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STANDARDS & GUIDANCE BRIEF · INTERNATIONAL · ACCREDITATION STANDARD

ISO 15189:2022

Medical laboratories — Requirements for quality and competence

DOCUMENT	QES-WP-160, Rev B	DATE	November 7, 2026
ISSUED BY	International Organization for Standardization (ISO/TC 212)	PREPARED BY	Conner Davidson
EDITION	Fourth edition (2022)	STATUS CHECKED	October 24, 2026
INDUSTRIES	Laboratories & Calibration, Medical Devices	ONLINE	qesisbest.com/standard-iso-15189.html

CURRENT EDITION The transition from the 2012 edition ended in December 2025; point-of-care testing requirements are now included.

What It Covers

Quality and competence requirements for medical laboratories, including point-of-care testing, with an emphasis on risk to patients.

Who It Applies To

Clinical and medical laboratories seeking accreditation.

Key Requirements

- Risk management focused on patient safety.
- Pre-examination, examination, and post-examination processes controlled.
- Measurement uncertainty and validity of results assured.
- Point-of-care testing brought inside the laboratory's quality system.

What an Auditor Asks to See

- How risks to patients are identified and controlled across the examination process.

Where Systems Fall Short

- Point-of-care testing managed outside the laboratory's system.

How QES helps. Gap assessments and internal audits against the 2022 edition. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. ISO — ISO 15189:2022 — www.iso.org/standard/76677.html; de Grandson — ISO management system revisions, 2026–2030 (September 2026) — www.degrandson.com/blog/iso-management-system-standards-revisions-2026-2030.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.