STANDARD OPERATING PROCEDURE TEMPLATE · SPECIALTY AND SUBSPECIALTY PROCEDURES

Chemistry Analyzer Operation

Governing requirement: 42 CFR 493.1251, 493.1256 and 493.1267

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 operate the chemistry analyzer and report accurate results.

2. Scope

Routine chemistry testing on **[Analyzer make and model]**.

Analyzer make and model

3. Responsibility

- Testing personnel: perform the procedure as written and record QC and patient results.
- Technical supervisor / technical consultant: approves criteria, reviews QC and resolves problems.
- General supervisor (high complexity): provides day-to-day supervision and result review.
- Laboratory director: approves the procedure and is responsible for overall test quality.

4. Definitions

Flag: Instrument message indicating a result may be unreliable.

5. Materials, equipment and records

- Analyzer **[Analyzer ID]**

Analyzer ID

- Reagents, calibrators and controls **[Lists]**

Lists

6. Procedure

1. Perform daily startup and maintenance per the maintenance log.

2. Check reagent inventory and onboard stability.

3. Calibrate as required; run two levels of QC per test each day (more often per manufacturer or IQCP).

4. Review QC; do not run patients if QC fails.

5. Load samples; check for clots, bubbles and adequate volume.

6. Review results for flags, indices (hemolysis, icterus, lipemia), delta checks and critical values.

7. Dilute and rerun results above the reportable range per protocol **[Dilution protocol]**.

Dilution protocol	

8. Release results; notify critical values.

9. Perform end-of-day maintenance.

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

• See analyte procedures for interferences.

• 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

• Manufacturer's package insert, operator manual and safety data sheets for each test system in use

• eCFR, 42 CFR 493.1251 https://www.ecfr.gov/current/title-42/section-493.1251

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

• eCFR, 42 CFR 493.1267 https://www.ecfr.gov/current/title-42/section-493.1267

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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