SureStepPro

Professional Blood Glucose Management System

Technical Bulletin

Number: 054-867A
Date Prepared: 6/97

Accuracy and Precision

Purpose

This technical bulletin is intended to provide basic protocols for assessing the accuracy and precision of the SureStepPro Professional Blood Glucose Management System and the SureStep Blood Glucose Monitoring System.

Overview

The accuracy of a blood glucose measurement system is the degree to which its results agree with the "true" glucose concentrations of samples over a wide range of concentrations. Since the concept of "true" glucose concentration is hypothetical, it is operationally defined as the samples' blood glucose concentrations when measured with a laboratory reference instrument.

Precision (often referred to as "reproducibility") is the extent to which tests performed on the same sample(s) with the same blood glucose monitoring system (bedside unit or meter, test strips, control solutions) agree with one another. The smaller the variation between results, the higher the precision of that system.

Factors to Consider in Conducting Blood Glucose Tests

Defining Your Needs

The most important factors in performing an accuracy or precision test are the needs of the testing institution, in terms of both a) levels of performance and b) regulatory requirements. The range of glucose concentrations in a study should reflect the operating range of the monitoring system and the levels of glucose seen in day-to-day monitoring. These protocols are not intended to fulfill the requirements of any particular regulatory agency. Interpretation of regulatory requirements will vary from institution to institution, and each laboratory is ultimately responsible for its own compliance. For a more comprehensive approach to assessing system suitability, refer to NCCLS Documents EP9-A[1] and EP5-T2,[2] which provide guidelines for evaluating the accuracy and precision (respectively) of in vitro diagnostic devices.

1 National Committee for Clinical Laboratory Standards. Method comparison and bias estimation using patient samples; Approved Guideline. NCCLS document EP9-A (ISBN 1-56238-283-7), 1995.

2 National Committee for Clinical Laboratory Standards. Evaluation of precision performance of clinical chemistry devices - Second Edition; Tentative Guideline. NCCLS document EP5-T2 (ISBN 1-56238-145-8), 1992.

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Blood Samples

- Observe universal precautions for handling blood samples.
- The SureStepPro and SureStep Systems are calibrated to report plasma glucose concentrations. Use whole blood for bedside unit or meter tests; use plasma from the same samples for comparison tests (with a laboratory reference instrument).
- Use blood samples whose hematocrits fall between 25% and 60%. Avoid the use of blood samples from dehydrated subjects, whose elevated hematocrits may cause inaccurate results.
- Collect blood samples in heparin tubes. Do not use fluoride collection tubes, as this additive interferes with bedside unit or meter tests.
- Do not combine blood samples from different donors.
- Test blood samples within 24 hours of drawing.

Effects of Glycolysis

The concentration of glucose in a whole blood sample will diminish with time due to glycolysis. If not properly managed, this effect can have a negative influence on accuracy and precision testing.

To assure that changes in the sample's glucose concentration do not substantially affect the outcome of an accuracy study, plasma samples should be prepared (by centrifugation) within 10 minutes of testing with the bedside unit or meter. (Removal of red blood cells from the sample effectively eliminates the glycolysis effect.) Comparison testing of plasma samples may then be performed at a later time, preferably within 30 minutes of the bedside unit or meter tests of the sample.

Precision testing can be similarly affected by glycolysis. One way to minimize the effect is to perform the bedside unit or meter tests over as short a period of time as possible. Testing the samples on the reference instrument before and after bedside unit or meter testing can provide a gauge of the glycolysis effect; a decrease of more than 5% indicates a potential impact on precision results. A preferred option is to use SureStepPro Glucose Control Solutions as test samples. Use of control solutions reduces sample-dependent imprecision (due to sample inconsistency, sample instability, etc.), eliminates concerns related to the handling of blood samples, and simplifies the procedure, especially when testing several systems.

Reference Instrument

Comparison testing with a reference instrument is a primary element of the accuracy procedure and of secondary importance in precision testing. Since the SureStepPro bedside unit and the SureStep meter report plasma-calibrated results, the reference instrument must be capable of testing plasma samples. Handheld meters or bedside units should not be used as reference instruments.

Quality Control

All instruments must be operated in accordance with manufacturers' instructions. Before performing an accuracy or precision test, thoroughly familiarize yourself with the correct operation of the SureStepPro or SureStep System and perform all quality control procedures specified in the SureStepPro Bedside Unit Operator's Guide or the SureStep Owner's Booklet.

Spiking

A procedure called “spiking” (described below) allows the adjustment of the glucose concentration of a whole blood sample to desired levels. Spiking gives the experimenter a high degree of control over glucose concentration but requires careful management of time and materials. If whole blood samples with wide-ranging glucose concentrations are readily available, spiking may not be necessary.

Spiking is performed by adding a small volume of concentrated glucose solution to a whole blood sample and mixing thoroughly; a simple calculation (below) is used to determine the volume of glucose solution required to achieve the target concentration.

The initial concentration of the whole blood sample must be known and must be lower than (or equal to) the target concentration. Using a whole blood sample whose endogenous glucose has been depleted by glycolysis (see below) will simplify the spiking procedure, especially when testing at low glucose concentrations. To ensure that depletion is complete (or nearly so), start with a blood sample whose glucose concentration is less than 100 mg/dL.

To spike a whole blood sample to a target glucose level:

1. Incubate the sample at room temperature for at least 16 hours to deplete the glucose in the sample (if necessary).
2. Obtain a standard D10W solution (or prepare a 10% glucose solution by dissolving 10 grams of anhydrous D-glucose in 100 ml of distilled or deionized water).

Note: The 10% glucose solution must be prepared at least 24 hours before use, or erroneous results will be obtained.

3. Determine the initial glucose concentration of the sample with a reference instrument, bedside unit, or meter.
4. Calculate (to the nearest microliter) the volume of 10% glucose solution needed to attain the target glucose concentration, using the formula:

$$V_s = \frac{V_b\,(\text{Target Concentration} - \text{Initial Concentration})}{10}$$

where V_s is the volume of 10% D-glucose solution required (in μL) and V_b is the volume of blood being spiked (in mL). For instance, if you wish to spike a 1 mL aliquot of blood (that has an initial glucose concentration of 10 mg/dL) to a target concentration of 50 mg/dL:

$$V_s = \frac{1\text{ mL}\,(50\text{ mg/dL} - 10\text{ mg/dL})}{10} = 4\ \mu\text{L 10\% glucose solution}$$

5. Combine the blood and 10% glucose solution in a capped test tube; mix the sample gently but thoroughly (e.g. 10 minutes on a test tube rocker).

Note: The calculations presented above are approximate; attaining an exact target concentration is generally not important, since the “true” glucose concentration of the spiked sample is measured with the reference instrument. If the calculated volume (V_s) is too small to be pipetted accurately, dilute the spiking solution with distilled or deionized water and adjust the spiking volume accordingly.

Accuracy

Introduction

The procedure described below assumes that you will need to adjust the glucose concentrations of aliquots of whole blood by spiking. The volume of each aliquot of spiked sample in this procedure (1 mL) is sufficient for testing several bedside units or meters at the same time and can be adjusted according to your specific needs. If you are able to obtain fresh whole blood samples whose glucose concentrations cover the desired concentration range, you may skip the spiking procedure and begin testing.

A minimum of 20 samples (each tested in duplicate) is recommended. Several samples may be spiked simultaneously. To minimize the effect of glycolysis, plasma samples for comparison testing should be prepared within 10 minutes of bedside unit or meter testing.

Before beginning the accuracy test, ensure that the SureStepPro or SureStep System(s) have been prepared for testing and that all quality control procedures have been successfully performed, in accordance with the SureStepPro Bedside Unit Operator's Guide or the SureStep Owner's Booklet.

Materials

- SureStepPro bedside unit(s) or SureStep meter(s)
- SureStepPro Test Strips - Approximately 50 test strips per bedside unit or meter, from the same lot
- Venous whole blood - Approximately 20 mL, collected in heparin tubes within the previous 24 hours from one healthy donor.
- 10% Glucose solution or standard D10W solution
- Test tubes with stoppers (approximately 20)
- Transfer pipettes
- Adjustable pipettors - 0 to 1000 µL
- Test tube rocker
- Centrifuge
- Laboratory reference glucose analyzer
- Accuracy Study Record(s) - one per bedside unit or meter

Procedure

1. Record bedside unit/meter and test strip information on the Accuracy Study Record. Confirm that test strips have not reached their expiration date.
2. Prepare spiked sample(s) (1 mL each) for testing (as described above). Mix samples gently but thoroughly to ensure uniform distribution of red blood cells.
3. Perform two separate bedside unit or meter tests on the first sample; record results on the Accuracy Study Record.

Note: Refer to the SureStepPro Test Strips package insert ("Blood Application") for an explanation and illustration of correct sample application.

4. Centrifuge an aliquot of the spiked whole blood to obtain a plasma sample.
5. Perform duplicate comparison tests (with reference instrument) on the plasma sample; record results on the Accuracy Study Record.
6. Calculate the mean comparison result and record on the Accuracy Study Record.
7. Repeat the testing procedure for other spiked samples.

Data Analysis

Estimations of accuracy may be determined for each bedside unit or meter and for the combined results of two or more units. Calculate the slope, y-intercept, and correlation coefficient (r) by comparing each of the meter results with the corresponding mean comparison result [two meter (y value) results for each mean comparison (x value) result]. These calculations can be performed with a multifunction pocket calculator or appropriate statistical software.

Aberrant results may be identified by calculating the "bias" between each bedside unit or meter result and the corresponding comparison result. For glucose values greater than or equal to 100 mg/dL, calculate the percent difference :

$$\% \text{ Difference} = \frac{\text{Bedside Unit/Meter Result} - \text{Mean Comparison Result}}{\text{Mean Comparison Result}} \times 100$$

For glucose values less than 100 mg/dL, calculate the difference :

$$\text{Difference (mg/dL)} = \text{Bedside Unit/Meter Result} - \text{Mean Comparison Result}$$

Note: Absolute difference (rather than percent difference) is used for values below 100 mg/dL to avoid exaggerated biases resulting from low glucose values.

Record the results on the Accuracy Study Record. Compare the results to the requirements established within your institution.

Accuracy Study Record

Bedside Unit/Meter Name & Serial # ____

Test Strip Lot # ________________________ Reference Instrument ______________________

Sample ID	Comparison Results (mg/dL)			Bedside Unit/Meter Results			
	Dupl. 1	Dupl. 2	Mean	Test 1 (mg/dL)	Difference/ % Difference	Test 2 (mg/dL)	Difference/ % Difference

Slope = y-intercept = r =

Performed by ______________________________ Reviewed by ______________________________

Signature/Date Signature/Date

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Precision

Introduction

The procedure described below uses SureStepPro Glucose Control Solutions (Low, Normal, and High) to estimate within-run precision. Spiked whole blood samples, or fresh whole blood samples whose glucose concentrations cover the desired concentration range, may be substituted for control solutions.

Three levels of testing are recommended, one each at glucose concentrations reflecting the hypoglycemic, normal, and hyperglycemic physiological states.

Before beginning the precision test, ensure that the SureStepPro or SureStep System(s) have been prepared for testing and that all quality control procedures have been successfully performed, in accordance with the SureStepPro Bedside Unit Operator's Guide or the SureStep Owner's Booklet.

Materials

- SureStepPro bedside unit(s) or SureStep meter(s)
- SureStepPro Test Strips - At least 60 test strips per bedside unit or meter, from the same lot
- SureStepPro Glucose Control Solutions (Low, Normal, and High)
- Precision Study Record(s) - one per bedside unit or meter

Note: Additional materials (10% glucose solution, test tubes with stoppers, transfer pipettes, adjustable pipettors, test tube rocker, centrifuge, laboratory reference glucose analyzer) are required if whole blood samples are used.

Procedure

1. Record bedside unit/meter, test strip, and control solution information on the Precision Study Record. Confirm that test strips and control solutions have not reached their expiration dates.
2. Perform 20 consecutive bedside unit or meter tests with one of the control solutions; record results on the Precision Study Record.

Note: Control solutions and whole blood are applied to test strips in the same manner. Refer to the SureStepPro Test Strips package insert ("Blood Application") for an explanation and illustration of correct sample application. Shake vials gently before applying solution to test strip; wipe vial tips clean and reseal vials tightly after use.

3. Repeat the testing procedure for the other control solutions.

Data Analysis

Calculate the mean result, standard deviation, and coefficient of variation for the 20 bedside unit or meter values at each level. These calculations can be performed with a multifunction pocket calculator or appropriate statistical software. The Trend Graph Report and QC Statistics Report functions of the SureStepPro Professional Blood Glucose Management System may also be useful for data analysis; refer to the SureStepPro System Administrator's Guide for details.

Record the results on the Precision Study Record. Compare the results to the requirements established within your institution.

Precision Study Record

Bedside Unit/Meter Name & Serial # _____ Test Strip Lot # _____

	Low Level	Normal Level	High Level
Lot No.			
Test 1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
Mean			
SD			
CV			

Performed by _____ Reviewed by _____

Signature/Date Signature/Date

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Printed in USA

054-867A