



中华人民共和国国家标准

GB/T 22576—2008/ISO 15189:2007

GB/T 22576—2008/ISO 15189:2007

医学实验室 质量和能力的专用要求

Medical laboratories—
Particular requirements for quality and competence

(ISO 15189:2007, IDT)

中华人民共和国
国家标准
医学实验室

质量和能力的专用要求

GB/T 22576—2008/ISO 15189:2007

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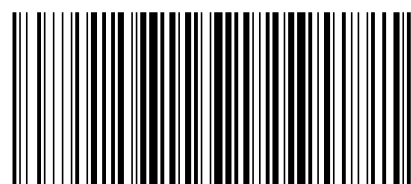
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前 言

本标准等同采用 ISO 15189:2007《医学实验室 质量和能力的专用要求》。

为便于使用,本标准做了下列编辑性修改:

本“国际标准”一词改为:“本标准”;

删除国际标准前言。

本标准与 GB/T 27025—2008/ISO/IEC 17025:2005 的关系为“专用标准”和“通用标准”的关系,是将 GB/T 27025—2008《检测和校准实验室能力的通用要求》在医学实验室领域的具体化和细化。

本标准的附录 A、附录 B、附录 C 为资料性附录。

应注意,本标准中的某些条款可能涉及专利权的问题,起草单位并不负责对任何专利权的鉴别。

本标准由国家食品药品监督管理局提出。

本标准由全国医用临床检验实验室和体外诊断系统标准化技术委员会归口。

本标准起草单位:北京市医疗器械检验所、中国合格评定国家认可委员会。

本标准主要起草人:丛玉隆、陈文祥、章兆园、吕京、邓新立、郭健、翟培军、廖睿、胡冬梅、贺学英。