



Course technical sheet

Auditor/Lead Auditor ISO 15189 (Medical laboratories)

Fee

99,00 €

Final exam only

Course code

ISO15189_LA

Test duration

60 min

Passing score

70%

Issued

28/05/2026

Executive summary

The "Auditor/Lead Auditor ISO 15189 (Medical laboratories)" course is designed to train professionals in performing internal and external audits in compliance with the ISO 15189 standard, specific to medical laboratories. Participants will gain in-depth skills in interpreting and applying quality management and technical competence requirements within diagnostic laboratory settings. Knowledge areas include specimen pathway analysis, risk management, biosafety, data integrity, and accreditation compliance procedures. The course also equips learners with practical tools to plan, conduct, and report audits, emphasizing ISO 19011 guidelines for effective audit processes. Intended for current or aspiring auditors and quality managers in clinical laboratories, the program explores realistic case studies and critical scenarios to prepare attendees for certification. The 60-minute duration offers a focused and efficient learning experience, concluding with an assessment featuring questions based on real professional situations. Passing the final exam ensures robust theoretical knowledge essential for supporting compliance and continuous improvement in healthcare diagnostic facilities.

Certification process

- Registration or login to the Academy platform.
- Completion of the final course examination only. Any training or preparation may be completed externally or through other channels.
- The test questions refer to the objectives, skills and topics described in this technical sheet.
- Assessment of the result, possible validation and certificate issuance according to the rules applicable to the course.

Important note

On Academy, candidates take only the final course examination. Any training or preparation activity may be delivered externally or through other channels. The test questions refer to the topics described in this technical sheet and in the course syllabus summary.

Syllabus summary

ISO 15189; ISO 19011

Learning Objectives

Acquire skills to conduct audits in medical laboratories according to ISO 15189; understand related standards and guidelines; develop critical analysis and non-conformity identification abilities.

Competencies Obtained

Audit planning and execution; interpretation of ISO 15189; evaluation of specimen pathways; risk and

Certification Bodies Management systems

IFZA Business Park - Building A2 - Nadd Hessa - Dubai Silicon Oasis
United Arab Emirates
Phone: +971 502475030
Email: info@certificatowz.org
VAT/Tax ID: 104216397000003

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biosafety management; verification of IT procedures and documentation.

Target Audience

Healthcare and diagnostic professionals, auditors, quality managers, laboratory technicians, and staff involved in medical laboratory certification.

Prerequisites

Basic knowledge of laboratory processes and quality management standards; recommended work experience in healthcare settings.

Course Content

- Introduction to ISO 15189 and ISO 19011
- Structure and requirements of ISO 15189
- Audit planning and conducting
- Specimen handling and risk management
- Biosafety and process validation
- Documentation, reporting, and data integrity
- Non-conformity assessment and management

Teaching Methodology

Theoretical lessons combined with case studies, real scenario analyses, practical exercises, and audit simulations.

Assessment Method

Final exam with multiple-choice questions based on practical scenarios; minimum passing score 70%.

Duration

60 minutes.

Certification

Certificate of attendance upon passing the exam.

Expected Outcomes

Ability to perform ISO 15189-compliant audits; identify critical issues in specimen pathways and laboratory management; implement effective corrective actions.