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

Blood Glucose Meter Testing (Waived POCT)

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 perform capillary blood glucose testing accurately with the **[Meter make and model]**.

Meter make and model

2. Scope

[Testing sites] performing the Blood Glucose Meter 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

Control solution: Solution with an expected range printed on the strip vial or insert.

5. Materials, equipment and records

- Meter **[Meter ID]**

Meter ID

- Test strips **[Strip lot tracking]**

Strip lot tracking

- Control solutions (levels per manufacturer)
- Lancets, alcohol, gauze

6. Procedure

1. Check strip and control expiration and open-vial dating.

2. Run control levels per manufacturer **[QC frequency per manufacturer]** and with each new strip lot.

QC frequency per manufacturer	

3. Identify the patient with two identifiers.

4. Clean the finger with alcohol, let dry; puncture the side of the fingertip.

5. Apply blood to the strip per instructions; read the result.

6. Record result, time and tester.

7. Results below **[Low critical value]** or above **[High critical value]** or reading LO/HI: act per protocol and send a venous sample to the lab when required.

Low critical value	
High critical value	

8. Clean and disinfect the meter between patients with an approved disinfectant **[Disinfectant per manufacturer]**.

Disinfectant per manufacturer	

7. Quality control

• Do not test patients if control results are outside range.

8. Interpretation, reporting and documentation

• Report units mg/dL.

9. Limitations and cautions

• Some meters are not cleared for critically ill patients; use only as the meter's labeling allows.

• 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

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

Free template from Sound Lab Consultants, soundlabconsult.com. Download more free templates at soundlabconsult.com/laboratory-sop-library.