China Beijing Entry-Exit Inspection and Quarantine Bureau, People's Republic of China Liaoning Entry-Exit Inspection and Quarantine Bureau, People's Republic of China Jiangsu Entry-Exit Inspection and Quarantine Bureau, Beijing Municipal Veterinary Drug Control, China Accreditation Board for Conformity Assessment.

Introduction

Reliable detection methods consistent with the regulatory requirements of all international and national requirements in the field of detection. Veterinary Diagnostic Laboratory recognition Only movable in all laboratory methods have been fully recognized the premise makes sense. Accredited laboratories should be given Test results are highly reproducible,

but if confirmed the process approach is not appropriate, the test results can also be done on the infection status of animals A misjudgment. To make a proper test method is applied, the method should be fully recognized, confirmation should follow OIE diagnostic manual confirmation chapter the Principle Festival. Method validation is an integral part of the laboratory quality system, the process should be based on laboratory quality management system Requirements.

Confirmed that in order to prove the method is suitable for the intended purpose. If the method is used for the intended purpose Census animal antibody activity (Screening Party Method), the method is highly sensitive to the need to achieve as much as possible to detect infected animals; if the intended purpose of the method is used to diagnose Test, then we need a method with a high specificity. If these two goals can not be achieved, then the need for reagents or for calibration on behalf of, or abandon this approach.

Diagnostic sensitivity and specificity for the diagnosis of infectious diseases is an important indicator of animal testing technology, due to the diagnostic sensitivity and diagnostic specificity Review Assessment requires a specific number of reference animals, and to know that these animals background reference, infection status and the infection status in the target animal population.

In the entry-exit inspection and quarantine, since the objective Method fauna from different countries and regions, making it difficult to achieve diagnostic sensitivity and to assess the diagnostic specificity and therefore not covered in this standard diagnostic sensitivity and diagnostic specificity.

Animal diseases ELISA detection technology to confirm specification

1 Scope

This standard specifies the zoonosis ELISA detection technology to confirm repeatability, reproducibility, sensitivity, specificity, robustness and other methods Various elements of performance evaluation.

This standard applies to confirm the detection of animal diseases ELISA method.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB/T 27025 testing and calibration laboratories General requirements (ISO/IEC 17025:2005, IDT)

3 Terms and Definitions

GB/T 27025 and defined by the following terms and definitions apply to this document.

Method validation confirmation Confirmed after proper way to build, optimize and standardize the method is suitable for the intended purpose of the process. Including confirmation of the test and analysis Performance evaluation of the performance of the diagnostic process.

Sample

From animals used for detecting the target substance.

Reference Animal History/infection status target animal diseases/infections, and source countries/regions are aware of the animals.

Reference substance referencematerials Uncertainty can be traced to international standard known substance in the matrix matching case, it can be used to simultaneously evaluate all sources Bias (method, laboratory, and laboratory deviations).

Standard Method standardtestmethod the best way to international and national recognition, or can be applied to the best way to provide the well-known publications.

Analytical specificity analyticalsensitivity, Asp the method is not the degree of cross-reactivity with other analytes.

Sensitivity analysis analyticalspecificity, Ase Minimum target analytes detectable amounts, ie, the method detection limit.