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

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**Guideline on the external quality assessment schemes in
clinical molecular pathology
(English Translation)**

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents" to be drafted:

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying patents:

Introduction

With the development of individualized disease diagnosis and treatment and precision medicine, clinical molecular pathology has been increasingly used in daily clinical disease diagnosis:

It has become an important means of clinical disease diagnosis and treatment: External quality assessment (sometimes called "proficiency testing") is a clinical it is an important part of the quality assurance system of pathology laboratories, and the organization and implementation of corresponding external quality assessment projects can promote clinical molecular pathology:

Continuous improvement of laboratory quality and improvement of technical level:

In:2012, GB/T 27043 "General Requirements for Proficiency Verification for Conformity Assessment" was released and implemented:

General requirements for the establishment, operation and implementation of interim quality evaluation projects: This document is based on GB/T 27043, combined with clinical molecular pathology According to the professional characteristics and requirements of the department, guidance is given to the technical requirements of the key links of the external quality assessment project in this field, which is helpful to standardize the clinical molecular Organization and implementation of pathology external quality assessment project:

This document aims to standardize and promote the activities of external quality assessment/proficiency testing in the field of clinical molecular pathology, and to enhance and perfect the external quality assessment:

Value/ability to verify the service capability of the provider and make it meet the requirements of GB/T 27043:

This document does not serve as the basis for judging whether the external quality assessment provider meets the requirements of relevant regulations:

Clinical molecular pathology external quality assessment project Implementation Guide

1 Scope

This document presents the resources needed for an external quality assessment program, the design of the program, the items for external quality assessment, data analysis and results evaluation:

pricing, reporting and operational guidance:

This document is applicable to groups organizing and implementing external quality assessment programs for tissue- and cell-based clinical molecular pathology clinical molecular pathology organization, implementation and management:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references for documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document:

GB/T 20470 External Quality Evaluation Requirements for Clinical Laboratories GB/T 27043 General requirements for proficiency testing for conformity assessment

3 Terms and Definitions

The following terms and definitions defined in GB/T 27043 and GB 20470 apply to this document:

Based on molecular detection and analysis of samples such as tissues and cells, assisting in diagnosis and pathological typing, guiding treatment and evaluating prognosis, etc:

Multiple specimens are periodically sent to laboratories for analysis and/or identification, and results from each laboratory are compared with other laboratories in the same group the results or specified values are compared and the results of the comparison are reported to the participating laboratories:

[Source: GB/T 20470,2:4] 3.3 Proficiency testing; PT Using inter-laboratory comparisons, participants' competencies were assessed against pre-established criteria:

Note 1: This definition includes EQA (external quality assessment or external quality assessment) that is commonly used in the medical field and conforms to this definition:

Note 2: Also known as proficiency testing activities, including various types of external quality assessment projects, measurement audits and comparison plans that meet this definition:

[Source: GB/T 27043, 3:7, modified] 3.4 External quality assessment sample EQAitem proficiency testing item proficiencytestitem Samples, products,, reference

materials/standard samples, measurement standards, data sets or others for external quality assessment/proficiency testing information: