Evaluation of the Performance and Stability of a Novel A1c-Cellular Control

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Research shows lifestyle changes and regular monitoring of diabetes indices are the most effective means to manage diabetes.[1,2] Measuring hemoglobin A1c (A1C) is an accepted means of diagnosis and a helpful indicator when monitoring diabetes status. Hemoglobin A1c analyzers are usually based on three analytical principles: high-performance liquid chromatography, immunoturbidimetry, and boronate affinity. The A1C values obtained from different analyzers often vary because of the differences in analytical principles and matrix effects.[3] Thus a quality control that consistently provides similar A1C values within a relevant range across various analyzers would be helpful when correlating results from various methodologies. Clinical and Laboratory Standard Institute regulations state that control materials should be treated in the same manner as a patient specimen.[4] A whole blood control would be ideal; however, the instability of whole blood and the unavailability of large volumes of diabetic blood, as well as ethical concerns, are major limitations. Streck A1c-Cellular®, a ready-to-use bi-level liquid control, resembles whole blood, as it contains intact red cells and is used in the same manner as a patient sample. In this letter, we describe the performance of this control across multiple analyzers and report the stability of the recovered A1C values and the stability of the intact red cells that constitute the control.

Table 1 shows that the mean A1C values of 10 consecutive runs of the control across different analyzers are within their respective ±2 standard deviation (SD) ranges [A1C values are expressed in National Glycohemoglobin Standardization Program (NGSP) percentage units]. The imprecision values [percentage coefficient of variation (CV)] for all instruments are within 3.0%, a traceability criteria approved by the NGSP.[5] The interinstrument mean values for two levels are 5.8% and 11.6%. The interinstrument ±2 SD ranges are 4.5–7.1% and 10.5–12.8%, respectively. Therefore, the mean A1C values of all instruments are within an interinstrument ±2 SD range for both levels of the control. These results indicate that the A1c-Cellular can be used as a quality control for multiple analyzers. The variation between the mean values for each instrument may be the result of matrix effects.

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Abbreviations: (A1C) hemoglobin A1c, (CV) coefficient of variation, (NGSP) National Glycohemoglobin Standardization Program, (SD) standard deviation

Keywords: A1C, A1C-Cellular control, A1C control, A1C correlation, diabetes diagnosis, hemoglobin A1c

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Table 1.
Reproducibility of Bi-Level A1c-Cellular across Multiple Analyzers[a]

Run number	A1c-Cellular level 1							A1c-Cellular level 2						
	Arkray Menarini ADAMS™ A1c HA-8160	Beckman Coulter® UniCel® 800 Synchron®	Siemens Healthcare Diagnostics Inc. Dimension	Ortho-Clinical Diagnostics VITROS® Fusion	Roche INTEGRA®	Tosoh A1c G8	Bio-Rad® Variant™ II Turbo	Arkray Menarini ADAMS™ A1c HA-8160	Beckman Coulter® UniCel® 800 Synchron®	Siemens Healthcare Diagnostics Inc. Dimension	Ortho-Clinical Diagnostics VITROS® Fusion	Roche INTEGRA®	Tosoh A1c G8	Bio-Rad® Variant™ II Turbo
1	6.4	5.2	5.5	5.2	5.8	6.1	6.8	11.2	11.2	10.8	11.7	11.8	11.5	12.7
2	6.3	5.0	5.4	5.3	5.6	6.1	6.8	11.2	11.4	10.8	11.7	11.6	11.6	12.7
3	6.4	5.0	5.4	5.3	5.8	6.2	6.9	11.3	11.4	10.8	11.6	12.0	11.6	12.6
4	6.3	4.8	5.4	5.3	5.6	6.1	6.9	11.1	11.5	10.8	11.8	11.9	11.7	12.6
5	6.3	5.0	5.4	5.3	5.8	6.1	6.9	11.2	11.3	10.9	11.8	12.0	11.6	12.5
6	6.3	5.0	5.4	5.2	5.8	6.1	6.9	11.2	11.1	10.8	11.9	11.8	11.7	12.7
7	6.5	5.0	5.4	5.3	5.8	6.1	6.9	11.3	11.3	10.9	11.7	11.8	11.7	12.7
8	6.4	5.0	5.4	5.3	5.9	6.1	6.9	11.1	11.2	10.8	11.9	11.8	11.7	12.6
9	6.2	5.0	5.4	5.3	5.8	6.1	6.9	11.1	11.6	10.9	12.0	11.8	11.6	12.6
10	6.3	5.0	5.4	5.3	5.8	6.2	6.9	11.2	11.3	10.8	12.0	11.8	11.7	12.5
Mean	6.3	5.0	5.4	5.3	5.8	6.1	6.9	11.2	11.3	10.8	11.8	11.8	11.6	12.6
SD	0.08	0.09	0.03	0.04	0.09	0.04	0.04	0.07	0.15	0.05	0.14	0.12	0.07	0.08
CV%	1.33	1.89	0.58	0.80	1.64	0.69	0.61	0.66	1.32	0.45	1.16	0.98	0.60	0.63

[a] The A1C values are expressed in NGSP percent units. The interinstrument mean A1C values are 5.8% and 11.6% for level 1 and level 2. The respective ±2 SD ranges are 4.5–7.1% and 10.5–12.8%.

The control is stable for 6 months in closed vial and 30 days in open vial when stored at 2–10 °C. We measured the A1C values of both levels of the control using the Tosoh G8 A1c analyzer over 6 months and found that the A1C values are within the ±2 SD range of the mean. The control also maintains the integrity of intact red cells throughout its stability claim. The presence of intact red cells in A1c-Cellular can detect errors in lysing steps that would be bypassed by lysate-based controls.

In conclusion, A1C values for A1c-Cellular control, obtained from various analyzers, are reproducible, and the impression values are within the NGSP acceptable range. The mean A1C values for each instrument are within the interinstrument ±2 SD ranges. The control resembles whole blood by containing stable intact red cells that could also be useful to indicate malfunctions in the lysing step.

Funding:

This research is funded by Streck Inc.

Disclosures:

Kausik Das, Gary K. Krzyzanowski, Stephanie M. Wigginton, and Joel M. Lechner are employees of Streck Inc. Wayne L. Ryan is CEO of Streck Inc.

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