

Whole Blood Glucose Proficiency Surveys

Many institutional customers, who purchase blood glucose meter systems, must enroll their systems in proficiency testing programs in order to maintain accreditation or meet regulatory requirements. Proficiency programs are intended to notify participants about possible systematic, random, or use errors so that they can be corrected to optimize patient testing. However, a poor score on a proficiency test may or may not indicate that there is a true problem with a blood glucose meter system.

1. Whole blood proficiency materials do not contain human whole blood

Providers of proficiency materials (e.g. American Association of Bioanalysts, College of American Pathologists, and others) distribute artificial glucose solutions to their participants. These solutions often contain bovine or human hemoglobin, preservatives, stabilizers, and buffers. If the solution contains (bovine or human) erythrocytes, the cells are 'stabilized' in order to minimize cellular lysis and inhibit glycolysis. Buffers and preservatives are used to allow the solution to be stored at room temperature, to stabilize glucose, and to extend shelf life. These chemicals can produce a 'matrix effect'¹ in analytical systems that have been optimized to measure glucose in human whole blood. None of the artificial solutions successfully mimics the characteristics of human whole blood.

2. Whole blood proficiency assay values are not known and are not traceable.

The proficiency survey provider does not assay each survey sample vial for its definitive glucose concentration. Instead, the data from participants are grouped by instrument-specific method and the resultant method-specific average becomes the target value. This target value is not traceable to a higher order glucose concentration such as a standard reference material.

3. Whole blood proficiency materials cannot be used to assess accuracy

The International Federation for Clinical Chemistry classifies proficiency solutions as 'tertiary controls' because their target values are assigned by repetitive measurements of routine methods². According to the IFCC, 'tertiary controls' should not be used to assess method inaccuracy. However, these materials may be used to assess method imprecision. Therefore, perhaps the best use of proficiency reports is to compare method precision data (SD and %CV). However, even these data are not totally reliable

¹ A 'matrix effect' is: "the physiochemical effect(s) (e.g. interference) of the matrix on the measurement procedure's ability to accurately measure an analyte." [CLSI terminology database].

² Tertiary controls have retrospectively assigned values and are not assayed by reference methods.

because they may include random (use error) and matrix effects caused by lot-to-lot differences. These differences may not be observed when whole blood is tested.

4. Whole blood methods are designed and calibrated for human whole blood.

Whole blood glucose assays, including blood glucose meters, are designed, optimized, calibrated, tested, and factory-released using data from human whole blood glucose. Glucose test strip performance is optimized to the fluid flow characteristics of human whole blood. Whole blood glucose assays are not optimized for artificial solutions. The viscosity, solubility, and flow characteristics of artificial solutions may be significantly different and could produce method-specific effects depending on the different reagent test strip designs.

Proficiency test solutions have different compositions and characteristics when compared to human blood and this explains the observed differences in the glucose measurements between different meter methods.

All whole blood glucose methods have been optimized to accurately measure glucose in human whole blood samples – and their accuracy should be assessed with human whole blood.

References:

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CLSI terminology database [<http://www.nccls.org>]