

**I. PRINCIPLE:**

The test employs a dry reagent technology based on the glucose oxidase method that is specific for D-glucose. When a small drop of whole blood is applied to a SureStepPro test strip, glucose oxidase on the test strip triggers the oxidation of glucose in the blood sample. Gluconic acid and hydrogen peroxidase are produced as a result of this reaction. Peroxidase on the test strip then causes the hydrogen peroxide to react with dyes to produce a blue color in the presence of oxygen. This blue color is visible through the confirmation dot on the back of the test strip---the darker the blue, the higher the glucose level in the blood sample. SureStep brand blood glucose meters measure the color intensity of the confirmation dot and report a plasma-calibrated glucose result.

**II. SCOPE:**

This procedure is standardized for all associates/personnel who perform bedside glucose testing with the SureStep Flexx glucose meter. Personnel who have demonstrated competency by direct observation and by successfully completing the competency (skills) checklist and/or exam may perform the test.

**III. CLINICAL SIGNIFICANCE:**

The bedside glucose is a **waived**, definitive test that provides a quick, accurate, quantitative blood glucose result at the patient's bedside. The speed of the test performance allow for rapid intervention when a patient's blood glucose level is extremely elevated or decreased, especially for patients being treated with insulin.

**IV. SPECIMEN:****A. Patient/Specimen identification**

Refer to site positive patient identification policy.

**B. Specimen type**

1. Preferred sample is fresh, capillary whole blood from a fingertip or heel stick tested immediately upon collection.
1. Venous, arterial, or neonatal cord blood may also be used.
2. Venous and capillary blood may differ in glucose concentration by as much as 70 mg/dl, depending on the time of blood collection after food intake.
3. Anticoagulants such as heparin and EDTA may be used.
4. Do not use serum or plasma samples.
5. Do not use preservatives that contain fluoride (gray top tubes).

**C. Specimen collection**

1. Refer to site specimen collection policy.
2. The puncture site should be cleaned and thoroughly dried before obtaining the blood sample.
3. To increase blood flow to obtain a capillary specimen:
  - a. Non-neonate: Allow the hand to dangle and/or massage the finger to be used. The puncture should be made in the central, fleshy portion of the finger, slightly to the side of center and perpendicular to the whorls (grooves) of the fingerprint.
  - b. Neonates: pre-warm the heel by cupping the heel for several minutes, raising the head of the bed to increase blood flow via gravity when possible.

**D. Specimen handling**

1. If using fresh whole blood in the absence of an anticoagulant, test immediately to prevent clotting from affecting the results.
1. When whole blood from a tube is used, the tube must be well mixed before testing.
2. Test the anticoagulated blood sample as close as possible to the time the sample was collected.
3. The test should be performed within 10 to 15 minutes to minimize the effect of glycolysis; the blood glucose concentration decreases over time because red blood cells continue to consume glucose.

**V. MATERIALS:**

- A. SureStep Flexx glucose meter
- B. Disposable sterile lancets
- C. Disposable gloves
- D. Alcohol wipes
- E. Disinfectant wipes
- F. AA Batteries
- G. SureStepPro test strips

1. Test strip vials must be labeled with the date opened (at a minimum).

2. Expiration date is 4 months after opening or manufacturer's printed expiration date, whichever comes first. Do not use after expiration date.
3. Test strips must be kept in tightly capped bottle and used **immediately** once removed from the bottle. Contact of test strips with light and moisture may cause inaccurate results.
4. Store test strips in original containers, in a cool, dry place below 30 degrees Centigrade (C) or 86 degrees Fahrenheit (F). Keep away from heat and direct sunlight. Do not refrigerate or freeze.

#### VI. CALIBRATION:

- A. Operators must enter the correct test strip lot number for each new test by matching the lot number on the test strip vial to the lot number displayed on the LCD screen.
- B. Test strip lot numbers with their corresponding code numbers are programmed into the Flexx Blood Glucose Meters through the workstation by the POCT personnel. The bedside glucose meters are calibrated by the use of lot specific test strips.

#### VII. QUALITY CONTROL:

**One High and one Low level of Quality Control must be performed and within acceptable range each 24 hours a meter is in use.**

##### A. Daily Cleaning and Disinfecting Procedure

1. Follow Standard Precautions including the use of gloves.
2. Wipe the surface of the meter with a hospital approved disinfectant at least once every 24 hours and whenever the meter appears soiled.
3. Caution - Do not use alcohol, glass cleaners, or any cleansers containing abrasives, phenol, or ammonia to clean the test strip holder and lens area.
4. Caution – Do not use anything abrasive e.g. paper towels to dry the meter. If residue from the disinfectant wipe remains on the LCD screen and barcode scanner, wipe with tissue slightly dampened with water.
4. Caution – Do not get water inside the unit. Never immerse the unit or hold it under running water.
5. To document that the meter has been disinfected, select appropriate comment, "DISINFECTED Mtr" on "Enter Notes" screen when performing high or low control to document that meter has been disinfected.

**B. Quality Control (QC) Material**

1. High glucose control solution and low glucose control solution.
2. Reagent requirements:
  - a. QC solutions must be labeled with an expiration date.
  - b. Expiration date is 90 days after vial is opened or manufacturer's printed expiration date, whichever comes first. Do not use after expiration date.
  - c. Store control solution in original container below 30 degrees C / 86 degrees F. Do not refrigerate or freeze.

**C. Quality Control Testing Procedure**

1. Follow Standard Precautions including the use of gloves.
2. Turn on the meter.
3. Check the battery status to ensure adequate power. Press "Cont" to continue.
4. Select QC Test from the Main Menu by touching the screen over the words "QC Test".
5. Scan (preferred, where possible) or enter your operator ID (payroll number/employee ID number).
6. Select either high or low control level.
7. Select the QC lot number on the screen that corresponds to the lot number on the QC vial.
8. Select the test strip lot number on the screen that corresponds to the lot number on the test strip vial.
9. Shake the control solution vial. Apply one drop of control solution to the pink test square on test strip being careful not to overdose strip. If white pad becomes completely saturated, you have applied too much control (overdosed). Check the confirmation dot on the back of the test strip to ensure appropriate application.
10. Wipe the control solution tip with a lint-free cloth before replacing the cap.
11. Insert the test strip into the test strip holder within 2 minutes of applying control solution. Push the strip until it comes to a complete stop.
12. The result appears on the bedside unit LCD in approximately 30 seconds.

*Uncontrolled when printed*

- a. If the result is "PASSED", press Enter Notes, select "DISINFECTED Mtr" and press OK.
- b. If the result is "FAILED", press Enter Notes and choose the appropriate comment(s) to document your corrective action:
  - (1) Procedure Error
  - (2) Shook Control
  - (3) Repeated Ctrl
  - (4) Used New Ctrl
  - (5) New Strip Vial
- c. Then press OK and repeat the QC test.

13. Repeat the above steps until you pass both the high and low QC tests. Press the "Menu" button to return to main menu.

**D. Quality Control Limitations**

1. Applying too much or too little control solution to the test strip may cause inaccurate results.
2. You must use SureStepPro Glucose Control solutions only.
3. You must select correct control and test strip lot numbers.

**E. Quality Control Procedural Notes**

1. Test results outside the acceptable range must be repeated.
2. Meter cannot be used for patient testing until both control solutions falls within acceptable range as set by manufacturer.
3. Test results outside the acceptable range may indicate:
  - a. expired, contaminated or inadequately mixed glucose control solution
  - b. incorrect test strip lot number entered in the meter
  - c. debris in the lens area and test strip holder
  - d. expired, deteriorated or damaged test strip
  - e. meter malfunction
  - f. procedure error
  - g. control solution tested outside the system temperature range

*Uncontrolled when printed*

(18 – 30 degrees Centigrade / 64 – 86 degrees Fahrenheit)

4. Discard controls 3 months after opening.
5. Do not use controls after manufacturer's shelf life expiration date printed on vial.

#### VIII. PATIENT TESTING PROCEDURE:

- A. *Test is only to be performed with physician's orders or per hospital policy. These may include standing orders for appropriate response to patients displaying clinical signs of hypo- or hyperglycemia.*
- B. Follow Standard Precautions including the use of gloves.
- C. For isolation patients, please see site-specific policies.
- D. Verify positive patient identification according to site policy.
- E. Turn the meter on and check the battery status to ensure adequate power. Press CONT. Perform QC testing if indicated.
- F. Select Patient Test from the Main Menu.
- G. Scan (preferred where possible) or enter your operator ID number.
- H. Scan (preferred where possible) or enter the patient's ID number.
- I. Refer to Section XIV, #1 for alpha entry for patient ID.
- J. Select test strip lot number on the screen that corresponds to the lot number on the test strip vial.
- K. Select and clean puncture site according to site policy. Perform fingerstick/heelstick according to site policy.
- L. Apply the blood to the test strip:
  1. Touch pink test square of test strip to the drop of blood.
  2. Blood may be absorbed into the white pads, but the white pads should not be completely saturated. In this case the strip would be overdosed and the meter may give an inaccurate result. **Caution: Avoid applying too much blood when using a syringe.**
  3. Check the test strip confirmation dot on the back of the test strip to ensure it is completely blue. If white patches or streaks are visible, you have not applied enough blood for an accurate test. Repeat application with a new test strip.

- M. Insert the test strip into the test strip holder within 2 minutes of applying blood to strip. (The black tip of the test strip should be facing down). Push the strip until it comes to a complete stop. If you insert the test strip after 2 minutes, you may get an error code or inaccurate results. Discard test strip and repeat using a new test strip.
- N. The result appears on the bedside meter LCD in approximately 30 seconds.
- O. If a critical result is obtained (Adult critical values are less than 50 mg/dL or greater than 450 mg/dL. See Section XI, C in this policy for infant critical values), you must press Enter Notes and choose one of the following comments as appropriate:
1. Notified RN
  2. Notified MD
- Additional comments that apply to the patient's current situation and treatment given (up to 2) may be chosen.
- P. Discard the test strip according to site policy. Discard used lancet in appropriate sharps container.
- Q. *For electronic charting, the meter should be downloaded to allow for interfacing of patient's results to chart. For areas with manual charting, results should be documented appropriately.*

**IX. CALCULATIONS:**

N/A

**X. INTERPRETATION OF SUBJECTIVE RESULTS:**

N/A

**XI. REPORTING RESULTS:**

**A. Reference Ranges (fasting)**

1. Male and Female according to age:
  - a. 7 Days and older: 65-99 mg/dL
  - b. 5 Days up to 7 Days 60-110 mg/dL
  - c. 2 Days up to 5 Days: 45-100 mg/dL
  - d. Newborn up to 2 Days: 40-100 mg/dL
2. Use caution when interpreting neonatal blood glucose results that are less than 50 mg/dL.

- B. Questionable Results (results not within expected range or not matching patient's clinical picture) Troubleshooting steps may include:
1. Verify that correct lot number of test strip was selected.
  2. Repeat test.
  3. Repeat QC.
  4. Send a sample to laboratory for confirmation.
  5. Follow POCT "Protocol for Questionable Results" if the laboratory result does not confirm bedside glucose result. Contact POCC/Lab for evaluation as soon as possible or send form to POCC as soon as possible.
- C. **Critical Values**
1. 28 Days and older: Glucose less than 50 mg/dL or greater than 450 mg/dL.
  2. 2 Days up to 28 Days: Glucose less than 45 mg/dL or greater than 200 mg/dL.
  3. Newborn up to 2 Days: Glucose less than 40 mg/dL or greater than 200 mg/dL.
  4. If a patient's bedside glucose result is in the critical range, select an appropriate documentation comment or document per site policy.
  5. The RN and/or physician should be notified and the appropriate steps to monitor the patient and provide medical treatment should be initiated per site nursing policy. Repeat testing and laboratory confirmation is as dictated by site policy.
- D. **Charting Results**
1. Results must be recorded in the patient's permanent record. For sites with an electronic medical record and laboratory interface, this charting occurs when glucose meters are downloaded and results with a valid patient ID are interfaced to the electronic medical record.
  2. For sites without glucose meter interfacing ability, results should be manually charted per site policy.
- E. **Reportable Ranges**
1. The Reportable Range is 0-500mg/dL. Results greater than (>) 500 mg/dL will read as "HIGH" in the meter and are reported as >500 in the electronic medical record or documented greater than 500 mg/dL on the paper chart.
  1. Verification of results low results or greater than 500 mg/dL with a laboratory glucose test is determined by site policy.
  2. Neonatal (infants 0 to 28 days old) reportable range: The reportable range for neonatal samples is 0-200 mg/dL with hematocrit range of 25% to 65%. Results outside these glucose and hematocrit ranges may be inaccurate.

3. If neonatal values are unexpected, inconsistent, or if repetitive errors occur, obtain a laboratory blood glucose test result.
4. For non-neonates, a laboratory glucose is recommended if the hematocrit is outside of the 25% to 60% range.

**F. Transmitting Data**

Patient results are transmitted via modem, serial server, or Datalink Sync depending on site. All glucose meters must be downloaded according to site policy.

**G. Interfaced Results**

1. Only bedside glucose results with a valid medical record number are sent to the Hospital Information System for sites with a bedside glucose interface to the Laboratory Information System.
2. **Procedure Error:** ALL results entered with a valid medical record number will become part of the permanent record **unless** the comment "Procedure Error" is selected from the comment screen immediately following the result.
3. See site specific policy for any additional comments affecting interfacing of results.

**XII. LIMITATIONS:**

- A. Venous and Capillary blood may differ in glucose concentration by as much as 70 mg/dL, depending on time of blood collection after food intake. Shock, administration of vasoactive agents, and other factors affecting peripheral circulation such as Raynaud's disease may also cause discrepancies between venous and capillary glucose results and may limit the use of finger stick blood for those patients.
- B. When a syringe is used to dose the test strip with arterial or venous blood, care should be taken not to overdose the test strip that may cause inaccurate readings.
- C. Use only fresh whole blood, do not use serum or plasma. Anticoagulants such as heparin or EDTA may be used. Do not use preservatives that contain fluoride (gray top tubes).
- D. Use an adequate amount of blood to cover the pink test square.
  1. Too much blood may give inaccurate, high results. If the entire white pad is saturated with blood, you have applied too much. Repeat the application with new test strip and apply a smaller drop of blood.
  2. Too little blood may give inaccurate, low results. If the confirmation dot on the back of the test strip is not completely blue, and shows white lines or streaks, you have underdosed the strip. Repeat the application with a new test strip and apply a larger drop of blood.

- E. Extremes in hematocrit can affect test results. High hematocrits (>60%) and low hematocrits (<25%) on non-neonatal samples can cause inaccurate results; neonatal hematocrit range is 25-65%. Results >200mg/dL may be inaccurate for neonates. (In these situations, a laboratory blood glucose test is recommended.)
- F. Excessive water loss or dehydration may cause inaccurate, low results.
- G. Highly lipemic blood samples (up to 3000 mg/dL triglycerides) have no significant effect on results.
- H. Contraindications to capillary blood specimen collection include:
  - 1. Do not collect from the hand of an arm on the side where a lymph node dissection has been performed.
  - 2. Do not collect from a hand where cyanosis or infection is present.
  - 3. Preferably, do not collect if patient has an abnormal hematocrit level for their age.
- I. Testing outside operating temperature of 18-30 degrees C (64-86 degrees F) and operating relative humidity of 30-70% may cause inaccurate results.
- J. Interfering substances:
  - 1. L-Dopa >20 mg/dL
  - 2. Dopamine >6 mg/dL
  - 3. Gentissic Acid >10ng/dL
  - 4. Mannitol >5000 micrograms/dL
  - 5. Vitamin C has no effect up to 3 mg/dL
  - 6. Bilirubin has no effect up to 20 mg/dL. For patients with bilirubin levels higher than 20 mg/dL, a laboratory draw is recommended.
  - 7. Low oxygen content of sample (for example, venous blood), low hematocrit (near 25%) and high glucose (greater than 200 mg/dL) may cause inaccurate results.

### **XIII. ATTACHMENTS:**

Lifescan SureStep Flexx Training Checklist Template

### **XIV. REFERENCES:**

- A. SureStep Flexx Meter Operator Guide. LifeScan Inc.; 10/2002.
- B. SureStep Pro Test Strip Package Insert; LifeScan Inc.; Rev. 1/2004

- C. SureStep Pro Glucose Control Solutions (Low & High) package insert. Lifescan, Inc. Milipitas, CA 95035 1/2003
- D. LifeScan Datalink System Administrator's Guide 4/2000.
- E. McCall RE, Tankersley, CM Phlebotomy Essentials, Lipincott, Williams & Wilkins, 2003: 341,345.

**XV. PROCEDURAL NOTES:**

**A. Patient sample identification by alpha entry (as determined by site and location):**

1. On the "Enter Patient ID" screen, press the alpha/numeric key with desired letter.
2. The number on that key is automatically selected, and the corresponding letters will appear on the right.
3. You must press the desired letter then to select it and it will replace the original number.
4. Continue in this manner until alpha entry is complete, and then press OK.
6. Patient samples entered with alpha format will not be sent to the Laboratory Information System or the electronic medical record.

**B. Batteries:**

1. The meter is powered by 3 AA alkaline batteries.
2. If the battery bar on the main screen appears low, the "Scan" button disappears, the meter has difficulty downloading, or a "Low Battery" message appears, all three batteries should be changed.
3. To change the batteries, turn the meter off and turn the meter over. Press down on the battery door latch and lift open the door. Remove the old batteries and replace with new, taking care to match the + end of each battery with the + sign inside the battery compartment. Replace cover.
4. There is a lithium battery in each meter that powers the internal clock and maintains data. If you receive a "Lithium Battery Low" message, please contact the Laboratory/Point of Care for meter replacement.

**C. Troubleshooting-Please note: Take appropriate steps to monitor the patient and provide medical care while resolving any issues.**

1. Error Codes: Refer to Lifescan Quick Reference Guide for a brief listing of error codes and solutions or contact Point of Care/Laboratory.

2. Cleaning the Test Strip Holder and Lens (Error 5 Optics):
  - a. Press down on the left side of the blue test strip holder and slide it to the right.
  - b. Clean the test strip holder and lens area (being careful not to scratch the lens area) with a 10 percent bleach solution. Follow this by wiping area with a cotton swab or tissue dampened with water. Dry both areas thoroughly with a lint free cloth. Be sure this area is clean.
  - c. Slide the test strip holder back into the meter until you hear it CLICK into place. If you receive a Kernel error--Self Tests failed message when the meter is powered on, the test strip holder is not seated properly.
3. Lifescan's 24 hour Service number is 800-524-7226.

# Lifescan SureStep Flexx Training Checklist

Employee \_\_\_\_\_ Date \_\_\_\_\_

(print and sign name)

Employee number \_\_\_\_\_ Unit \_\_\_\_\_

Instructor signature \_\_\_\_\_ Date \_\_\_\_\_

## Operator has completed and demonstrated knowledge of the following:

- \_\_\_\_\_ **A. Read procedure (POCT172, located in ACL POC Testing Procedure Manual)**
- \_\_\_\_\_ **B. Specimen**
1. Fresh, capillary whole blood from a fingertip or heel stick which is tested immediately
  2. Venous, arterial, or cord blood with heparin or EDTA as the anticoagulant
  3. Do **not** use serum or plasma samples, or blood collected in tubes containing fluoride (gray-top tubes)
- \_\_\_\_\_ **C. Materials**
1. **BEDSIDE METER** : Identifies the location of the following:
    - a. ON/OFF button
    - b. LCD touch screen
    - c. Battery Compartment (holds 3 size AA batteries)
    - d. Laser barcode scanner (never point towards eyes)
    - e. Test strip holder
  2. **TEST STRIPS**:  
Properly labels bottle with open date (expire 4 months after opening)
  3. **CONTROLS**:  
Properly labels control vials with open date (expire 3 months after opening)
- ADDITIONAL INFORMATION:**
- Only strip lots and control lots that have been tested by the laboratory are approved for your use.
  - If the strip lot or control lot is not listed in your meter, you must upload your meters so that the information for the new lot can be downloaded to the meter.
  - The accuracy of the test is dependent on your selecting the correct lot number for controls and test strips being used.
  - On occasion, there may be more approved lots of a control or test strip than can fit on the screen. If there is an arrow in the lower right hand portion of the screen, that means that there is another page of information.
- \_\_\_\_\_ **D. Infection Control**
1. Follows all standard precautions including use of gloves when working with bedside meter.
  2. Prior to contact with patient, cleanses hands with ETOH hand gel or with soap and water for 20-30 seconds.
  3. Bedside meter not to be in contact with patient.
  4. Meter and tote should **not** be taken in to contact isolation rooms. If they are, they should be disinfected with hospital-approved disinfectant upon leaving room.
  5. Transports bedside meter in tote.
  6. Demonstrates knowledge of proper procedure for disposal of all puncture equipment in sharps container
- \_\_\_\_\_ **E. Cleaning**
1. Wipes the surface of the meter and tote with a hospital-approved disinfectant at least once every 24 hours and whenever the meter or tote appears soiled.
  2. Documents that the meter has been disinfected by choosing "Disinfected Mtr" on the Enter Notes screen when performing the high or low control
  3. Error 5 Optics Message indicates that the test strip holder and optics need to be cleaned. **Carefully** clean test strip holder, contact points and lens area with a swab or soft cloth dampened with a 10% bleach solution, followed by water to remove residual bleach.  
Dry with a clean, soft, lint-free tissue.
- \_\_\_\_\_ **F. Quality Control**
1. 2 levels run every 24 hours, high and low
  2. Selects QC TEST from Main Menu.

# Lifescan SureStep Flexx Training Checklist

3. Scans (preferred method) or enters operator ID (payroll number).
4. Selects control level, verifies expiration date, chooses correct control lot # and test strip lot # from screen.
5. Shakes the control solution bottle prior to applying drop to test strip.
6. For any failed control, presses "Enter Notes", selects the appropriate corrective action comment and repeats failed control

## \_\_\_\_\_ G. Patient Test Procedure

1. Understands and follows proper patient identification procedures.
2. Demonstrates ability to assemble all appropriate equipment for blood sample collection.
3. Cleanses puncture site using appropriate cleansing product.
4. Obtains blood sample using appropriate age-specific lancet device following site-specific blood collection techniques
5. Applies adequate sample to pink test square area
6. Ensures confirmation dot on back of strip is completely blue
7. Does not saturate the entire white pad
8. Selects PATIENT TEST from Main Menu.
9. Scans (preferred method) or enters operator ID (payroll number).
10. Scans (preferred method) or enters patient ID (MR#).
11. Verifies expiration date of test strips and selects test strip lot # that corresponds to the lot number on the test strip bottle.
12. Inserts strip firmly into the test strip holder, blood side up, within 2 minutes of sample application

## \_\_\_\_\_ H. Reporting Results

1. Confirms any unusual or unexpected result with repeat on bedside unit or with laboratory testing
2. Records results in patient's chart. (If applicable, results cross to electronic medical record once meter is downloaded.)
3. **Reportable ranges:**
  - 0-500 mg/dL "HIGH" reported as >500 mg/dL
  - **Neonatal (0-28 days)** 0-200mg/dL
4. **Fasting reference ranges based on patient population:**
  - **Age 7days and older:** 65-99 mg/dL
  - **Age 5 days up to 7 days:** 60-110 mg/dL
  - **Age 2 days up to 5 days:** 45-110 mg/dl
  - **Age Newborn up to 2 days:** 40-100 mg/dL
5. **Critical values based on patient population:**
  - **Age 28 days and up:** less than 50 mg/dL or greater than 450 mg/dL.
  - **Age 2 days up to 28 days:** less than 45 mg/dL or greater than 200mg/dL
  - **Age 0 up to 2 days:** less than 40 mg/dL or greater than 200 mg/dl
  - a. **Presses "Enter Notes" and selects comment to document next action.**
  - b. **Communicates critical results to the appropriate person**

## \_\_\_\_\_ I. Limitations (causes of possible inaccurate results)

1. Improper dosing of test strips.
2. Test strip bottle not tightly capped.
3. Extremes in hematocrit of patient
  - a. low hematocrit <25%
  - b. high hematocrit >60% (>65%for neonates)
4. Severe vomiting or diarrhea/edematous patients.
5. For patients with bilirubin levels higher than 20 mg/dL, a laboratory draw for glucose is recommended.

## \_\_\_\_\_ J. OPTIONAL: RESPONSIBILITIES OF THE KEY OPERATORS AND/OR TRAINERS ONLY:

1. Ensure all quality control is performed according to specifications.
2. Review and initial all quality control reports as required
3. Ensure all reagents are properly dated and stored.
4. Assist in keeping a record of all certified operators and assuring competency assessment is completed.