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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 22576.6-2021

Medical laboratories - Requirements for quality and competence - Part 6: Requirements in the field of clinical microbiological examination

医学实验室 质量和能力的要求 第6部分：临床微生物学检验领域的要求

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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 of Standardization Documents" Drafting. This document is part 6 of GB/T 22576 "Requirements for the Quality and Capability of Medical Laboratories". This document and GB/T 22576.1 Cooperate and use together. GB/T 22576 has released the following parts.

1.General requirements;

2.Requirements in the field of clinical hematology testing;

3.Requirements in the field of urine testing;

4.Requirements in the field of clinical chemistry testing;

5.Requirements in the field of clinical immunological testing;

6.Requirements in the field of clinical microbiology testing;

7.Requirements in the field of blood transfusion medicine. Please note that some of the contents of this document may involve patents. The issuing agency of this document is not responsible for identifying patents. This document was proposed by the State Drug Administration. This document is under the jurisdiction of the National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC136). Drafting organizations of this document. China National Accreditation Center for Conformity Assessment, Tongji Hospital Affiliated to Tongji Medical College of Huazhong University of Science and Technology, Capital Medical Department Beijing Friendship Hospital affiliated to the university, and the Clinical Laboratory Center of the National Health Commission. The main drafters of this document. Sun Ziyong, Hu Dongmei, Zhai Peijun, Zhou Yali, Li Junyan, Su Jianrong, Hu Jihong.

The services of medical laboratories are necessary for patient healthcare, so it is necessary to satisfy all patients and clinical personnel responsible for patient healthcare. The needs of the staff. These services include application acceptance, patient preparation, patient identification, sample collection, transportation, storage, clinical sample processing and inspection And the interpretation of the results, reports and recommendations; in addition, the safety and ethical issues of medical laboratory work must also be considered. As long as national laws and regulations and relevant standards require permission, it is expected that the services of medical laboratories include diagnosis and patient management, as well as Examination of patients in consultations and active participation in disease prevention. Each laboratory should provide its professionals with appropriate educational and scientific research opportunity. GB/T 22576 stipulates the capabilities and quality of medical laboratories in all disciplines in the currently recognized medical

laboratory service field. The requirements are to be composed of 11 parts.

1.General requirements. The purpose is to specify general requirements for the quality and competence of medical laboratories.

2.Requirements in the field of clinical hematology testing. The purpose is to regulate the quality and capacity of medical laboratories for clinical hematology Specific requirements in the inspection field.

3.Requirements in the field of urine testing. The purpose is to regulate the quality and capacity of medical laboratories in the field of clinical urine testing Specific requirements.

4.Requirements in the field of clinical chemistry testing. The purpose is to regulate the quality and capability of medical laboratories for clinical chemistry testing The specific requirements of the field.

1 Scope

GB/T 22576.6-2021 is the Chinese national standard on medical laboratories - requirements for quality and competence - part 6: requirements in the field of clinical microbiological examination, in the field of services and company organization. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 21 May 2021 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 June 2022. Classification: ICS 03.120.10, CCS C30. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document specifies the quality and capability requirements of clinical microbiology testing laboratories. This document is applicable to clinical microbiology testing laboratories. This document does not apply to virus serological testing, genetic testing, and parasite testing involved in clinical microbiology testing.

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 reference documents, the latest version (including all amendments) is applicable to This document.

GB/T 22576.1-2018 Requirements for the quality and competence of medical laboratories Part

3 Terms and definitions

The terms and definitions defined in GB/T 22576.1-2018 apply to this document.

4.1.1 Organization

4.1.1.1 General requirements It shall meet the requirements of

4.1.1.1 in GB/T 22576.1-2018.

4.1.1.2 Legal entities It shall meet the requirements of

4.1.1.2 in GB/T 22576.1-2018.

4.1.1.3 Ethical behavior It shall meet the requirements of

4.1.1.3 in GB/T 22576.1-2018.

4.1.1.4 Laboratory Director Should comply with GB/T 22576.1-2018

4.1.1.4 and the following regulations. Ensure that the laboratory's biological safety protection level is compatible with the experimental activities engaged in. Should be based on new developments in biosafety theory and technology Formulate and revise corresponding biosafety operating procedures and conduct training to reduce the risk of occupational exposure. Should be based on the work process and nature on a regular basis The implementation of biosafety risk assessment, when the work process and nature change, the reassessment should be implemented in a timely manner.