STANDARD OPERATING PROCEDURE TEMPLATE · WAIVED TESTING AND POINT-OF-CARE TESTING

Rapid Influenza and SARS-CoV-2 Antigen Testing

Governing requirement: 42 CFR 493.15(e) (follow manufacturer's instructions) and 493.1773-1775

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 detect influenza A/B and/or SARS-CoV-2 antigens with a waived rapid test.

2. Scope

[Testing sites] performing the Rapid Influenza and SARS-CoV-2 Antigen Testing under the lab's CLIA certificate.

Testing sites	

3. Responsibility

- Testing personnel: follow the manufacturer's instructions exactly and document QC and results.
- Site supervisor / testing coordinator: trains staff, reviews logs and orders supplies.
- Laboratory director: approves the procedure and holds responsibility for the certificate.

4. Definitions

Serial testing: Repeat testing over days when a negative antigen result is recommended to be confirmed.

5. Materials, equipment and records

- Kit **[Kit name and lot]**

Kit name and lot	

- Swabs
- Controls
- PPE

6. Procedure

1. Collect the specimen type the insert specifies.

2. Process immediately or within the stated time.

3. Run the test exactly per insert and read at the specified time.

4. Record and report results; report to public health as required **[Reporting requirements]**.

Reporting requirements	

5. Run controls per insert and with each new lot or shipment.

6. Consider molecular confirmation of negatives when clinically indicated.

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

• Antigen tests are less sensitive than molecular tests.

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

10. References

• CDC, Ready? Set? Test! Patient testing is important (waived testing booklet) https://www.cdc.gov/clia/php/waived-tests/index.html

• CDC, Clinical Laboratory Improvement Amendments (CLIA) https://www.cdc.gov/clia/php/about/index.html

• FDA, CLIA test categorization database https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/search.cfm

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

• FDA, In vitro diagnostics and emergency use authorizations https://www.fda.gov/medical-devices/products-and-medical-procedures/in-vitro-diagnostics

• eCFR, 42 CFR 493.15 https://www.ecfr.gov/current/title-42/section-493.15

11. QC and patient testing log

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

Date	Kit lot / exp	Pos control	Neg control	Acceptable	Tech	Notes

12. Lab-specific notes

Notes and local requirements	

13. Revision history

Version	Date	Description of change	Author	Approved by

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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