

DIN EN ISO 15189:2014-11 (E)

Medical laboratories - Requirements for quality and competence (ISO 15189:2012,
Corrected version 2014-08-15)

Contents	Page
Foreword	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 Management requirements	10
4.1 Organization and management responsibility	10
4.2 Quality management system	13
4.3 Document control	14
4.4 Service agreements	15
4.5 Examination by referral laboratories	16
4.6 External services and supplies	16
4.7 Advisory services	17
4.8 Resolution of complaints	17
4.9 Identification and control of nonconformities	17
4.10 Corrective action	18
4.11 Preventive action	18
4.12 Continual improvement	18
4.13 Control of records	19
4.14 Evaluation and audits	20
4.15 Management review	22
5 Technical requirements	23
5.1 Personnel	23
5.2 Accommodation and environmental conditions	25
5.3 Laboratory equipment, reagents, and consumables	27
5.4 Pre-examination processes	30
5.5 Examination processes	34
5.6 Ensuring quality of examination results	37
5.7 Post-examination processes	39
5.8 Reporting of results	39
5.9 Release of results	41
5.10 Laboratory information management	42
Annex A (informative) Correlation with ISO 9001:2008 and ISO/IEC 17025:2005	44
Annex B (informative) Comparison of ISO 15189:2007 to ISO 15189:2012	49
Bibliography	54