Evaluation of the Quo-Test Hemoglobin A1c Point-of-Care Instrument: Second Chance

To the Editor:

We previously reported the evaluation of 8 different hemoglobin A1c (Hb A1c) point-of-care instruments (1). Two of 8 manufacturers withdrew from that study after initial unpromising results. One of the 2 instruments withdrawn was the Quo-Test A1c (Quotient Diagnostics), which was withdrawn because of a technical problem. The manufacturer claimed to have resolved the problem and asked us to reevaluate the instrument.

The Quo-Test method is based on affinity separation and the use of fluorescence quenching and gives results in 3 min. The instrument was certified by the National Glycohemoglobin Standardization Program (NGSP) as of September 2009 (2).

We used the same approach for evaluation as in the initial study, following the CLSI EP-5 protocol for imprecision and the CLSI EP-9 protocol for method comparison. Because the American Diabetes Association has recommended Hb A1c as the preferred test for the diagnosis of diabetes (3), we added an additional sample of approximately 6.5% Hb A1c in the EP-5 protocol. The EP-9 protocol was performed twice with 2 different lot numbers and compared with 3 IFCC and NGSP secondary reference measurement procedures (SRM): the Roche Tina-Quant Gen.2 Hb A1c on an Integra 800, immunoassay, IFCC, and NGSP SRM (Roche Diagnostics); the Primus Ultra1, affinity chromatography HPLC, IFCC, and NGSP SRM (Primus Diagnostics, a Trinity Biotech Company); and the Tosoh G8, cation-exchange HPLC, IFCC SRM (Tosoh Bioscience N.V./S.A.).

To check overall calibration and bias, we compared the EP-9 protocol results to the mean of the 3 SRM results and also used the EP-9 protocol results to calculate the NGSP certification criterion with 2 reagent lot numbers.

In monitoring therapy, the reproducibility of Hb A1c assays is critical. The total CV should be <3% (realistic goal) and for optimal clinical use <2% (desirable goal) (1). The total CVs in the EP-5 protocol for the Quo-Test at Hb A1c values of 5.0%, 6.2%, and 10.2% were 5.9%, 4.5%, and 2.9%, respectively.

Comparisons between the Quo-Test with 2 reagent lot numbers and the mean of the 3 SRM are shown in Fig. 1 with the individual EP-9 results and the NGSP certification calculations. The 95% CI of the differences between the SRM and test methods should fall within ±0.75% Hb A1c (total error) to pass the current NGSP criteria (4). The Quo-Test NGSP certification was granted in September 2009 (2) before the tightening of the NGSP criteria from ±0.85% Hb A1c to ±0.75% Hb A1c. To evaluate this method in the same way as the other methods in our previous study (1), we used the old criteria. The calibration of the first lot number appeared adequate, but with the EP-5 protocol we observed high variability reflected by a high total CV, and a high SE of estimates was still a matter of concern. The discrepancy with the second lot number may have been attributable to problems associated with up-scaling of the production of cartridges.

The Quo-Test recently passed the NGSP criteria compared with 1 SRM procedure (Tosoh G8) with 1 lot number but failed the NGSP criteria for all the other comparisons (Fig. 1). Tests performed by using Chow-statistics for the overall differences in slope and intercept per method for lot numbers 1 and 2 showed significant differences in analytical performance between the 2 lot numbers ($P<0.001$).

The manufacturer provided 2 controls with wide ranges: low control 4.2% to 7.5% and high control 10.5% to 15.3%. The manufacturer should narrow these ranges as was described recently (1).

Results of analysis of the analytical performance of the Quo-Test showed a high total CV, large bias with 1 lot number, failed NGSP criteria, and significant differences between lot numbers. The Quo-Test is officially NGSP certified and passed the NGSP criteria with only 1 lot number as tested at the manufacturer’s site (2). The results we report here demonstrate the large lot-to-lot variability in quality of the Quo-Test Hb A1c point-of-care test.

Health care professionals should be aware of the clinical implications for an Hb A1c value that is determined by using a point-of-care instrument (5). Moreover, to properly interpret the result, health care professionals must know the analytical performance of the Hb A1c method used. This study and the previous study (1) prove that an NGSP certification does not guarantee the quality of results produced in the field and confirms the recommendation of the American Diabetes Association not to use Hb A1c point-of-care assays for diagnostic purposes at this time (3).

Validation of a new method is always necessary and cannot be expected to be carried out by health care professionals. For this reason we think that point-of-care

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1 Nonstandard abbreviations: Hb A1c, hemoglobin A1c; NGSP, National Glycohemoglobin Standardization Program; SRM, secondary reference measurement procedure.
devices should be guided by and fall under the responsibility of a central laboratory.

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**Fig. 1.** Hb A1c results for 2 different lot numbers from the Quo-Test point-of-care instrument compared to the mean Hb A1c results from 3 SRM procedures (individual EP-9 regression lines and NGSP certification criteria are shown below the graph).

The P-value of the regression lines between the 2 lot numbers was <0.001, which confirmed the statistically significant difference between the 2 regression lines.

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**References**


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