

Laboratory Internal Audit Checklist

ISO/IEC 17025:2017 Conformance Review

Audit Identification		Audit Team	
Document ID:	VAL-AUD-2026-014	Lead Auditor:	Dr. Elena Marsh (Meridian QP)
Revision:	3.0	Co-Auditor:	Farid Osei, CQA
Audited Entity:	Vertex Analytical Laboratories	Auditee – Lab Manager:	Rajiv Nandan
Site:	Site B – Instrumentation Wing	Auditee – QA Officer:	Priya Sen
Audit Type:	Scheduled Internal Audit	Standard Reference:	ISO/IEC 17025:2017
Audit Date(s):	2026-07-14 – 2026-07-15	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

Clause	Requirement	Objective Evidence	Rating
6.2.5	Authorisation records define scope per staff member	Authorisation matrix VAL-QF-014 current as of 2026-05-01	CONFORMS
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

Clause	Requirement	Objective Evidence	Rating
6.4.13	Equipment records include maintenance and adjustment history	Maintenance log complete for all sampled equipment except VAL-EQ-014	MINOR NC
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

Clause	Requirement	Objective Evidence	Rating
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
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

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.

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

6.2 Corrective Action Register

ID	Clause	Finding & Root Cause	Corrective Action	Ac-	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	

ID	Clause	Finding & Root Cause	Corrective Action	Ac-	Owner Due	/
CAR-092	8.7	Two CARs from VAL-AUD-2025-031 remain open past their due date; owner re-assigned 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	
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.