



TOOLKIT 24 · LABORATORY QUALITY · TOOL 4 OF 4

Laboratory Quality — Stepwise Self-Check

The twelve quality-system essentials, four phases, one score. Where a laboratory is on the road to ISO 15189, and what to do next

Quality-system essential	Score 0–4 (0 nothing · 1 started · 2 partly · 3 mostly · 4 in place and audited)	Evidence
1 · Organisation — quality policy, laboratory lead, quality officer, organogram		
2 · Personnel — job descriptions, competence assessment, training records, health and vaccination		
3 · Equipment — inventory, calibration, maintenance and QC logs (Tool 3)		
4 · Purchasing and inventory — supplier evaluation, stock control, reagent lot records, no stock-outs		
5 · Process control — SOPs for every test; internal QC daily; EQA participation; validation of methods		
6 · Information management — request and report formats; confidentiality; result verification; turnaround times		
7 · Documents and records — controlled SOPs, version numbers, review dates; records retained		
8 · Occurrence management — nonconformities and incidents recorded, analysed, corrected (Toolkit 8)		
9 · Assessment — internal audits yearly; management review; external assessment planned		
10 · Process improvement — indicators tracked (rejection rate, TAT, critical-value times); improvement projects		
11 · Customer service — clinician feedback, complaints, the critical-value procedure (Tool 2)		
12 · Facilities and safety — layout, biosafety, waste, spill kits, PPE, fire, staff safety		
Total ____ / 48	Phase 1 (0–12): make the laboratory safe and the primary process reliable · Phase 2 (13–24): control and assure — SOPs, QC, EQA, documents · Phase 3 (25–36): measure and improve — audits, indicators, occurrence management · Phase 4 (37–48): ready for external assessment / ISO 15189	

Next actions (the three lowest-scoring essentials)

Essential	Action	Owner	Due

Condensed from the WHO Laboratory Quality Stepwise Implementation tool (LQSI) and the WHO/CDC/CLSI Laboratory Quality Management System handbook. ASF does not certify ISO 15189; this self-check maps the road to it.

