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

# Swab Specimen Collection (Nasopharyngeal, Nasal, Throat and Wound)

Governing requirement: 42 CFR 493.1242(a)

**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 collect swab specimens that give reliable results for antigen, molecular and culture tests.

## 2. Scope

Nasopharyngeal, anterior nasal (mid-turbinate), throat and wound swabs.

## 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

**Transport medium:** Medium that preserves organisms or nucleic acid until testing **[Approved transport media]**.

## 5. Materials, equipment and records

- Swabs specified by the test manufacturer
- Transport tubes
- PPE: gloves, gown, eye protection, respirator or mask per risk assessment

## 6. Procedure

**1.** Use only the swab type listed in the test's instructions.

**2.** Nasopharyngeal: tilt head back slightly, insert swab along the nasal floor to the nasopharynx, rotate and hold **[Hold time per manufacturer]**, withdraw.

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|---|---|
| **Hold time per manufacturer** | |

**3.** Anterior nasal: insert about 1/2 to 3/4 inch, rotate against the nasal wall **[Rotations per manufacturer]** in each nostril.

| Rotations per manufacturer | |
|---|---|

**4.** Throat: depress tongue, swab both tonsillar areas and the posterior pharynx without touching tongue or cheeks.

**5.** Wound: clean surface debris with sterile saline, swab the viable base or edge using the Levine technique when appropriate.

**6.** Place swab in transport medium, break shaft at the score line, cap tightly and label.

**7.** Store and transport per manufacturer: **[Storage temperature and time limits]**.

| Storage temperature and time limits | |
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## 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 | |
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• 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

• Wrong swab type or transport medium can cause false negatives; reject per policy.

• 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

• CDC, Infectious diseases laboratory test directory: specimen collection and submission
https://www.cdc.gov/laboratory/specimen-submission/index.html

• 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


## 11. Lab-specific notes

| Notes and local requirements | |
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## 12. Revision history

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