ISO 15189 Medical Laboratory Quality: Specimen Control, QC and Result Reporting

7 – 11 June 2027
London - Central London four-star



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Introduction:

ISO 15189 medical laboratory quality depends on every patient specimen being collected, identified, analysed and reported without error, yet most laboratory mistakes arise before or after the analyser, in mislabelled tubes, unnoticed control shifts and critical values that never reach the clinician. This Core Concept course equips clinical laboratory staff to control the total testing process against ISO 15189 requirements: specimen acceptance, internal quality control with Westgard rules, external quality assessment, method verification, critical result notification, turnaround time, LIS traceability and biosafety. Participants produce a Medical Laboratory Total Testing Process Control Plan.

Course Objectives:

- Map the pre-analytical, analytical and post-analytical phases of a clinical laboratory against the clauses of ISO 15189 and identify control gaps
- Apply specimen collection, patient identification, labelling and rejection criteria at phlebotomy and specimen reception
- Operate internal quality control using Levey-Jennings charts and Westgard multirule decisions to accept or reject analytical runs
- Evaluate external quality assessment and proficiency testing reports and verify examination methods, including basic measurement uncertainty estimates
- Control critical result notification, turnaround time and LIS-based traceability from test request to authorised report
- Prepare biosafety controls and accreditation evidence that demonstrate conformity with ISO 15189 during an assessment visit

Target Audience:

- Clinical laboratory supervisory staff responsible for daily bench operations, staffing and result release in chemistry, haematology, microbiology or blood bank sections
- Medical technologists and laboratory scientists who run analysers, review quality control and verify patient results
- Laboratory quality staff responsible for document control, nonconformity records, internal audit and accreditation preparation
- Phlebotomy and specimen reception staff responsible for patient identification, labelling and specimen acceptance
- Point-of-care testing coordinators who oversee devices and operators outside the central laboratory
- LIS administration staff who maintain test catalogues, reference ranges and result flagging rules

Course Outline:

Day 1: The Clinical Laboratory Total Testing Process and ISO 15189

- ISO 15189 Clause Structure: Structural, Resource, Process and Management System Requirements for Medical Laboratories
- Total Testing Process Map: Test Request, Collection, Examination, Reporting and Clinical Interpretation
- Error Distribution Across Pre-Analytical, Analytical and Post-Analytical Phases with Incident Log Review
- Laboratory Director, Section Supervisor and Result Authoriser Responsibilities and Competence Records
- Current-State Gap Checklist for a Hospital or Reference Medical Laboratory

Day 2: Pre-Analytical Control: Specimen Collection, Labelling and Acceptance

- Two-Identifier Patient Identification and Bedside Barcode Labelling Procedure
- Venepuncture Order of Draw, Tube Additives, Fill Volume and Haemolysis Prevention
- Specimen Transport Conditions, Stability Limits and Pneumatic Tube Validation
- Specimen Rejection Criteria Matrix: Mislabelled, Clotted, Haemolysed and Insufficient Samples
- Primary Sample Collection Manual and Laboratory User Handbook Content

Day 3: Analytical Quality: Internal QC, EQA and Method Verification

- Control Material Selection, Target Mean and Standard Deviation Establishment
- Levey-Jennings Chart Plotting and Westgard Multirule Interpretation: 1-2s, 1-3s, 2-2s, R-4s, 4-1s, 10x
- External Quality Assessment and Proficiency Testing Report Review with Z-Score Follow-Up
- Method Verification Protocol: Precision, Trueness, Linearity and Reference Interval Transfer
- Measurement Uncertainty Basics from Internal QC and EQA Data for Quantitative Examinations

Day 4: Post-Analytical Risk: Critical Results, TAT, LIS and Biosafety

- Critical Result Notification Procedure: Alert Thresholds, Read-Back and Escalation Log
- Turnaround Time Indicators: Receipt-to-Verify Intervals, STAT Prioritisation and Delay Analysis
- LIS Traceability: Accession Numbers, LOINC Test Codes, Autoverification Rules and Audit Trails
- Biosafety Risk Assessment in the Clinical Laboratory: Biological Safety Cabinets, PPE and Sharps Control
- Nonconforming Examination Handling: Result Recall, Amended Reports and Corrective Action

Day 5: Case Study Workshop: Accreditation Readiness and the Control Plan

- Case Study: Tracing a Mislabelled Specimen from Phlebotomy to an Amended Report
- Case Study: Westgard Rule Violation, Run Rejection and Patient Result Look-Back
- Accreditation Checklist Concepts and Peer Inspection Evidence Index at Overview
- Quality Indicator Dashboard for Management Review: Rejection Rate, TAT and EQA Performance
- Build and Peer Review: Medical Laboratory Total Testing Process Control Plan

Skills You Will Gain:

- Total Testing Process Mapping
- Specimen Acceptance Control
- Westgard Multirule Quality Control
- Proficiency Testing Evaluation
- Examination Method Verification
- Critical Value Communication
- Laboratory Information System Traceability
- Clinical Laboratory Biosafety

Why Attend This Course:

- Leave with a Medical Laboratory Total Testing Process Control Plan built around your own laboratory sections and test menu
- Reduce avoidable specimen rejections and relabelling by fixing identification and collection steps at their source
- Make confident accept-or-reject decisions on analytical runs and know which patient results to look back on after a QC failure
- Compare practice with peers from hospital, reference and point-of-care laboratory settings across different health systems

Conclusion:

Patient care relies on laboratory results that are correct, timely and traceable to the right person. The course follows the specimen through the total testing process: ISO 15189 structure and gap review, collection and acceptance control, internal quality control with Westgard rules, external quality assessment and method verification, then critical results, turnaround time, LIS traceability and biosafety. The final day applies case studies to accreditation readiness and produces a Medical Laboratory Total Testing Process Control Plan ready for use in each laboratory section.