



PROCEDURE # 945.8021

BLOOD GLUCOSE USING SURE STEP FLEXX

PREPARED BY	DATE ADOPTED	SUPERSEDES PROCEDURE #
Janet Swaim	March, 2004	POC-1

REVIEW DATE	REVISION DATE	SIGNATURE

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PRINCIPLE:

A small drop of blood is applied to SureStep Pro Test Strip. A glucose oxidase reaction occurs between the blood and reagents in the test strip resulting in the formation of a blue color. This 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. When the test strip is inserted into the SureStep Flexx, the meter measures the color intensity and reports a plasma-calibrated glucose result.

OPERATORS:

Registered Nurses, Licensed Practical Nurses, Student Nurses, Student Nurse Extern, Nursing Assistants, Emergency Room and Cardiac Cath Lab Technicians who are properly trained on the SureStep Flexx blood glucose testing system perform the procedure.

All personnel must demonstrate their proficiency in performing Quality Control and patient testing activity in the annual skills lab competency or peer review. New employees will have their competency assessed six months after initial competency and annually thereafter.

SPECIMEN:

Patient Preparation:

None required.

Type:

Fresh whole blood—capillary, venous, arterial or neonatal blood is used. Venous and capillary blood may differ in a glucose concentration by as much as 70 mg/dL, depending on the time of blood collection after food intake. Shock, administration of vasoactive agents, and other factors affecting the peripheral circulation may also cause discrepancies between venous and capillary glucose results. Do not use serum or plasma samples. Blood samples in anticoagulants and preservatives (heparin and EDTA) may be used. Do not use preservatives that contain fluoride (gray top tubes).

Collection:

A. Patient Identification/Preparation:

1. Patient is identified using their identification band to verify name and date of birth.
2. If a patient without known identity is tested, the results are kept with the chart and identifying information is recorded once information is obtained.
3. Patient preparation—none required.

B. Fingerstick and Heelstick:

1. Collect the capillary blood using a lancing device and an appropriate technique.
2. Avoid squeezing the puncture site excessively.
3. Apply the drop of blood directly to the pink test square on the test strip.
4. Check the confirmation dot on the back to ensure it is completely blue.

C. Venous Blood Sample:

1. Blood samples in anticoagulants and preservatives (heparin, EDTA) may be used. Do not use preservatives that contain fluoride (gray top tubes).
2. When whole blood in a test tube is used, care should be taken to uniformly distribute red cells throughout the tube before testing. This can be accomplished by gently inverting the capped tube.
3. Apply the drop of blood directly to the pink test square on the test strip.



4. Check the confirmation dot on the back to ensure it is completely blue.

D. Arterial Blood Sample:

1. Clear the arterial line before drawing a blood sample into a syringe that contains sodium or lithium heparin.
2. If the sample is placed on ice, let it reach room temperature before performing the test. Use the sample within 30 minutes of collection.
3. Mix the syringe several times immediately before applying the sample to the target area on the test strip.
4. Allow a drop of blood to form at the tip of the syringe.
5. Apply the drop of blood directly to the pink test square on the test strip.
6. Check the confirmation dot on the back to ensure it is completely blue.

Handling Conditions:

Fingerstick specimens are tested immediately. Test the venous and arterial blood sample as close as possible to the time the sample was collected. The test is performed within 30 minutes of sample collection to minimize glycolysis. The blood glucose concentration decreases over time because red blood cells continue to consume glucose. If using fresh whole blood in the absence of an anticoagulant, test immediately to prevent clotting from affecting the results. When whole blood in a test tube is used, care should be taken to uniformly distribute red cells throughout the tube before testing. This can be accomplished by gently inverting the capped tube.

EQUIPMENT AND MATERIALS

Equipment:

1. SureStep Flexx meter and operator's guide.
2. DataLink Blood Glucose Management System software.

Materials:

1. SureStep Pro Test Strips.
2. SureStep Pro High and Low Glucose Control Solutions.

Reagent Strip Handling/Storage Requirements:

1. Assignment of new expiration date: All reagent test strip files used through the health system are initially delivered to the Torresdale Campus. The manufacturer's stated expiration date listed on the vial will be crossed out, and the container will be relabeled by lab personnel with a new expiration date of four months from the date of receipt. [Experience dictates that the vast majority of test strips will be utilized within 1-2 months of receipt on the testing unit. The practice of relabeling with a new expiration date (regardless of the date opened) will ensure compliance with manufacturer instructions and regulatory agencies.]
2. Do not use any reagent strips beyond the new expiration date indicated on the Aria Health affixed label.
3. Store test strips tightly capped in their original bottle in a cool, dry place below 30° C (86° F). Keep away from heat and direct sunlight. Do not refrigerate or freeze.

Liquid Control and Linearity Handling/Storage Requirements:

1. Store control and linearity solutions below 30° C. Do not refrigerate or freeze.
2. QC material is stored in the instrument case. The Laboratory Point of Care Testing Coordinator or designee will replace the QC material every 90 days to be in compliance with manufacturer's instructions and regulatory agency requirements. In no instance will QC or linearity material be used beyond the printed expiration date on the vial label.



3. Linearity testing is performed by the central laboratory. When opening a new bottle of linearity solution, the container will be relabeled with a new expiration date 90 days from the date of opening.

QUALITY CONTROL:

SureStep Pro Low and High Glucose Control Solutions are used to check the SureStep Flexx blood glucose monitoring system performance:

1. Low and High controls are run once per 24 hours. On units that do not use the meter on a daily basis, quality control must be run prior to patient testing. Controls are also be run if the meter is dropped and to troubleshoot the system.
2. Valid results depend on the correct test strip lot number (and corresponding code) being correctly entered in the meter. Results that fall within the range, when testing in the meter's QC Test mode are indicated by PASSED on the meter display. Results that are not within the range are indicated by FAILED.
3. Control solution test results must fall within the ranges programmed into the meter to verify that the system is working properly and the correct test procedure is followed. If control solution test results fall outside the expected range, repeat the test. The meter will not allow patient testing to occur until the control solution results fall within the expected range. Results that fall outside the expected range may indicate:
 - Procedural error.
 - Old or contaminated glucose control solution.
 - Incorrect lot number or code number entered in the meter.
 - Debris in the lens area and test strip holder.
 - Test strip deterioration.
 - Meter malfunction.
 - Control solution outside the 15^o - 35^o C functional temperature range.

PROCEDURE:

SureStep Flexx Meter:

1. Turn on the meter.
2. Check the battery status for adequate power. Press Cont.
3. Select QC Test from the Main Menu.
4. Select the Low control.
5. Enter your operator ID.
6. Select the test lot number from the list displayed.
7. Gently shake the control solution vial. Apply one drop of control solution to the pink test square on the test strip. Check the confirmation dot on the back of the test strip to ensure it is completely blue.
8. Insert the test strip into the test strip holder within 2 minutes of applying control solution. Firmly push the strip until it comes to a complete stop.
9. The result appears in approximately 30 seconds.
10. If PASSED appears, repeat above for high control. If FAILED appears, enter a comment and repeat testing.
11. Remove and dispose of test strip.

TROUBLESHOOTING FOR OUT OF RANGE QC:

1. Check that the appropriate level was run.



2. Check that the vial of control is not expired.
3. Check that the correct test strip lot number and corresponding code are correctly entered in the meter.
4. Open a new set of controls.
5. Repeat the out of range control. If it is acceptable, proceed with testing, if not, discontinue testing and obtain a new meter from the Lab. Call 2-4536 and leave a message for the Point of Care Testing Coordinator.

QUALITY CONTROL COMMENT CODES:

1. Procedure error.
2. Repeated test.
3. Shook control.
4. Wiped vial tip.
5. Used new control.
6. Cleaned meter.
7. Matched code.

PROCEDURE—STEPWISE:

1. Turn on the meter.
2. Check the battery status for adequate power. Press Cont.
3. Select Patient Test from the main menu.
4. Enter your operator ID.
5. Enter the patient's medical record number. If a medical record number has not been assigned, use the patient's name. When you press an alphanumeric key, the letters associated with that key will be displayed along the right side of the keypad. Choose the correct letter from the right hand display.
For example, to select W:
 - a. Press the 9 key. [9 is selected and W, X, Y, Z appear to the right].
 - b. Press the W key at the right [W replaces the 9].Press OK when you have completed the entire entry. To delete the last character(s) entered, press DEL.
6. Select the test strip lot number from the list displayed.
7. Apply blood to the test strip by carefully touching the pink test square on the test strip to the drop of blood. Check the confirmation dot on the back of the test strip to ensure it is completely blue.
8. Insert the test strip into the test strip holder within 2 minutes of applying blood. Firmly push the strip until it comes to a complete stop.
9. The result appears in approximately 30 seconds.
 - Press Menu to continue testing.
 - Or press Enter Note and choose one to three comments that correspond to the patient's current situation. Press OK.
 - When a result falls within the critical range, you will be prompted to enter a comment code. Critical low or critical high will be displayed beneath the result. Press the enter note box displayed on the lower right corner of the screen. On the next screen choose the appropriate comment. **If you do not want the result to cross the interface into the computer, choose the procedure err comment at the top of the list.**
10. Remove the test strip and dispose of in a biohazard container.

REPORTING RESULTS:

Reference Ranges:

Blood glucose levels for people without diabetes are as follows:



Adults:	70-110 mg/dL		
1 year-18 years	Male 56-145	Female	56-144
1 week-1 year	Male 70-123	Female	55-114
Neonates	30-60 mg/dL (Ref #5)		

The color chart on the test strip vial label shows the approximate color of a test strip confirmation dot for 50 mg/dL and 350 mg/dL results. You may check your meter result by comparing the test strip confirmation dot to the colors on the color chart. If the color chart and test result are clearly inconsistent, perform another test and/or confirm with an alternate test. Do not use the color chart as a replacement for a meter result.

Results:

Results beyond linearity require laboratory verification. A fresh venous sample should be sent to the central laboratory when SureStep Flexx result:

- Is more than 500 mg/dL.
- Does not agree with clinical impression.

Critical values of < 50 mg/dL and > 400 mg/dL must be resultated with an appropriate comment code.

Patient Comment Codes:

1. Procedure error
2. Notified RN/MD.
3. Repeated test.
4. Entered note.
5. Lab confirmation.
6. Treated patient.

On a semi-annual basis, the Point of Care Coordinator will randomly compare the glucose results of ten patients done on the SureStep Flexx to the results of these ten patients run on analyzers in the central laboratory. If a difference of greater than 10% is noted, there will be an investigation and corrective action will be taken.

Procedure Notes:

1. For in vitro diagnostic use.
2. Use SureStep Pro Test Strips with SureStep brand blood glucose meters only.
3. The confirmation dot of an unused test strip is off-white. Do not use a test strip if the confirmation dot is discolored. A color chart on the test strip bottle label shows the color of an unused test strip's confirmation dot.
4. Use test strips before the expiration date printed on the test strip bottle label.
5. You have up to 2 minutes to insert the test strip after applying blood.
6. If the patient is experiencing symptoms which are not consistent with the blood glucose result obtained and you have followed the test procedure as described in this procedure, consult with a physician for treating the symptoms and confirm the blood glucose results with a laboratory test.

LIMITATIONS OF THE PROCEDURE:

1. Use only fresh whole blood. Do not use serum or plasma.
2. Use an adequate amount of blood—just enough to cover the pink test square.



- Too much blood may cause false high results. If the entire white pad is saturated with blood, you have applied too much blood. Repeat the application with a new test strip and apply a smaller drop of blood.
 - Too little blood may cause false low results. If the confirmation dot on the back of the test strip is not completely blue but shows patches of white, you have not applied enough blood. Repeat the application with a new test strip and apply a larger drop of blood.
3. Extremes in hematocrit can affect test results. Extremely high (above 60%) and low (below 25%) hematocrits (non-neonatal samples) can cause false results. At low hematocrits test results can, on average, be higher than those obtained with reference methods; while at high hematocrits test results can, on average, be lower than reference methods.
 4. Blood glucose results obtained with SureStep Pro Test Strips may be affected if excessive water loss or dehydration occurs. Severe dehydration can lead to many serious medical complications. One complication which is of particular importance in diabetes management is a hyperglycemic-hyperosmolar state, with or without ketosis, which may be life-threatening if left untreated.
 5. Whenever inadequate fluid intake or excessive water loss occurs, results may be affected.
 6. Do not use blood collection tubes containing fluoride. Sodium fluoride interferes with test results.
 7. Highly lipemic (fatty) blood samples up to 3000 mg/dL triglycerides have no significant effect on results.
 8. Ascorbic acid, at concentrations up to 3 mg/dL, has no significant effect on results.

Linearity

1. The Flexx meter is linear from 0-500 mg/dl. Aria Health reports any glucose below 10 mg/dl as less than 10 mg/dl.

Additional Precautions for Neonatal Testing:

1. All abnormal neonatal values should be confirmed by a clinical laboratory test method. All neonates exhibiting hypoglycemic symptoms, regardless of blood glucose monitoring results, should have their glucose tested by a clinical laboratory test method.
2. Use caution when interpreting neonatal blood glucose results which are less than 50 mg/dL.

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14. SureStep Pro Test Strips package insert.
15. SureStep Pro Glucose Control Solutions (High, Low, Normal) package insert.
16. SureStep Pro Linearity Test Kit package insert.
17. DataLink System Administrator's Guide.



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