



مختبر فرايبورج الطبي الشرق الأوسط (ذ.م.م.)
FREIBURG MEDICAL LABORATORY MIDDLE EAST (L.L.C.)

Medical Diagnostic Laboratories: Accreditation according to ISO 15189

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For Medical Diagnostic Laboratories, many accreditation and quality standards exist such as CPA (National Clinical Pathology Accreditation, United Kingdom, currently still shifting to ISO 15189), CAP (College of American Pathologists; National Accreditation Program, USA, now offering CAP-ISO15189) or ISO 15189 (the recognized International Standard worldwide).

Accreditation allows us to make an informed decision when selecting a laboratory, as it demonstrates competence, impartiality and capability. It helps to underpin the credibility and performance of services.

Accreditation bodies around the world, which have been evaluated as competent, have signed an agreement that enhances the acceptance of products and services across national borders. The purpose of this arrangement, the International Laboratory Accreditation Cooperation (ILAC) Arrangement, is to create an international framework and to remove technical barriers (www.ilac.org). ILAC denotes the collaboration of accreditation bodies that accredit calibration laboratories, testing laboratories and/or inspection bodies as well as medical laboratories. The ILAC network currently consists of > 140 bodies representing >90 different economies. Current standards recognized as meeting the accreditation requirements of ILAC, for inclusion in the ILAC Mutual Recognition Arrangement include: ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories and ISO 15189:2007 Medical laboratories – Particular requirements for quality and competence medical testing laboratories

In case of any questions please contact FREIBURG MEDICAL LABORATORY www.fml-dubai.com

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The international ISO 15189 standard, designed specifically for medical laboratories, covers 15 management requirements and 8 technical requirements. The standard is concise and to the point and is now part or requirement in other national standards, such as CPA or CAP. In brief, the organization and management requirements are: quality management system, document control, review of contracts, examination by referral laboratories, external services and supplies, advisory services, resolution of complaints, identification and control of nonconformities, corrective action, preventive action and continual improvement. The technical requirements include educated personnel, accommodation and environmental conditions, laboratory equipment, pre-examination procedures, examination procedures, assuring quality of examination procedures, post-examination procedures and reporting of results.

The lecture gives an overview on the accreditation according to ISO 15189 in the worldwide context with special focus on requirements in the UAE (www.dac.dm.ae).

Learning Objectives:

- **International Accreditation**
- **ISO 15189**
- **UAE Recommendation: Accreditation for Medical Facilities**
- **Advantages and Disadvantages in Accreditation**

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