STANDARD OPERATING PROCEDURE TEMPLATE · SPECIALTY AND SUBSPECIALTY PROCEDURES

# Microbiology Media and Reagent Quality Control

Governing requirement: 42 CFR 493.1256(e) and 493.1261

**Applies to:** ☐ Waived ☑ Moderate complexity ☑ High complexity

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|---|---|---|---|
| **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 ensure media and reagents perform correctly.

## 2. Scope

Purchased and prepared media, stains and reagents.

## 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

**Exempt media:** Commercial media for which the lab may rely on the manufacturer's QC when allowed.

## 5. Materials, equipment and records

- QC organisms
- Media log

## 6. Procedure

**1.** Inspect each shipment for breakage, contamination, color and drying.

**2.** Check performance with control organisms for media not exempt **[Media requiring user QC]**.

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|---|---|
| **Media requiring user QC** | |

**3.** Check sterility of prepared media.

**4.** Test reagents for positive and negative reactivity as required.

**5.** Record results; reject failing lots.

## 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

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

## 11. Media QC log

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

| Date | Medium | Lot | Appearance | Growth check | Acceptable | Tech |
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## 12. Lab-specific notes

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| **Notes and local requirements** | |

## 13. Revision history

| Version | Date | Description of change | Author | Approved by |
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## 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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