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

# Hemoglobin A1c (Waived POCT)

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

**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 measure HbA1c for diabetes monitoring with a waived analyzer.

## 2. Scope

**[Testing sites]** performing the Hemoglobin A1c 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

**Intended use:** Whether the device is cleared for monitoring only or also diagnosis.

## 5. Materials, equipment and records

- Analyzer **[Analyzer ID]**

**Analyzer ID**

- Cartridges **[Lot]**

**Lot**

- Controls

## 6. Procedure

**1.** Confirm the device's cleared intended use **[Intended use]**.

**Intended use**

**2.** Bring cartridges to room temperature as specified.

**3.** Collect capillary blood; fill the collector per instructions.

**4.** Run and record result.

**5.** Run controls per manufacturer and new lot.

**6.** Refer results outside the reportable range to the lab.

## 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

• Report as % (and mmol/mol if used).

## 9. Limitations and cautions

• Hemoglobin variants and conditions affecting red cell lifespan can affect results.

• 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

• 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 |
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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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