Waived Testing and Glucometer Use

PURPOSE

To define circumstances under which waived tests may be done at Spring Grove Hospital Center, methods by which waived tests will be completed, and ensure compliance associated with functionality of equipment and competency of personnel approved for use of equipment.

To comply with glucometer manufacturer recommendations, The Joint Commission Standards on Waived Testing and CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities.

To ensure patients receive safe, timely and optimum treatment for abnormal blood glucose levels.

DEFINITION

Waived Test: Tests that meet the Clinical Laboratory Improvement Act of 1988 (CLIA 88) requirements for waived tests. Waived tests are cleared by the Food and Drug Administration (FDA) for home use and defined as those so simple and accurate that there is low risk for erroneous results.

Glucometer testing is the only waived test at Spring Grove Hospital Center and is considered to be a diagnostic/quantitative study to be used to identify states of hypoglycemia and hyperglycemia in context with overall clinical assessment of the patient and other clinical studies.

SCOPE

All registered nurses and all licensed practical nurses who provide direct patient care.

POLICY/PROCEDURE

A. Waived testing for blood glucose will only be performed by licensed members of the nursing staff who are currently qualified and deemed competent to perform the procedure and operate the equipment correctly. Qualifications include specific training with the equipment used, participation in the appropriate orientation program, demonstration of competency for recertification (at least annually through competency assessment tests).

B. Equipment: Hospital-approved glucometer and associated materials/supplies.

C. Materials:
   a. Test strips
   b. Lancets (single-use)
   c. Alcohol wipes
   d. Gauze pads
   e. Gloves
   f. Band aids (bandages)
   g. Disinfectant wipes

D. Preparation
   a. Don gloves prior to cleaning/disinfecting glucometer. Clean/disinfect glucometer per manufacturer recommendations and allow to dry thoroughly and per dwell time on the disinfectant wipe label. *Glucometer must also be cleaned in between patients and when it is visibly soiled. Doff gloves after cleaning/disinfecting glucometer.
   b. All health care workers must follow standard precautions, practice hand hygiene, and wear personal protective equipment (PPE) appropriate for the task.
   c. Perform proper hand hygiene immediately after cleaning equipment before each patient test and when hands appear visibly soiled or contaminated.
   d. Don gloves after proper hand hygiene and before each patient test. Doff gloves after each patient test and when gloves are soiled or damaged. Perform proper hand hygiene after doffing gloves.

E. Quality Control (QC) Testing
   a. All glucometers will be control tested at least every 24 hours using manufacturer recommended control level solutions. Quality control testing is conducted each night shift (which is typically designated as 11:15pm-7:15am).
   b. Additional quality control testing is conducted per manufacturer recommendations.
   c. When first opening the control solutions or test strips, label the container(s) with the expiration date (EXP__) and the date opened (OPENED__). Control solutions and test strips are typically usable for 3 months after first opening or expiration date on

label; whichever comes first. *Always discard expired products.

d. Ensure supplies are room temperature. Store supplies in areas that have stable room temperature and do not have extreme hot or cold temperatures.

e. Gently swirl or invert control solution bottle to mix. Do not shake.

f. Remove one test strip from vial at a time. Close strip vial immediately after removing test strip. Use test strip quickly after removal from vial.

g. Follow manufacturer's instructions for quality control testing.

h. Record results on the glucometer quality control log. Report any QC failures to the Nursing Administrative Office RN Manager and record results and corrective actions on the shift report.

F. Patient Sampling

a. Identify the patient by using at least two patient identifiers –

i. Ask the patient to state his/her name and compare the name on the medication administration record (MAR), chart, photo, or order sheet.

ii. Ask the patient to state his/her birth date or medical record number and compare with the addressograph or face sheet information.

iii. Compare the individual photograph (found in the MAR and chart) with the patient

iv. Ask a staff who is familiar with the patient to verify his/her identification.

v. Follow Preparation section of this policy/procedure.

vi. Select fingertip. Clean area with soap/water and rinse or use an approved skin disinfectant (such as an alcohol wipe) to clean the area. Dry thoroughly.

vii. Lance finger.

viii. To help blood drop form, lower the hand to a level below the heart and gently massage the finger from palm to fingertip. Allow blood drop to form before attempting to apply to test strip. Apply sample per glucometer manufacturer instructions.

ix. Clean patient's finger and apply a band aid (bandage). Apply pressure as needed to stop bleeding.

x. Discard lancet into sharps container.

xi. Discard other used materials into trash receptacle that is out of patient reach.

xii. Doff gloves and perform proper hand hygiene.

b. Reporting Results

i. Normal blood glucose levels are:

1. Fasting 65-99 mg/dL
2. Two hours after meals, greater than or equal to 160 mg/dL

ii. Critical Results are equal to or below 60 mg/dL (low) and above 350 mg/dL (high) or as indicated by the provider based on individual patient condition or assessment. Comply with Critical Lab policy for reporting and documentation of all critical results.

c. Documentation

i. Test results shall be recorded on the MAR and critical results, or results associated with patient condition/symptoms shall be documented in the patient's chart, on shift report and NAO report. Patient assessment, new orders/interventions and patient condition following interventions shall also be recorded in the patient's chart and on shift report/NAO report.

ii. Comply with Hand-Off communication policy.

G. Glucometer Storage

   a. Glucometer must be stored in a dry, temperature-controlled location such as the medication or treatment room and must be covered for protection.

   b. Supplies must be kept in proximity to the glucometer.

H. Competency and Training

   a. Competency evaluation and training will occur in new employee orientation, annually and as needed.

References

The Joint Commission Waived Testing Standards/Chapter

Glucometer manufacturer instructions, recommendations for hospital-approved glucometers

CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities

SGHC Policy on Reporting Critical Values

SGHC Policy on Hand-Off Communication

SGHC Policy on Hand Hygiene

Approved by

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SPRING GROVE HOSPITAL CENTER

NURSING DEPARTMENT

NIGHTLY GLUCOMETER QUALITY CONTROL LOG

1. Perform quality control (QC) test every night shift using level 1 and level 2 control solutions per manufacturer recommendations.
2. If Level 1 and Level 2 QC results are out of range, enter comments and repeat QC test with Level 3 solution. Add comments on this log.
3. Report any QC failures to the NAO manager and the Clinic, and indicate the failures and corrective actions on the shift report.
4. Assure all opened glucometer strips and control solution containers are labeled with a date opened and expiration date. Cover dates with small piece of tape to prevent distortion of the date.
5. Clean the glucometer after each use, before storage and when visibly soiled per manufacturer recommendations using a disinfectant wipe.
6. Keep current month logs in a binder located near the glucometer and supplies. File prior month logs on the unit. Retain logs for six years.
7. Your signature and completion of this form indicates you have followed the above steps.

UNIT:	DATE	ACTUAL TIME	STRIP		LEVEL 1 SOLUTION		LEVEL 2 SOLUTION		LEVEL 3 SOLUTION		COMMENTS (on back if needed)	SIGNATURE	PRINT NAME LEGIBLY	RN or LPN
			EXP DATE	DATE OPENED	EXP DATE	PASS/ FAIL	EXP DATE	PASS/ FAIL	EXP DATE	PASS/ FAIL				
SUNDAY														
MONDAY														
TUESDAY														
WEDNESDAY														
THURSDAY														
FRIDAY														
SATURDAY														

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SPRING GROVE HOSPITAL CENTER
NURSING DEPARTMENT
WAIVED TESTING/GLUCOMETER COMPETENCY TEST: TEST VERSION A
(This test is to be completed in addition to the *glucometer skills competency and checklist*)

Obtain a Glucometer Competency Checklist from the instructor. Review the glucometer manufacturer instructions prior to your skills competency. Answer the following questions. A score of 90% is needed to pass.

Question	Circle one	
At SGHC, the glucometer quality control (QC) must be done at least every 24 hours on night shift.	TRUE	FALSE
Signs of hypoglycemia are: Fatigue, pale skin, sweating, hunger, shakiness.	TRUE	FALSE
A QC is necessary to determine if the glucometer is working properly.	TRUE	FALSE
All nursing licensed staff must maintain glucometer competency. I am responsible for my glucometer competency.	TRUE	FALSE
Normal fasting blood glucose is 150 mg/dL.	TRUE	FALSE
I must perform proper hand hygiene and don new gloves before each patient's fingerstick.	TRUE	FALSE
A single-use lancet is used for fingerstick and must be disposed of in a sharps container immediately after use.	TRUE	FALSE
Waived testing means that the testing is done at the point of care	TRUE	FALSE
The test strips and control solutions must be labeled with the date opened and the expiration date.	TRUE	FALSE
The glucometer must be cleaned with a disinfectant wipe before and after each use, and when soiled.	TRUE	FALSE

Score:_____

_____ _____
Licensed staff print name legibly AND signature Date

_____ _____
Instructor print name legibly AND signature Date

Comments:

DATE:_____ PRINT NAME LEGIBLY:_____

SPRING GROVE HOSPITAL CENTER
DEPARTMENT OF NURSING
MCKESSON TRUE METRIX PRO
PROFESSIONAL MONITORING BLOOD GLUCOSE METER
COMPETENCY CHECKLIST

PURPOSE: This competency checklist is to evaluate competency for all licensed nursing employees during orientation, yearly and whenever a refresher or remediation is indicated.

	PASS	FAIL	COMMENTS
GENERAL INFORMATION			
List signs and symptoms of hypoglycemia.			
List signs and symptoms of hyperglycemia.			
Read glucose meter instructions prior to use.			
Purchasing of supplies must be done through SGHC Procurement/Finance. If your unit needs more supplies, call the Clinic X7980.			
McKesson True Metrix Pro Professional Monitoring Blood Glucose Meter is a multiple patient use device for monitoring blood glucose.			
Follow manufacturer recommendations.			
Recognize buttons on the top of the glucose meter.			
Recognize features on the front & back of meter.			
Identify features on the full display screen.			
Only use auto-disabling single use lancets.			
Perform proper hand hygiene and don gloves prior each test, in between patients and if gloves are soiled or damaged.			
QUALITY CONTROL			
Quality Control tests must be performed: • Before using the system for the first time; • For practice to ensure testing technique is good; • When opening a new vial of test strips; • If results seem unusually high or low based on patient condition; • If a vial has been left opened or exposed to extreme heat, cold or humidity; • Nightly on night shift.			
Glucose meter will perform an automatic self-test each time a strip is inserted correctly into the Test Port.			
Only use McKesson True Metrix Pro Control Solutions for quality control tests – Level 1, Level 2, Level 3.			
Perform Control Tests with at least Level 1 & Level 2 of solution prior to using glucose meter for the first time.			
Identify the lot number, expiration date and control test range on **the test strip vial** label.			

DATE:_____ **PRINT NAME LEGIBLY:**_____

Date opened must be recorded on vial when vial is opened. *Discard 4 months after date opened or on date of expiration.			
Identify the lot number, expiration date and control solution level on **control solution** bottle label. Use at least two levels of control each time quality control testing is done. *Discard 3 months after date opened or on the expiration date.			
Do not use control solution or test strips that are expired.			
Make sure the control solution is room temperature.			
Gently swirl or invert control solution bottle to mix. DO NOT SHAKE!			
Remove one test strip from vial. Close test strip vial immediately. Use test strip quickly after removal from vial.			
Insert test strip into Test Port.			
Wait until Drop symbol appears in Display.			
With cap removed, turn control solution bottle upside down. Squeeze one drop of control solution onto clean tissue. Wipe off bottle tip and discard tissue.			
With the test strip in meter, touch edge of Sample Tip to top of drop of control solution. Allow drop to be drawn into test strip. Remove test strip from drop when meter beeps.			
Dashes appear across display to show meter is testing.			
Compare meter result to Control Test range printed on test strip vial label for level of control solution you are using. If result is in range, system can be used for testing blood. If result is not in range, repeat test using new strip and solution. Do not use meter if repeated results are out of range.			
After result is shown, Strip Release Button flashes. Hold meter with strip pointing down over trash can. Press Strip Release Button to release and discard test strip into trash can. Meter turns off.			
Doff gloves and perform proper hand hygiene.			
BLOOD GLUCOSE TESTING			
Fingertip Sampling: • Identify patient using two patient identifiers. • Select fingertip. • Clean area with soap and warm water or alcohol wipe. Dry thoroughly. • Lance finger. • Lower hand to a level below the heart and gently massage the finger from palm to fingertip. • Allow blood drop to form. • Insert test strip into Test Port. • Apply blood drop sample to Sample Tip. • Dashes appear across display to show meter is testing.			

DATE:_____ **PRINT NAME LEGIBLY:**_____

• Results will appear on Display. Record results. • Discard all used materials into trash can. • Doff gloves and perform proper hand hygiene.			
Forearm Sampling: • Check with patient's provider and obtain a provider order for forearm sampling. Results from forearm are not always the same as results from the finger. • Select area. Clean with soap and water or alcohol wipe. Dry thoroughly. • Rub area or apply warm, dry compress to increase blood flow. • Lance forearm. Apply sample to Sample Tip. • Discard all used materials in trash can. • Doff gloves and perform proper hand hygiene.			
CLEANING AND DISINFECTING			
Cleaning removes blood and dirt from the meter. Disinfecting removes infectious agents from the meter. Meter must be cleaned/disinfected immediately when visibly soiled AND between patients.			
Perform proper hand hygiene and don gloves prior to cleaning/disinfection.			
Make sure the meter is off and test strip is not inserted.			
Use ONLY PDI Super Sani Cloths to clean and disinfect the meter. Wipe entire outside of meter all sides using 3 circular wiping motions with moderate pressure on all sides, bottom, front & back. Repeat if needed until visible soil is gone.			
Let meter air dry thoroughly (at least 2 minutes dwell time) before using it to test.			
Ensure that no moisture or liquid enters the Test Port or any other opening on the meter.			
Discard used wipes in trash can.			

Employee Signature:_____

Instructor Signature:_____ **Date:**_____