STANDARD OPERATING PROCEDURE TEMPLATE · PRE-ANALYTIC: ORDERING, COLLECTION AND SPECIMEN HANDLING

Blood Culture Collection

Governing requirement: 42 CFR 493.1242(a)

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 collect blood cultures with low contamination and adequate volume.

2. Scope

Adult and pediatric blood culture collection.

3. Responsibility

- Collectors (phlebotomists, nurses, medical assistants): follow this procedure and document collection.
- Specimen processing / accessioning staff: check acceptability and document problems.
- Supervisor: trains staff, monitors pre-analytic errors and reviews rejection logs.
- Laboratory director: approves the procedure and acceptance criteria.

4. Definitions

Set: One aerobic and one anaerobic bottle from one venipuncture site (pediatric may be a single bottle).

5. Materials, equipment and records

- Blood culture bottles
- Skin antiseptic **[Antiseptic used]**

Antiseptic used	

- Butterfly set and holder

6. Procedure

1. Identify the patient; check the order for number of sets and timing.

2. Remove bottle caps and disinfect tops with 70% alcohol; let dry.

3. Disinfect the skin with the approved antiseptic and allow full contact and dry time per the product label; do not re-palpate.

4. Collect the target volume per bottle **[Target volume per bottle]**; inoculate aerobic bottle first when using a butterfly.

Target volume per bottle	

5. Collect additional sets from separate sites as ordered.

6. Label bottles without covering barcodes; record site and time.

7. Transport promptly; do not refrigerate.

7. Quality control

• Monitor contamination rate monthly; target **[Contamination rate target]**.

Contamination rate target	

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

• Underfilled bottles reduce sensitivity; overfilling may cause false positives.

• 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)

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

• eCFR, 42 CFR 493.1242 https://www.ecfr.gov/current/title-42/section-493.1242

• eCFR, 42 CFR 493.1261 https://www.ecfr.gov/current/title-42/section-493.1261

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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