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

SN/T 3223-2012

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

动物传染病PCR检测技术确认规范

(English Translation)

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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 Animals Manual of diagnostic tests and vaccines" in 2010 1.1.4/5 "Infectious disease diagnostic methods to confirm the principles and methods" related provisions.

This standard and OIE "terrestrial animal diagnostic tests and vaccines Handbook" 2010 1.1.4/5 "to confirm the original diagnosis of infectious diseases and the method "than the main technical difference is.

a) This standard specifies only how the non-standard methods, laboratory design (development) of the method, beyond the standard range of its intended use Method, and amplifications and modifications of standard methods to confirm, to confirm that the method is suitable for the intended use, the method does not involve the establishment of Process monitoring and effectiveness;

b) due to the entry and exit animal quarantine work hard to target animal population prevalence of a disease can be assessed for method the sensitivity and specificity of the diagnostic assessment is difficult, this method is limited to standard analytical specificity and sensitivity analysis Evaluation does not involve diagnostic sensitivity and diagnostic specificity.

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 method requires all international and national regulations and testing areas consistent with the requirements. Veterinary diagnostic laboratory accreditation in all events only laboratory methods have been fully recognized the premise makes sense. Accredited laboratories should be able to be issued There is a high degree of reproducibility of the test results, but if the confirmation process approach is not appropriate, the test results can also be made on the infection status of animals Misjudgment. OIE standards to clarify, to make a suitable test method is applied, the method should be fully recognized, the acknowledgment should follow OIE "Terrestrial animal diagnostic tests and vaccines Manual" about "Animal diseases diagnostic tests to confirm the principles and methods" section of the relevant method validation Regulations. Method validation is an integral part of the laboratory quality system, the process should be based on laboratory quality management system requirements get on.

Confirmed that in order to prove the method is suitable for the intended purpose. If the intended purpose of the method for the rapid screening of infected animals, the method Need to have a high sensitivity to achieve detect infected animals as possible; if the intended purpose is for the confirmatory test methods, We need to have a high specificity. If these two goals can not be achieved, then we need to be calibrated or alternative reagents, or abandon the method.

Zoonosis PCR detection technology to confirm specification

1 Scope

This standard specifies the zoonosis PCR detection analysis to confirm requirements and sensitivity, analytical specificity, repeatability, reproducibility peers each element of performance evaluation method.

This standard applies to confirmation of PCR detection of animal diseases, but also for animal products infectious pathogen PCR Detection Technology Confirmation surgery.

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 as defined in the following terms and definitions apply to this document.

Method validation confirmation for a test procedure (or diagnostic tests) be evaluated to determine the program or the test and for the intended purpose of the degree is the test performance characteristics Proof levy.

Analyte

Proof or measured by the analysis component, or a component thereof may be a pathogen.

Sensitivity analysis analytical sensitivity; ASe the minimum amount of analyte in the sample is capable of being detected, the lowest detection limit.

Analytical specificity; ASp the degree of cross-reactivity between the other components and the method can distinguish the analyte.

Repeatability Using the same method for the same analyte in the (equipment, operator, laboratory and time interval) the same conditions for testing the results even Continued consistency and independent outcomes.

Reproducibility by different operators using different laboratories using the same method on the same device to be detected derived analyte single test results Consistency between.