STANDARD OPERATING PROCEDURE TEMPLATE · ANALYTIC: QC, CALIBRATION, VERIFICATION AND EQUIPMENT

Pipette Calibration Verification

Governing requirement: 42 CFR 493.1254

Applies to: ☐ Waived ☑ Moderate complexity ☑ High complexity

Laboratory name		**CLIA number**	
Document number		**Version**	
Effective date		**Next review due**	
Author		**Department / section**	
Approved by (laboratory director)		**Director signature**	
Approval date		**Supersedes document**	

Important: Template only. Before use, this document must be reviewed, adapted to your laboratory's instruments, test systems and the manufacturer's instructions, and approved, signed and dated by the laboratory director. Check current federal, state and accreditation requirements. Not legal advice. Sound Lab Consultants is not affiliated with or endorsed by CMS, CDC, FDA, OSHA, CAP, COLA, The Joint Commission, CLSI or any manufacturer.

1. Purpose

To verify pipettes deliver accurate and precise volumes.

2. Scope

All pipettes used in testing and reagent preparation.

3. Responsibility

- Testing personnel: perform the procedure, record results and stop patient testing when criteria are not met.
- Technical consultant / technical supervisor: sets acceptance criteria, reviews records and approves corrective action.
- Supervisor: ensures schedules are met and records are reviewed on time.
- Laboratory director: approves the procedure and any change to criteria.

4. Definitions

Gravimetric check: Weighing dispensed water to calculate delivered volume.

5. Materials, equipment and records

- Analytical balance
- Distilled water, thermometer
- Pipette inventory **[Inventory location]**

Inventory location	

6. Procedure

1. Verify each pipette **[Frequency, e.g. every 6 months]** and after repair.

Frequency, e.g. every 6 months	

2. Dispense **[Number]** replicates at nominal (and min/max for adjustable) volumes.

Number	

3. Convert weight to volume with the water density correction.
4. Calculate inaccuracy and imprecision; compare to **[Acceptance limits]**.

Acceptance limits	

5. Remove failing pipettes from service.
6. Label with date checked and next due.

7. Quality control

• Follow the laboratory's QC policy and the manufacturer's instructions; record QC before reporting patient results.

• Stop patient testing and take corrective action when QC or acceptance criteria are not met.

8. Interpretation, reporting and documentation

• Record the activity, date, result and initials on the form or log, and have the supervisor review records **[Review frequency]**.

Review frequency	

• Keep records per the record retention SOP (at least 2 years under 42 CFR 493.1105 unless a longer period applies).

9. Limitations and cautions

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

10. References

• eCFR, 42 CFR Part 493 Laboratory Requirements (CLIA) https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

• CMS, State Operations Manual Appendix C: Survey procedures and interpretive guidelines for laboratories https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_lab.pdf

• ISO 8655 Piston-operated volumetric apparatus (referenced by name)

• eCFR, 42 CFR 493.1254 https://www.ecfr.gov/current/title-42/section-493.1254

11. Pipette check log

Fill in electronically or print. Keep completed forms per the record retention policy.

Pipette ID	Volume	Mean	% error	CV %	Pass	Next due

12. Lab-specific notes

Notes and local requirements	

13. Revision history

Version	Date	Description of change	Author	Approved by

14. Annual review log

Procedures and changes must be approved, signed and dated by the current laboratory director before use (42 CFR 493.1251(d)).

Review date	Reviewed by	Signature	Changes needed (Y/N)	Comments

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