

SUBJECT: WAIVED TESTING	REFERENCE #13001
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**POLICY:**

- \_\_\_\_\_ HHA shall instruct and train appropriately licensed staff to perform specified types of clinical laboratory specimen testing at the point of care rendered. This type of testing will be referred to as waived testing and is understood to be performed by those individuals who have the clinical expertise and licensure to perform, evaluate and take appropriate action on waived tests.
- The HHA will obtain and maintain current certificates of waiver as specified by federal CLIA '88 regulations.
- Any test requested for inclusion in the Waived Testing Index (list of those tests that may be performed at the point where care is rendered), must be approved by the \_\_\_\_\_ and must meet FDA and CLIA requirements for waived testing.
- The HHA shall ensure that the referral laboratory where any specimens are referred for testing are CLIA certified by requesting and maintaining a copy of the referral lab's current CLIA certificate in its administrative records.
- Clinical laboratory tests approved by the HHA and ordered by a physician are performed by licensed HHA staff, in accordance with the \_\_\_\_\_ State professional practice guidelines and State and Federal regulatory requirements (CLIA).
- Any individual performing approved tests listed on the Waived Testing Index must meet the following requirements:
  - Level of licensure required by the State Board of Nursing
  - Level of licensure required by the State Department of Health Services
  - Successful completion of instruction and training course on the specific test, for which the individual will perform waived testing on an annual basis
  - Successful completion of orientation specific to this HHA upon which the waived test is performed

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- Successful completion of competency evaluation on specific test, for which the individual will perform waived testing
- Successful completion of competency for an instrument that is used for a test; staff must be trained on the use and maintenance of the instrument
- Staff competency shall be evaluated, at a minimum, at orientation and annually thereafter
  - Skilled nurses shall demonstrate, either by documented written evaluation and/or verbal assessment by the Patient Care Services Director/designee, familiarity with the HHA's policies, procedures, scope of services and patient population needs.
  - Competency evaluation must consist of at least two (2) of the following per staff member per test:
    - ◆ Blind (unknown source) test performance and resulting
    - ◆ Periodic observance of routine work by the Patient Care Services Director/designee
    - ◆ Monitoring of the user's quality control performance (QC = equipment calibration, outdating, troubleshooting, etc.)
    - ◆ Written testing specific to the method assessed
  - If waived testing requires the use of an instrument, staff shall be trained on the instrument's use and maintenance. Training shall be documented by the educator.
  - Demonstrate, via documented written evaluation and/or verbal assessment by supervisor, familiarity of the HHA's policies, procedures, scope of services and patient population needs.
  - \_\_\_\_\_ shall evaluate and document evidence of orientation, training and competency of staff who perform waived testing in staff members' human resource file.

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- Any test approved for use by the Governing Body must:
  - Meet FDA and CLIA requirements for waived testing
  - Pose no risk to the patient if performed incorrectly
  - Incorporate such simple and accurate testing methods that the likelihood of incorrect results is virtually negligible
  
- At the present time, the Governing Body has approved the following tests for use by HHA staff:
  - Blood glucose by glucose monitors (glucose monitoring devices cleared by the FDA specifically for home use) owned by the patient
    - The HHA does not provide glucose monitors for use by patients.
  - Dipstick/tablet reagent urinalysis
  - Some prothrombin time tests
  - Some glycosolated hemoglobin tests
  - Other
  
- Any test listed on the Waived Testing Index shall be specifically detailed in written policy and procedure format:
  - Policies and procedures shall be available to individuals performing waived testing.
  - The policies and procedures shall indicate the extent to which the test results are to be used in the care of the patient, noting whether the result is of screening value only or if the result is to be deemed definitive for diagnosis and treatment.

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- The policies and procedures shall indicate whether the nurse is to provide treatment/intervention, based on the test result and pursuant to a physician's order or in accordance with an approved protocol.
- The policy and procedure shall be kept current and be readily available.
- The policy and procedure for the specific test shall include, but may not be limited to:
  - Specimen type, collection, identification and required labeling, as appropriate
  - Specimen preservation, as appropriate
  - Instrument maintenance and function checks, such as instrument calibration
  - Quality control and remedial action
  - Storage conditions for test components
  - Reagent use, including not using reagents that have expired
  - Result reporting and recommendations to repeat the test when results are not in the reportable range of the test
  - Equipment performance evaluation
  - Test performance
  - Documentation of quality control test results
  - Manufacturer's instructions, recommendations, suggestions

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- Manufacturers' manual or package inserts may be used as the policy and procedure for a specific test, as long as the procedure includes:
  - Specific operational procedures, i.e., detailed quality control protocols
  - Specific organizational procedures regarding the test or instrument
- \_\_\_\_\_ shall review and approve all policies and procedures before the initial use of the test for patient testing.
  - Policies and procedures shall then be reviewed at least every three (3) years, and as needed.
  - Policies and procedures shall be reviewed when changes in procedures occur.
- The policy and procedure shall indicate documentation requirements in the medical record, including:
  - Criteria for confirmatory testing and result follow-up recommendations
  - Reference ranges specific to the test method used and appropriate to the patient population served
  - All test results shall be documented in the medical record
- The policy and procedure shall indicate the type, frequency and extent of quality control checks, and remedial action to be conducted for the specific waived test procedure.
  - Quality control checks shall be performed as recommended by the manufacturer.
  - Quality control procedures shall be performed on each instrument used for patient testing, per manufacturers' instructions.

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- Documentation of quality control result records, test result records and instrument records shall be maintained for a minimum of two (2) years
- All quality control results shall be documented, including internal (electronic, liquid or control zone) and external (liquid or electronic).
  - ◆ Quality control documentation may be located in the medical record
  - ◆ Quality control and instrument records shall be associated with individual test results
- Corrective action shall be documented in the log when control results exceed defined acceptance limits.
- Quality control documentation shall include rationale and be based on:
  - ◆ How the test is used
  - ◆ Reagent stability
  - ◆ Manufacturer's recommendations
  - ◆ The organization's experience with the test
  - ◆ Currently accepted guidelines
- The results of quality controls shall be reviewed for acceptability and documented before reporting results.
- \_\_\_\_\_ shall review all quality control documentation.

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**EQUIPMENT USED IN THE PERFORMANCE OF WAIVED TESTS:**

- Equipment used for performing waived testing shall be used according to the manufacturer's instructions.
- Patient-owned glucose monitors shall be calibrated one time a week by HHA nursing staff. The results of the calibration shall be documented in the patient's medical record. Patient-owned equipment is not subject to the CLIA quality control regulations.
  - Simulation of test performance with training equipment/materials for waived testing performed infrequently.

**NOTES:**

- See the FDA for a list of approved waived tests under the Clinical Laboratory Improvement Amendments (CLIA).

U.S. Food and Drug Administration	<a href="http://www.fda.gov/MedicalDevices/">http://www.fda.gov/MedicalDevices/</a>
Centers for Disease Control and Prevention	<a href="http://wwwn.cdc.gov/clia/">http://wwwn.cdc.gov/clia/</a>
Centers for Medicare and Medicaid Services	<a href="https://www.cms.gov/clia/">https://www.cms.gov/clia/</a>

**REFERENCES:**

- Centers for Disease Control and Prevention (CDC). (October 20, 2017). Waived Tests. Clinical Laboratory Improvement Amendments (CLIA). Retrieved from <https://wwwn.cdc.gov/clia/resources/waivedtests/>
- Food and Drug Administration (FDA). (August 5, 2015). *Follow Good Laboratory Practices with Waived Laboratory Tests*. Retrieved from <https://wayback.archive-it.org/7993/20170112085449/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109420.htm>

# GLUCOSE MONITOR OPERATOR PROFICIENCY RECORD

Staff Nurse/Physician Name	Date Certified	1 Year Review Record (Quarterly)				Signature
		1st	2nd	3rd	4th	



SUBJECT: GLUCOSE MONITOR QUALITY CONTROL	REFERENCE #13003
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**PURPOSE:**

- To ensure accurate blood glucose testing of \_\_\_\_\_HHA’s patients.
- To maintain quality control checks of glucose monitors in compliance with applicable laws, regulations, standards and guidelines.
- To uphold the patient’s rights to appropriate care, treatment and services.

**POLICY:**

- Results obtained from blood glucose monitors are only used for monitoring treatment regimens, not for diagnostic purposes.
- \_\_\_\_\_ HHA shall maintain quality control checks of glucose monitors in accordance with CLIA standards and all other applicable laws, regulations and standards.
- The use and quality control checks of blood glucose monitors shall be monitored by the HHA’s Quality Assessment and Performance Improvement (QAPI) Committee as part of the organizationwide QAPI program.
- Quality control checks of glucose monitors shall be performed by licensed HHA staff, with current documented competency in the performance of blood glucose monitor quality control checks.
- Competency of licensed HHA staff shall be conducted in accordance with HHA Human Resource and Clinical Competency policies.

**PROCEDURE:**

- HHA nurses who have been determined competent to perform glucose monitor quality control checks shall:
  - Perform quality control checks of glucose monitors each day prior to patient testing.
  - Perform check strip quality test, low-control quality test and high-control quality test according to the manufacturer’s recommendations and/or instructions.

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- Document results of check strip, quality tests, low-control and high-control on the glucose monitor quality control log or in the patient visit note.
- The quality control log shall be maintained according to glucose monitor serial number.
- Date the glucose monitor test strip vial with the date the vial is opened.
- Initiate a new quality control log whenever a new vial of test strips is opened.
- Discard unused test strips four (4) months from the date opened.
- Date low-control and high-control solution bottles with the date they are opened.
- Discard unused portion of low-control and high-control solutions three (3) months from the date opened.
- Repeat any control checks that fall outside of accepted quality control parameters.
- Not perform glucose testing with a glucose monitor that has quality controls outside of accepted parameters.
- Clean the glucose monitor according to manufacturer's instructions, in order to maintain the monitor in proper working order.
- Store glucose monitors and test strips in such a manner as to protect them from moisture, light, and extremes of hot or cold. Glucose monitors shall not be stored in the nurse's car for extended periods of time, to prevent machine malfunction and test strip deterioration.
- Standard/Universal Precautions are to be adhered to while performing quality control, patient testing, daily maintenance and when discarding waste materials.

**REFERENCE:**

Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services. Code of Federal Regulations, Chapter 4, Title 42, Part 493, Laboratory Requirements.

# BLOOD GLUCOSE MONITORING COMPETENCY CHECKLIST

Name: \_\_\_\_\_ Date: \_\_\_\_\_

## **Instructor observes staff member performing a blood glucose test using the “One Touch” blood glucose meter and checks the following skills:**

- Turns on blood glucose meter, examines Code # and ensures that Meter Code # and Test Strip Code # match. Demonstrates calibration of the meter.
- Inserts test strip into meter correctly.
- Selects and prepares site for fingerstick correctly.
- Obtains a large drop of blood with the lancet device and applies blood to test area correctly.
- Obtains result and identifies when to notify the physician.
- Follows correct Standard Precautions and disposes of lancet and test strip properly.
- Documents results in the patient’s medical record.

## **Performs the following quality control checks (follows manufacturer's instructions):**

- Glucose Control Solutions: High and Low tests
- Checks Strip Test
  - Ensures strips have not expired
- Verbalizes when and how often to do quality control checks

Pass       Fail

## GLUCOSE MONITOR QUALITY CONTROL LOG

Glucose Monitor Serial #: \_\_\_\_\_ Model: \_\_\_\_\_

Issued to (Nurse's Name): \_\_\_\_\_

Test Strip	Low Control	High Control
Lot #:	Lot #:	Lot #:
Code #:	Ranges (if applicable):	Ranges (if applicable):
Date Opened:	Date Opened:	Date Opened:
Expiration Date: (4 months from date bottle opened)	Expiration Date: (3 months from date opened)	Expiration Date: (3 months from date opened)

Date	Time	Low Control Results	High Control Results	Check Strip Results	Patient Name and MR#	Cleaned?	Nurse's Signature
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	

**This log, or a form provided by the manufacturer specific to the type of glucose monitor being used, may be used to document Quality Control checks.**

SUBJECT: FINGERSTICK AND POINT OF CARE BLOOD TESTING DEVICES	REFERENCE #13006
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**DEFINITIONS:**

- Reusable Devices: These devices often resemble a pen and have the means to remove and replace the lancet after each use, allowing the device to be used more than once.
- Single-Use, Auto-Disabling Fingerstick Devices: These are devices that are disposable and prevent reuse through an auto-disabling feature.

**POLICY:**

- \_\_\_\_\_ HHA shall ensure that fingerstick and point of care (POC) blood testing devices are used in accordance with manufacturer’s instructions and in a manner that prevents the transmission of bloodborne infection.
- Only a certified operator may perform fingerstick or other POC blood testing (heelstick, iron levels, etc.).
- Staff shall **never** use personally purchased fingerstick or other POC testing devices to perform patient testing procedures. Staff shall only use agency-provided equipment or the patient’s personal fingerstick or other POC blood testing device.
- Lancets used to perform fingerstick or other POC blood testing shall **never** be used for more than one (1) person.
- Whenever possible, single-use, auto-disabling fingerstick and POC blood testing devices, such as blood glucose meters and PT/INR anticoagulation meters, shall be used only on one patient and not shared.
- If a reusable device must be used, it must be manufacturer- approved for multiple use and must be cleaned and disinfected per manufacturer’s instructions between each use.
  - If cleaning/disinfection per manufacturer’s instructions cannot be conducted in the field, testing equipment **must** be returned to the HHA office for proper cleaning and disinfection before being reused.
- The HHA shall provide staff with appropriate supplies for cleaning/disinfection of fingerstick and other POC blood testing devices.

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- Staff performing fingerstick and POC blood testing shall receive education and training at orientation, annually thereafter, and as needed in the following (not all inclusive):
  - Operation of fingerstick and POC blood testing devices per manufacturer’s instructions
  - Performance of testing procedures per manufacturer’s instructions
  - Infection control procedures to prevent transmission of bloodborne infections
  - Disinfection/cleaning of equipment following manufacturer’s instructions
- Staff competency shall be evaluated, at a minimum, at orientation and annually thereafter.
- Staff shall provide education to patient and patient’s family on infection control related to fingerstick devices and procedures (i.e., never sharing lancets/fingerstick devices, handwashing, proper disposal, etc.).

**PROCEDURE:**

- Hand hygiene shall be performed before and after the procedure.
- Gloves shall be worn by healthcare staff when performing the fingerstick procedure to obtain the sample of blood, and shall be removed after the procedure, followed by hand hygiene.
- Perform patient identification; a minimum of two (2) patient identifiers are required.
- Perform point of care testing procedure adhering to manufacturer's instructions.
- All specimens collected must be immediately labeled or processed before leaving the patient. Labels (when required) should contain patient’s name, medical record number, date, time, specimen control number and collector’s initials.

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- The following guidelines shall be utilized for pediatric patients who are difficult sticks:
  - A heelstick or fingerstick should be attempted to obtain specimens whenever possible depending on amount, type of specimen needed and age of child.
  - One person should make no more than two (2) attempts.
- Clean and disinfect the device per manufacturer’s instructions or return the device to the HHA for cleaning/disinfection.
- Document testing procedure, results and education provided to patient/patient’s family in patient’s medical record.

**REFERENCES:**

- The Joint Commission (TJC). (July 26, 2017). Patient Safety: On-site survey focus: Minimizing exposure to bloodborne pathogens for waived testing. *Home Care Bulletin*, Issue 3. Retrieved from <https://www.jointcommission.org/issues/detail.aspx?Issue=gPRa7JZPi0inAMGFz0b5nHtuABRttpc2wUeRu2WGGEQU%3d>
- Centers for Medicare and Medicaid Services (CMS). (November 9, 2012). *Patient Safety Initiative FY 2013 Pilot Phase - Revised Draft Surveyor Worksheets*. REF: S&C: 13-03-Hospital. Retrieved from <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-03.pdf>
- Centers for Disease Control and Prevention (CDC). (February 9, 2011). CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens. Retrieved from <https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html>