Laboratory Quality Manual

Quality Management System Documentation

Meridian BioAnalytical Laboratories

Document Code:	QM-001
Document Title:	Laboratory Quality Manual
Version:	4.0
Effective Date:	01 March 2026
Document Owner:	Quality Manager
Classification:	Internal — Controlled Document
Scope of Accreditation:	Chemistry, Microbiology, and Molecular Diagnostics Testing

Ver.	Date	Description of Change	Author
1.0	14 Jan 2021	Initial issue following ISO/IEC 17025:2017 gap assessment	M. Chen
2.0	03 Jun 2022	Added molecular diagnostics testing scope; revised org. chart	M. Chen
3.0	22 Sep 2024	Incorporated risk-based thinking clauses; updated PT schedule	S. Alvarez
3.1	11 Feb 2025	Editorial corrections following internal audit IA-2025-02	S. Alvarez
4.0	01 March 2026	Restructured document hierarchy; added complaints workflow	M. Chen

Prepared By	Reviewed By	Approved By
Marcus Chen	Priya Nair	Dr. Elena Kowalski
Quality Manager	Technical Manager	Laboratory Director
Signature: _____	Signature: _____	Signature: _____
Date: _____	Date: _____	Date: _____

Contents

1 Introduction

1.1 Purpose and Scope

This Quality Manual (QM-001) describes the Quality Management System (QMS) operated by Meridian BioAnalytical Laboratories ("the Laboratory") in support of its testing activities in chemistry, microbiology, and molecular diagnostics. The manual is written to satisfy the requirements of ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories* [1], and, where clinical specimens are involved, the complementary requirements of ISO 15189:2022 [3].

The manual applies to all permanent, temporary, and contracted staff working within the Laboratory's three testing sections, and to all locations listed in the current Scope of Accreditation held under certificate MBL-ACC-0347. It does not extend to research and development activities that are explicitly excluded from the accredited scope, although those activities remain subject to the Laboratory's general safety and ethics policies.

1.2 Quality Policy Statement

Quality Policy Statement

Meridian BioAnalytical Laboratories is committed to providing testing services of the highest technical validity, delivered with impartiality, confidentiality, and strict adherence to scientific and ethical practice. Management undertakes to:

- maintain a Quality Management System compliant with ISO/IEC 17025:2017 and continually improve its effectiveness;
- ensure all personnel are competent, adequately resourced, and free from any commercial, financial, or other pressure that could compromise the impartiality of results;
- base all technical decisions on objective evidence, traceable measurement, and validated methods;
- communicate this policy to all staff and require its acknowledgement as a condition of employment; and
- review the suitability of this policy at each Management Review (Section 4.7).

Dr. Elena Kowalski, Laboratory Director

Issued 01 March 2026

1.3 Distribution and Control

Controlled copies of this manual are issued, numbered, and tracked by the Quality Manager. Copy holders are recorded in the Master Document Register (QM-001-A) and are responsible for returning or destroying superseded copies within five working days of reissue.

Copy No.	Holder / Location	Format
01	Master copy — Quality Office, Building A	Controlled, paper
02	Laboratory Director's office	Controlled, paper
03	Chemistry Section supervisor station	Controlled, paper
04	Microbiology Section supervisor station	Controlled, paper
05	Molecular Diagnostics Section supervisor station	Controlled, paper
—	Intranet quality portal (all staff, read-only)	Controlled, electronic

Uncontrolled Copies

Any copy of this manual not listed in the Master Document Register, including printouts of the electronic version, is uncontrolled and must not be used for conformance decisions. Uncontrolled copies carry no assurance of currency against the version shown in the footer of this page.

2 Organization and Responsibility

2.1 Organizational Structure

The Laboratory's structure is designed to keep technical decision-making independent of commercial and administrative pressure. The Quality Manager reports directly to the Laboratory Director on all matters concerning the QMS, and holds authority to halt any activity that threatens the validity of results, independent of section management.

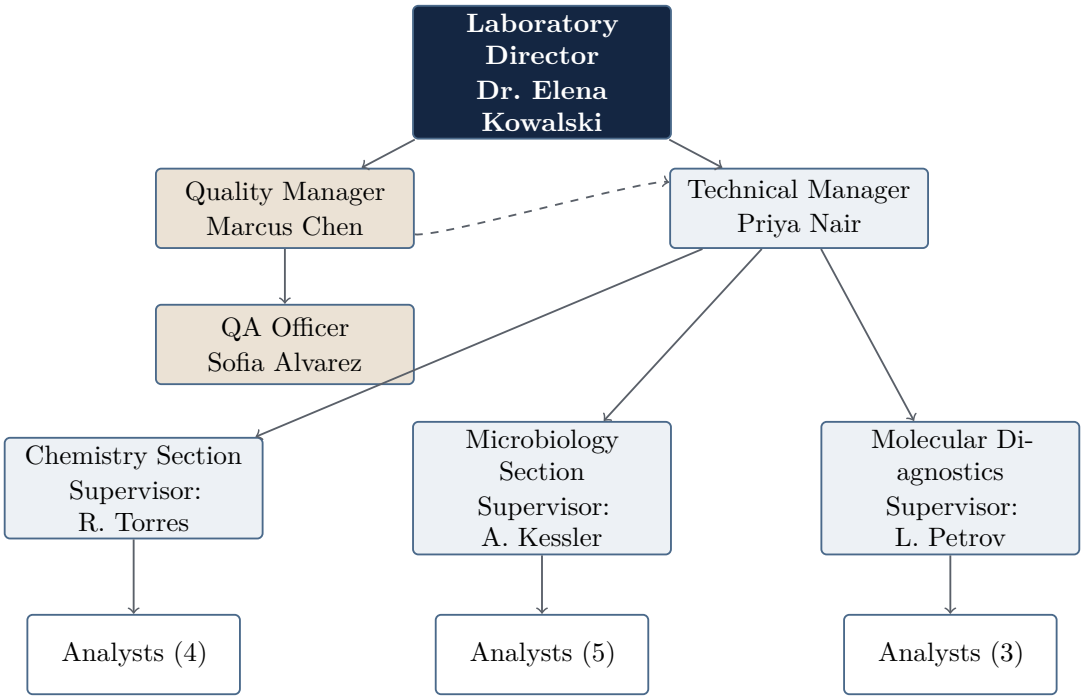

Figure 1: Organizational structure of Meridian BioAnalytical Laboratories. The dashed line indicates the functional liaison between the Quality Manager and Technical Manager on matters of technical validity.

2.2 Roles and Responsibilities

Role	Key Responsibilities
Laboratory Director	Overall accountability for the QMS; final authority on resourcing, impartiality, and accreditation decisions.
Quality Manager	Maintains this manual and its subordinate documents; oversees internal audits, corrective action, and management review; holds authority to stop non-conforming work.
Technical Manager	Owns technical decisions across all sections: method validation, equipment qualification, measurement traceability, and staff competency sign-off.
Quality Assurance Officer	Executes the internal audit programme, proficiency testing enrolment, document control, and record retention.
Section Supervisors	Day-to-day technical supervision, in-section training, and first-line review of test data prior to release.
Analysts	Perform testing per approved procedures; record raw data contemporaneously; report deviations to their supervisor immediately.

2.3 Impartiality and Confidentiality

No individual's remuneration is linked to the number of tests performed, samples passed, or outcomes reported, removing the principal financial incentive to bias results. Annual declarations of interest are collected from all staff and reviewed by the Quality Manager; any conflict identified is escalated to the Laboratory Director for a documented decision on mitigation. All client information, test results, and proprietary methods are treated as confidential and are disclosed only with the client's written consent or where required by law, in which case the client is notified unless legally prohibited.

3 Quality Management System Document Hierarchy

3.1 Hierarchy of Documentation

The QMS is organized into four tiers of increasing detail and decreasing readership, shown in Figure 2. Each tier is controlled at a level of rigour proportionate to its impact: this manual requires Laboratory Director approval, while a form template requires only Section Supervisor sign-off.

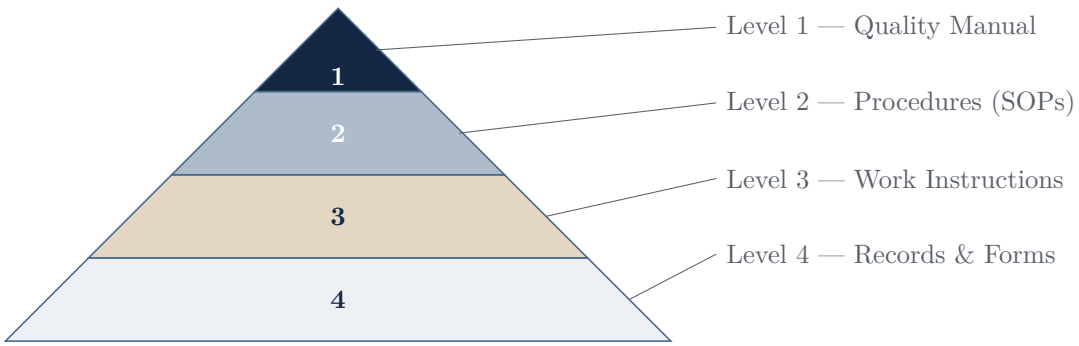

Figure 2: Document hierarchy of the QMS, apex to base.

Level	Document Type	Purpose	Approver
1	Quality Manual	States policy and QMS structure; one document, QM-001	Laboratory Director
2	Procedures (SOPs)	Define how a process is executed (e.g., SOP-CAL-014 Equipment Calibration)	Quality Manager
3	Work Instructions	Step-by-step detail for a single task or instrument (e.g., WI-HPLC-003)	Technical Manager
4	Records & Forms	Evidence that a procedure was followed (logs, worksheets, certificates)	Section Supervisor

3.2 Document Control Procedure

New or revised documents at any level follow the same control cycle, detailed in SOP-DOC-001:

1. **Drafting** — the process owner drafts or revises the document and assigns a unique code and draft revision marker.
2. **Review** — a technically qualified reviewer, independent of the drafter where practicable, checks the document against current practice and referenced standards.
3. **Approval** — the approver listed in the table above signs and dates the document; approval is recorded in the Master Document Register.
4. **Issue** — the Quality Manager assigns the effective date, updates the register, and withdraws all superseded copies from circulation.
5. **Periodic Review** — every controlled document is reviewed at least every 24 months, or sooner following an audit finding, incident, or regulatory change.
6. **Withdrawal** — obsolete documents are marked “Superseded” and archived for no less than the retention period in Section 7.1; a single reference copy may be kept for historical purposes, clearly stamped as such.

4 Management System Requirements

4.1 Structure of the Management System

The QMS covers all activities undertaken within the accredited scope, from sample receipt through to report release and archiving. It is structured to satisfy Clauses 4–8 of ISO/IEC 17025:2017 [1] and cross-references the risk management guidance of ISO 31000 [2] where risk-based decisions are required.

4.2 Control of Records

Quality and technical records are retained per the schedule in Section 7.1. Records may be paper-based or electronic; electronic records held in the Laboratory Information Management System (LIMS) are backed up nightly and are subject to the same retention and access controls as their paper equivalents. No record is altered without a dated, attributable correction that preserves the original entry.

4.3 Actions to Address Risks and Opportunities

Risk-Based Thinking

When planning changes to the QMS — a new test method, a change of premises, a new instrument platform — the Technical Manager and Quality Manager jointly assess the risk to impartiality, data integrity, and result validity before implementation, and document the assessment in the Change Control Log (QM-001-B).

Identified risks are scored on a 1–5 likelihood/consequence matrix and tracked to closure; any risk scoring 15 or above triggers immediate escalation to the Laboratory Director and suspension of the affected activity until mitigated.

4.4 Improvement

Opportunities for improvement are gathered from internal audits, client feedback, proficiency testing outcomes, and staff suggestions, and are reviewed at each Management Review (Section 4.7).

4.5 Corrective Actions

Nonconformities — whether identified internally or reported by a client — are logged in the Nonconformity Register within one working day of detection. The QA Officer determines whether the nonconformity affects previously issued results; if so, affected clients are notified within five working days. Root cause is established using the 5-Whys method or a fishbone analysis for complex cases, and corrective action effectiveness is verified no sooner than 30 days after implementation.

4.6 Internal Audits

Audit Area	Scope	Frequency
Chemistry Section	Sample handling, method conformance, equipment records	Annual
Microbiology Section	Aseptic technique, media QC, incubation records	Annual
Molecular Diagnostics	Contamination control, reagent lot tracking, data integrity	Annual
Document Control	Register completeness, version control, distribution	Semi-annual
Full QMS (all clauses)	Complete system against ISO/IEC 17025:2017	Annual, rotating auditor

Auditors are trained and, wherever section size permits, independent of the area under review; where full independence is not possible, the Quality Manager approves a suitably qualified cross-section auditor.

4.7 Management Reviews

The Laboratory Director chairs a Management Review at least every 12 months, with standing inputs of: internal and external audit results, proficiency testing performance, complaints and corrective actions, risk register status, resource adequacy, and progress against prior review actions. Minutes and resulting actions are recorded in the Management Review Log and tracked to closure by the Quality Manager.

5 Technical Requirements

5.1 Personnel Competency

All testing personnel are appointed against a documented competency profile for their role and are authorized, by named signature in the Personnel Authorization Register, only for the specific tests or equipment on which they have demonstrated competence. Competency is reassessed annually through witnessed testing and re-authorized following any extended absence exceeding six months or a change of method.

5.2 Equipment and Calibration

Every item of equipment affecting result validity carries a unique asset identifier and an equipment file recording its calibration history, maintenance, and any adjustment. Equipment is calibrated against a schedule set by risk and manufacturer recommendation, verified between calibrations using intermediate checks, and immediately removed from service and tagged "Out of Service" if it fails a check — see the companion Calibration Certificate template (QM-001-CAL) for the record format used to close out each calibration event.

5.3 Metrological Traceability

Measurement results are traceable to the International System of Units (SI) through an unbroken chain of calibrations, each contributing a stated uncertainty, performed by accredited calibration providers per ISO/IEC 17025:2017 Clause 6.5 [1]. Where SI traceability is not technically achievable (for example, certain microbiological reference materials), traceability is instead established to a certified reference material or an interlaboratory comparison, and this is documented in the relevant test procedure.

5.4 Environmental Conditions

Temperature and humidity in each testing area are continuously logged and reviewed daily by the section supervisor; excursions outside the range specified in the relevant procedure trigger an immediate review of any results generated during the excursion window.

5.5 Test and Calibration Methods

Standard methods are used wherever a suitable published method exists (e.g., recognized pharmacopoeial or regulatory methods); laboratory-developed methods are validated before first use and revalidated whenever a significant change is made to reagents, equipment, or scope. Method validation records include, at minimum: accuracy, precision, linearity range, limit of detection and quantitation, and measurement uncertainty — consistent with the Laboratory's Limit of Detection and Quantitation Report template (QM-001-LOQ).

5.6 Handling of Test Items

Samples are received, uniquely identified with a barcoded accession number, and logged in the LIMS with time, date, condition on receipt, and any deviation from the client's submission instructions noted before acceptance. Chain of custody is maintained for all regulatory and forensic submissions,

with each transfer of custody signed and time-stamped.

5.7 Ensuring Validity of Results

Mechanism	Description	Frequency
Proficiency testing	External interlaboratory comparison per test category	2 per year, per category
Certified reference materials	Analysis of CRMs alongside routine samples	Each analytical batch
Duplicate analysis	Blind re-analysis of a routine sample	1 in 20 samples, minimum
Internal QC charts	Control charting of QC sample results (Shewhart rules)	Every run
Staff comparison	Split-sample comparison between two analysts	Quarterly

Any proficiency testing result outside the acceptable z-score range ($|z| > 2$) triggers a mandatory root-cause investigation before the affected method is used again for reportable results.

6 Quality Assurance and Continual Improvement

6.1 Internal Quality Control

Each testing section maintains internal quality control appropriate to its discipline: control charts in Chemistry, sterility and growth-promotion checks on media batches in Microbiology, and no-template and positive-extraction controls in Molecular Diagnostics. Control results are reviewed by the section supervisor before any associated client result is released.

6.2 Proficiency Testing Participation

Section	Provider Scheme	Rounds/Year	Last Result
Chemistry	Nexa Reference Materials PT Scheme	2	Satisfactory
Microbiology	Synapse Interlaboratory Programme	2	Satisfactory
Molecular Diagnostics	Apex Molecular QA Scheme	3	Satisfactory

6.3 Nonconforming Work

Work identified as nonconforming — through equipment failure, QC breach, or procedural deviation — is immediately quarantined, and the analyst notifies the section supervisor before any further action. The supervisor evaluates the significance of the nonconformity, decides whether affected results must be recalled, and records the disposition in the Nonconformity Register. No nonconforming result leaves the Laboratory without an accompanying corrective action reference.

6.4 Corrective and Preventive Action Process

1. Detect and contain the nonconformity; halt affected work if validity is uncertain.
2. Record the event in the Nonconformity Register within one working day.

3. Investigate root cause using a structured method (5-Whys or fishbone).
4. Define and implement corrective action, with an owner and target date.
5. Verify effectiveness no sooner than 30 days after implementation.
6. Close the record and report the outcome at the next Management Review.

6.5 Customer Feedback and Complaints

Complaints may be submitted in writing, by phone, or through the client portal. Receipt is acknowledged within two working days, and the QA Officer determines whether the complaint relates to Laboratory activities within the accredited scope. Where it does, a written response — including root cause and any corrective action — is provided within 15 working days. Complaint outcomes are anonymized and included as a standing agenda item at Management Review to identify systemic trends.

Escalation

A complaint alleging falsification of data, undisclosed conflict of interest, or breach of impartiality is escalated directly to the Laboratory Director on the same working day, bypassing the standard response timeline above.

7 Records Control

7.1 Record Types and Retention

Record Type	Examples	Retention
Test and calibration records	Worksheets, instrument printouts, calibration certificates	10 years
Sample records	Accession logs, chain-of-custody forms, retention/disposal logs	7 years
Personnel records	Training files, competency assessments, authorizations	Duration of employment + 5 years
Quality records	Internal audit reports, management review minutes, CAPA records	6 years
Client reports	Final issued reports and any amendments	10 years
Complaint records	Complaint log, investigation, and response	6 years

Retention periods reflect the longer of internal policy and any applicable regulatory or contractual requirement; where a specific client contract specifies a longer period, that period governs for records relating to that client.

7.2 Record Security and Backup

Electronic records in the LIMS are backed up nightly to a geographically separate site, with monthly restoration tests performed by IT and witnessed by the QA Officer. Access to LIMS records is

role-based; amendment of a finalized record requires a documented, attributable correction and is never performed by deletion or overwriting. Paper records are stored in a locked, access-logged archive room with humidity and fire controls appropriate to the media.

7.3 Archiving and Disposal

At the end of its retention period, a record is reviewed by the QA Officer before disposal; records subject to an open investigation, complaint, or legal hold are retained beyond their nominal period until that hold is lifted. Disposal of paper records is by confidential shredding; electronic records are securely erased and the disposal event itself is logged, per the Sample Retention and Disposal Schedule (QM-001-DISP).

8 Appendices

8.1 Appendix A — Related Documents

- SOP-DOC-001 — Control of Documented Information
- SOP-CAL-014 — Equipment Calibration and Intermediate Checks
- SOP-SMP-002 — Sample Receipt, Handling, and Chain of Custody
- SOP-NCR-005 — Nonconforming Work and Corrective Action
- SOP-AUD-003 — Internal Audit Programme
- QM-001-DISP — Sample Retention and Disposal Schedule
- QM-001-CAL — Calibration Certificate Template
- QM-001-LOQ — Limit of Detection and Quantitation Report Template

8.2 Appendix B — Acronyms and Definitions

Term	Definition
CAPA	Corrective and Preventive Action
CRM	Certified Reference Material
LIMS	Laboratory Information Management System
PT	Proficiency Testing — external interlaboratory comparison of test performance
QC	Quality Control — internal checks confirming a process remains in statistical control
QMS	Quality Management System
SI	International System of Units
z-score	Standardized deviation of a proficiency testing result from the assigned value

8.3 Appendix C — Related Accreditation References

This manual is maintained with reference to the standards and guidance documents listed below.

References

[1] International Organization for Standardization. ISO/IEC 17025:2017 general requirements for the competence of testing and calibration laboratories. Technical Report ISO/IEC 17025:2017, ISO, Geneva, Switzerland, 2017.

[2] International Organization for Standardization. ISO 31000:2018 risk management — guidelines. Technical Report ISO 31000:2018, ISO, Geneva, Switzerland, 2018.

[3] International Organization for Standardization. ISO 15189:2022 medical laboratories — requirements for quality and competence. Technical Report ISO 15189:2022, ISO, Geneva, Switzerland, 2022.