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

Quality Control Policy (Nonwaived Tests)

Governing requirement: 42 CFR 493.1256

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 detect immediate errors and changes in test performance before patient results are reported.

2. Scope

All nonwaived testing.

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

Control: Material with known expected results run like patient samples.

Run: Interval within which accuracy and precision are expected to be stable, not exceeding 24 hours.

5. Materials, equipment and records

- Control materials **[Control products and levels]**

Control products and levels	

- QC software or Levey-Jennings charts

6. Procedure

1. Follow the manufacturer's QC instructions or CLIA minimums, whichever is more stringent, unless an approved IQCP applies.

2. Quantitative tests: at least two levels of control each day of patient testing.

3. Qualitative tests: a positive and a negative control each day of testing.

4. Graded or titered tests: a negative control and a control with graded or titered reactivity each day of testing.

5. Tests with an extraction phase: two controls each day, including one that detects extraction errors; molecular amplification: two controls plus an inhibition control when inhibition is a significant cause of false negatives (493.1256(d)(3)(iv)-(v)).

6. Electrophoresis: at least one control with each run; thin layer chromatography: calibrator and control on each plate (493.1256(d)(4)-(5)).

7. Run QC before resuming patient testing after a complete reagent change, major preventive maintenance or critical part replacement.

8. Run controls the same way as patient specimens and rotate operators.

9. Establish ranges for unassayed controls; verify ranges for assayed controls **[Range-setting method]**.

Range-setting method	

10. Check new lots of reagents and controls before use.

11. Review QC before reporting patient results; reject runs that fail acceptance rules **[Westgard or other rules]**.

Westgard or other rules	

12. When QC fails: do not report, investigate, correct, rerun and evaluate patient results since the last acceptable QC.

13. Supervisor reviews QC records at least **[Review frequency]**.

Review frequency	

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

• Keep QC records at least 2 years.

9. Limitations and cautions

• Specialty rules (e.g. 493.1261-1278) add requirements.

• 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

• CMS, Individualized Quality Control Plan (IQCP) frequently asked questions (PDF)
https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/faqs-iqcp.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

• eCFR, 42 CFR 493.1282 https://www.ecfr.gov/current/title-42/section-493.1282

11. QC review log

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

Week of	Test	Levels in	Failures	Action	Reviewed by	Date

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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