# Laboratory Internal Audit Checklist

ISO/IEC 17025:2017 Conformance Review

| Audit Identification | |
|---|---|
| Document ID: | VAL-AUD-2026-014 |
| Revision: | 3.0 |
| Audited Entity: | Vertex Analytical Laboratories |
| Site: | Site B – Instrumentation Wing |
| Audit Type: | Scheduled Internal Audit |
| Audit Date(s): | 2026-07-14 – 2026-07-15 |

| Audit Team | |
|---|---|
| Lead Auditor: | Dr. Elena Marsh (Meridian QP |
| Co-Auditor: | Farid Osei, CQA |
| Auditee – Lab Manager: | Rajiv Nandan |
| Auditee – QA Officer: | Priya Sen |
| Standard Reference: | ISO/IEC 17025:2017 |
| Scope Ref: | QM-04, §3.2 |

**Rating legend used throughout this checklist:** CONFORMS Requirement met with objective evidence OFI Opportunity for improvement, not a nonconformance MINOR NC Isolated lapse, contained, low recurrence risk MAJOR NC Systemic failure or repeat finding threatening result validity

## 1 Purpose and Scope

This checklist records the findings of the scheduled internal audit of Vertex Analytical Laboratories' management system and technical operations against ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*. The audit was commissioned by the Quality Manager as part of the 2026 internal audit programme (schedule ref. QM-04) and covers the calibration and chemical testing activities performed at Site B, Instrumentation Wing.

### 1.1 Objectives

- Verify that documented procedures under the current quality manual (rev. 9) remain implemented in day-to-day practice.
- Confirm that corrective actions raised at the previous audit (VAL-AUD-2025-031) have been closed and are effective.
- Identify nonconformances, observations, and opportunities for improvement ahead of the external accreditation surveillance visit scheduled for 2026-10-05.

### 1.2 Scope Boundaries

- **In scope:** sample reception, equipment calibration and maintenance records, method validation files, environmental monitoring, personnel competency records, and chemical/physical safety practices within the Instrumentation Wing.
- **Out of scope:** finance, procurement contracts unrelated to calibration services, and the Site A microbiology suite (covered under a separate audit, VAL-AUD-2026-015).

### 1.3 Document Control

| Prepared by | Reviewed by | Approved by | Effective date |
|---|---|---|---|
| Dr. Elena Marsh | Priya Sen | Rajiv Nandan | 2026-07-16 |

# 2 Audit Methodology and Rating Scale

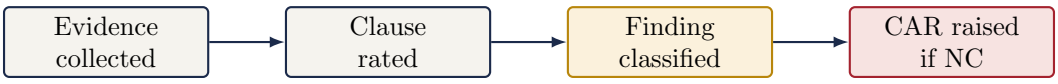
## 2.1 Approach

Evidence was gathered through document review, staff interviews, and direct observation of calibration and testing activities in progress. Each clause below is scored against *objective evidence* actually sighted by the audit team – verbal assurance alone was not accepted as conforming evidence. Sampling followed a risk-based selection: equipment with overdue calibration history or prior findings received priority coverage.

## 2.2 Conformity Rating Definitions

| Rating | Definition |
|---|---|
| CONFORMS | Requirement is met; objective evidence sighted and traceable to a record. |
| OFI | Requirement is met, but a more robust or efficient practice is available. |
| MINOR NC | An isolated lapse in an otherwise effective process; low risk to result validity. |
| MAJOR NC | A systemic breakdown, a repeat finding from a prior audit, or a lapse that directly threatens the validity of reported results. |

## 2.3 Finding Classification Workflow




Every MINOR NC or MAJOR NC rating in Sections 4–6 automatically generates a line in the Corrective Action Register (Section 7.2), with an owner and due date assigned before the closing meeting.

# 3 Checklist Part A – Management System Requirements

Clauses 5–8 of ISO/IEC 17025:2017 govern organisational structure, document control, and management review. Evidence sources: quality manual rev. 9, document register, minutes of the Q1–Q2 2026 management review meetings.

| Clause | Requirement | Objective Evidence | Rating |
|---|---|---|---|
| 5.6 | Impartiality risks are identified and reviewed annually | Impartiality risk register VAL-QF-011, last reviewed 2026-02-03 | CONFORMS |
| 6.2.2 | Personnel competency records exist for all signatories | Competency file sighted for 11 of 12 active signatories; one file missing refresher record | MINOR NC |
| 6.2.5 | Authorisation records define scope per staff member | Authorisation matrix VAL-QF-014 current as of 2026-05-01 | CONFORMS |

| Clause | Requirement | Objective Evidence | Rating |
|---|---|---|---|
| 7.5.1 | Technical records are sufficient to allow reconstruction of test | Sampled 8 job files; all reconstructable from raw data through report | CONFORMS |
| 7.8.1 | Reports contain all information agreed with the client | 2 of 20 sampled reports omitted the measurement uncertainty statement required by the client's specific agreement | MINOR NC |
| 8.2 | Quality manual reflects current organisational structure | Rev. 9 org chart matches current staff list; no discrepancy found | CONFORMS |
| 8.5 | Risk-based thinking is documented for key processes | Risk register exists but has not been updated since the 2025 audit cycle | OFI |
| 8.7 | Corrective actions from the prior audit are closed and verified | 7 of 9 CARs from VAL-AUD-2025-031 closed with effectiveness check; 2 remain open past due date | MAJOR NC |
| 8.9 | Management review addresses all mandated inputs | Minutes of 2026 review cover 8 of 10 required inputs; complaints trend analysis absent | MINOR NC |

## 4 Checklist Part B – Technical and Equipment Requirements

Clauses 6.3–6.5 and 7.2–7.7 cover facilities, equipment, metrological traceability, and method validation. Evidence sources: calibration certificates, equipment log VAL-EQ-002, method validation files for methods VAL-M-07 and VAL-M-12.

| Clause | Requirement | Objective Evidence | Rating |
|---|---|---|---|
| 6.3.2 | Environmental conditions are monitored where they affect results | Temperature/humidity logger data continuous for HPLC suite, no gaps in 90-day sample | CONFORMS |
| 6.4.4 | Equipment is calibrated before use where accuracy affects results | UV–Vis spectrophotometer VAL-EQ-014 in use 6 days past calibration due date | MAJOR NC |
| 6.4.6 | Calibration status is clearly indicated on equipment | Calibration labels present and legible on 22 of 24 sampled instruments | MINOR NC |
| 6.4.13 | Equipment records include maintenance and adjustment history | Maintenance log complete for all sampled equipment except VAL-EQ-014 | MINOR NC |

| Clause | Requirement | Objective Evidence | Rating |
|---|---|---|---|
| 6.5.2 | Metrological traceability to SI units is established | Reference standards traceable via accredited external calibration; certificates on file | CONFORMS |
| 7.2.1 | Methods are validated before use for non-standard applications | Validation file for method VAL-M-12 complete: range, precision, bias, uncertainty | CONFORMS |
| 7.2.2 | Method performance is confirmed capable of meeting requirements | Verification data for method VAL-M-07 dated 2024; due for re-verification | OFI |
| 7.6.1 | Measurement uncertainty is evaluated and documented | Uncertainty budget on file for 9 of 10 sampled test methods; one budget references superseded reference values | MINOR NC |
| 7.7.1 | Validity of results is monitored, e.g. via proficiency testing | PT scheme participation current; 2026 z-scores within ±2 for all parameters | CONFORMS |

## 5 Checklist Part C – Safety and Environmental Requirements

Covers chemical handling, waste disposal, and workspace safety, cross-referenced against internal SOP-SAF-003 and applicable facility safety regulations. Evidence sources: chemical inventory, waste manifest log, incident register, PPE issue records.

| Clause | Requirement | Objective Evidence | Rating |
|---|---|---|---|
| SOP-1 | Safety data sheets are current and accessible at point of use | SDS binder current for 41 of 43 chemicals on inventory; 2 SDS dated pre-2023 revision | MINOR NC |
| SOP-2 | Chemical waste is segregated and disposed per manifest schedule | Waste manifest log reviewed for Q2 2026; all pickups within scheduled window | CONFORMS |
| SOP-3 | PPE issue and fit-testing records exist for relevant personnel | Fit-test records current for all respirator users; one glove-issue record missing signature | OFI |
| SOP-4 | Emergency eyewash and shower stations are tested and logged monthly | Weekly test log complete for 11 of 12 months; one month's log unsigned | MINOR NC |

| Clause | Requirement | Objective Evidence | Rating |
|---|---|---|---|
| SOP-5 | Incident and near-miss reports are investigated with root cause | 2026 register shows 3 incidents, all with root-cause analysis and closed actions | CONFORMS |
| SOP-6 | Compressed gas cylinders are secured and segregated by hazard class | All cylinders in Instrumentation Wing correctly chained and segregated | CONFORMS |

# 6 Findings Summary and Corrective Action Register

## 6.1 Summary by Classification

| Classification | Count |
|---|---|
| CONFORMS | 11 |
| OFI | 3 |
| MINOR NC | 7 |
| MAJOR NC | 2 |
| Total clauses assessed | 23 |

**Overall verdict:** the management system remains substantially conformant. Two Major findings require closure with documented effectiveness checks before the October surveillance visit; both relate to overdue calibration and open prior-audit CARs.

## 6.2 Corrective Action Register

| ID | Clause | Finding & Root Cause | Corrective Action | Owner / Due |
|---|---|---|---|---|
| CAR-091 | 6.4.4 | UV–Vis spectrophotometer VAL-EQ-014 used 6 days past calibration due date; calibration reminder in scheduling tool was not renewed after the last service visit | Recalibrate before further use; add calendar redundancy to equipment scheduler | R. Nandan / 2026-07-25 |
| CAR-092 | 8.7 | Two CARs from VAL-AUD-2025-031 remain open past their due date; owner reassigned mid-quarter without handover | Close both CARs with effectiveness evidence; formalise CAR handover step in QA procedure | P. Sen / 2026-08-08 |
| CAR-093 | 6.2.2 | One signatory's competency file missing 2026 refresher record; refresher session was held but not logged | File refresher attendance record; audit remaining signatory files for the same gap | P. Sen / 2026-07-31 |

| ID | Clause | Finding & Root Cause | Corrective Action | Owner / Due |
|---|---|---|---|---|
| CAR-094 | 7.6.1 | Uncertainty budget for one method cites superseded reference values | Recalculate budget against current reference certificate; reissue budget document | Lab Technical Lead / 2026-08-15 |

# 7 Sign-off and Distribution

## 7.1 Closing Meeting Acknowledgement

The findings above were presented at the closing meeting held 2026-07-15 and were acknowledged by the auditee representatives present. Disagreement, if any, was to be raised in writing within five working days; none was received.

| Lead Auditor | Lab Manager | QA Officer |
|---|---|---|
| _____ | _____ | _____ |
| Dr. Elena Marsh | Rajiv Nandan | Priya Sen |
| Date: _____ | Date: _____ | Date: _____ |

## 7.2 Distribution List

- Quality Manager, Vertex Analytical Laboratories – controlled copy
- Lab Manager, Instrumentation Wing – controlled copy
- Meridian Quality Partners audit file – archival copy
- Accreditation body liaison – upon request, prior to surveillance visit

**Next audit:** the follow-up verification of CAR-091 through CAR-094 is scheduled for 2026-08-20, ahead of the external surveillance visit on 2026-10-05.