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

QC Review with Levey-Jennings Charts and Westgard Rules

Governing requirement: 42 CFR 493.1256(d)(8)

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 evaluate quantitative QC consistently and detect shifts and trends.

2. Scope

Quantitative nonwaived tests.

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

Mean and SD: Calculated from at least **[Number of data points, e.g. 20]** control results over **[Days]**.

1-2s warning: One control beyond 2 SD triggers inspection of other rules.

1-3s, 2-2s, R-4s, 4-1s, 10x: Common rejection rules.

5. Materials, equipment and records

- QC software or chart template

6. Procedure

1. Establish the mean and SD for each lot of each control.

2. Plot each result on the Levey-Jennings chart.

3. Apply rules: reject on 1-3s, 2-2s, R-4s, 4-1s, 10x **[Rules in use]**.

Rules in use	

4. When a run is rejected, do not report patient results; troubleshoot (reagent, calibrator, instrument, control material).

5. Document action and repeat results.

6. Review charts weekly for shifts and trends.

7. Update cumulative statistics monthly.

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

• Manufacturer ranges for assayed controls are often too wide for lab use; establish lab limits.

• 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

• CLSI guidelines relevant to this procedure (referenced by name only; obtain current editions from CLSI)

• eCFR, 42 CFR 493.1256 https://www.ecfr.gov/current/title-42/section-493.1256

11. Lab-specific notes

Notes and local requirements	

12. Revision history

Version	Date	Description of change	Author	Approved by

13. 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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