



The QMS at a Glance

How our documents fit together — and how a specimen becomes a result.

DOCUMENT HIERARCHY — 6 LEVELS

1

Quality Management Manual — LAB-QM-001

Sets the whole QMS: governance, responsibilities, quality framework. Parent of all QMS documents.

Answers: “What is the laboratory’s Quality Management System?”

▼ each level supports the level above it — and must not contradict it ▼

2

Quality Management Policies — LAB-QM-### and LAB-QM-[section]-###

Management requirements: expectations, responsibilities, governance, monitoring, ownership.

Answers: “What management requirements shall be implemented?”

3

Standard Operating Procedures — e.g. SOP-H-001, SOP-C-001, SOP-S-002

Standard methods for laboratory work, so testing is consistent and technically reliable.

Answers: “How is the work performed?”

4

Work Instructions — e.g. WI-C-002-A-V0, WI-QM-PRE-001-A-V0

Step-by-step guidance for one specific task: startup, maintenance, a bench method, a calculation.

Answers: “How is this specific task performed?”

5

Controlled Forms & Templates — e.g. F-QM-003-A-V0, F-QM-PRE-003-A-V0

Forms, checklists, worksheets, registers and logbooks that standardize documentation.

Answers: “Where is information recorded?”

6

Quality Records — no document numbers; made from completed forms

Completed QC logs, temperature records, audit and PT reports, competency and CAPA records, minutes.

Answers: “What objective evidence demonstrates compliance?”

PROCESS MAP — THE TOTAL TESTING PROCESS

MANAGEMENT PROCESSES OVERSEE EVERYTHING: leadership & quality planning · document control · risk management · quality indicators · internal audit · occurrence & CAPA · management review · continual improvement

1 · PRE-EXAMINATION

Test request → patient preparation → specimen collection → labeling → transport → receipt & triage

Output: specimens acceptable for analysis

2 · EXAMINATION

Accepted specimens tested with validated methods, competent personnel, controlled equipment & reagents, and internal quality control

Output: verified examination results

3 · POST-EXAMINATION

Result review → authorization → reporting → critical-result communication → retention of records & specimens

Output: results delivered to laboratory users

SUPPORT PROCESSES HOLD IT UP: personnel & competency · equipment management · purchasing & inventory · information management (LIS) · biosafety · facilities · supplier management · customer service

SERVICES COVERED: Clinical Chemistry · Hematology · Clinical Microscopy · Serology / Immunology · Blood Typing · Point-of-Care Testing (POCT) (LAB-QM-001 §2.5; detailed scope in LAB-QM-004)