



# ISO 15189

## Medical laboratories

Requirements  
for quality and competence

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To be the world's leading provider of high quality, globally relevant International Standards through its members and stakeholders.

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ISO develops high quality voluntary International Standards that facilitate international exchange of goods and services, support sustainable and equitable economic growth, promote innovation and protect health, safety and the environment.

## This document has been prepared by:

ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*

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## Executive summary

- Medical laboratory services are essential to patient care. It is estimated that 60% to 70% of healthcare decisions are based on diagnostic test results.
- Conformance to this International Standard ensures that the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver clinically valid results.
- This International Standard can be used by medical laboratories in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies.
- While this International Standard is intended for use in recognized disciplines of medical laboratory services, those working in other services and disciplines such as clinical physiology, medical imaging and medical physics could also find it useful and appropriate.