

Expanded platforms for hemoglobin A1c test

January 2014—Beckman Coulter Diagnostics has launched its next-generation Hemoglobin A1c assay with improved performance across its chemistry systems. The assay has been standardized for use on all platforms of the company's AU clinical chemistry systems for off-line sample preparation use and for online sample preparation use on the company's UniCel DxC systems and is FDA 510(k) cleared for both analyzers.

The assay is an enhanced reagent formulation developed to improve accuracy and precision to continue to meet the latest accuracy grading from the CAP and the recommendations of the National Glycohemoglobin Standardization Program and International Federation of Clinical Chemistry. When used in conjunction with the company's Synchron/AU Hemolyzing reagent or HbDil, the assay is intended for the quantitative determination of HbA1c concentration in human whole blood.

Additionally, Beckman Coulter has partnered with Canterbury Scientific to distribute the ExtendSure liquid ready-to-use control for the AU and UniCel DxC HbA1c assays. The control is value assigned specifically for the AU and UniCel DxC clinical systems and is available in two kit sizes, one of which represents a one-year supply of the same lot. It has an open-bottle stability of 30 days and a shelf life of 30 months.

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