Glucose Harmonization: The Role of Accurate Calibrators

To the Editor.—The article by Miller et al in the May issue of the Archives of Pathology & Laboratory Medicine contains critical data pertaining to the trueness of calibrators for glucose assays.1 As shown in their Figure 3, the mean concentration of glucose reported by 23 of 31 peer groups for sample C-02 was less than 1 mg/dL away from the reference target, but 9 of the remaining peer groups reported mean concentrations of glucose that were more than 2 mg/dL greater than target.

The deviant results are not surprising. During the past 10 years, my associates and I at Quest Diagnostics Inc (Madison, NJ) have detected 4 glucose calibrator problems upon receipt of new lots of calibrators. In each case, we changed the assigned glucose set point based on a rigorous internal validation protocol that uses NIST SRM (National Institute of Standards and Technology Standard Reference Materials) and the distribution of glucose concentrations of tens of thousands of patient samples. The deviation of vendor-assigned calibrator values from truth was always positive and ranged from +1.8% to +5.2%. Falsely assigned high values for calibrators lead to falsely high results for patient samples.

It is clear from the analysis of the survey data for C-02 that variation in glucose results is caused by variation from instrument type to instrument type and not by variation from reagent type to reagent type. The instrument to instrument variation is driven primarily by variation in the accuracy of the set points for the calibrators. The survey data and our experience point to the need for a program to harmonize glucose calibrators and patient results similar to that established for the National Glycohemoglobin Standardization Program.2

Finally, the need for tight control of glucose calibration is supported by the recent discovery that variation in fasting plasma glucose concentrations within the normal range is highly informative.3

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