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CERTIFICATION AND ACCREDITATION INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

RB/T 032-2020

Guidelines for Validation and Verification of Gene Amplification Testing Methods

基因扩增检测方法确认与验证指南

(English Translation)

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Foreword

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

This standard was proposed and managed by the National Certification and Accreditation Administration Committee:

Drafting organizations of this standard: China National Accreditation Center for Conformity

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Assessment, Dalian Customs Technology Center, Shenzhen Huada Gene Technology Co:, Ltd:, Zhejiang Jiangtianke High-tech Development Co:, Ltd:, Shenyang Customs Technology Center, Liaoning Provincial Center for Disease Control and Prevention:

1 Scope

This standard provides guidelines for the validation and verification of gene amplification detection methods:

This standard applies to methods developed by laboratories in the field of gene amplification, standard methods used beyond the predetermined scope, and other modifications the method confirmation of the standard method and the method verification of the laboratory before the formal use of the newly introduced standard method:

2 Normative references

The following documents are indispensable for the application of this document: For dated reference documents, only the dated version applies to this article Pieces: For undated references, the latest version (including all amendments) applies to this document:

GB/T 6379.2 Accuracy of measurement methods and results (accuracy and precision) Part 2: Determine the repeatability of standard measurement methods Basic methods of sex and reproducibility ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories (General requirements for thecompe-tenceoftestingandcalibrationlaboratories) ISO/IEC Guide 99:2007 Basic and general concepts and related terms of international metrology vocabulary [Internationalvocabulary ofmetrology-Basicandgeneralconceptsandassociateterms(VIM)]

3 Terms and definitions

The following terms and definitions defined in ISO/IEC Guide 99:2007 and ISO/IEC 17025:2017 apply to this document: in order to for ease of use, some terms and definitions in ISO/IEC Guide 99 are listed repeatedly below:

Method verification

The laboratory provides objective evidence to prove that it meets the requirements of the testing method through verification or testing: That is to provide objective evidence to prove the laboratory can use the method correctly to ensure that the required method performance is achieved:

Note 1: When applicable, the measurement uncertainty should be considered:

Note 2: Modified from ISO/IEC Guide 99:2007, definition 2:44:

Methodvalidation

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Through experiments, the laboratory provides objective evidence to prove that the method to be determined meets the intended use:

Note 1: Method validation should identify the factors that affect the performance of the method and the degree of influence, verify the performance characteristics of the method, and determine the applicable matrix and the used method limitation factor:

Note 2: Confirmation can include confirmation of sampling, disposal of test items and transportation procedures:

Note 3: Modified from ISO/IEC Guide 99:2007, definition 2:45:

Qualitativemethod

An analytical method that directly or indirectly detects the presence of an analyte:

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