STANDARD OPERATING PROCEDURE TEMPLATE · SPECIALTY AND SUBSPECIALTY PROCEDURES

PCR Workflow and Contamination Control

Governing requirement: 42 CFR 493.1256(d)(3)(v) and 493.1101

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 prevent amplicon and cross-contamination in molecular testing.

2. Scope

All nucleic acid amplification testing.

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

Unidirectional workflow: Movement from clean (reagent prep) to dirty (post-amplification) areas only.

5. Materials, equipment and records

- Separate rooms or hoods
- 10% bleach (fresh) and 70% ethanol
- Dedicated lab coats, pipettes

6. Procedure

1. Separate reagent preparation, specimen preparation and amplification/detection areas.

2. Move only from clean to dirty areas; never bring amplicons back.

3. Use dedicated equipment, coats and filtered tips in each area.

4. Decontaminate surfaces before and after work with **[Decontamination agent and contact time]**.

Decontamination agent and contact time	

5. Run no-template controls with each run.

6. Perform wipe tests **[Frequency]** to monitor contamination.

Frequency	

7. Investigate unexpected positives in negative controls; stop reporting until resolved.

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

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

• CDC and NIH, Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th edition https://www.cdc.gov/labs/bmbl/index.html

• eCFR, 42 CFR 493.1101 https://www.ecfr.gov/current/title-42/section-493.1101

• 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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