

FDA clearance for A1c testing system, 3/16

March 2016—Bio-Rad Laboratories announced that its D-100 System for A1c testing has obtained FDA clearance to monitor the long-term blood glucose control of individuals with diabetes, as an aid in the diagnosis of diabetes, and to help identify those who may be at risk for developing the disease.

The D-100 is a fully automated instrument using high-performance liquid chromatography technology. It is designed to meet the needs of medium- and high-volume clinical laboratories for greater throughput, high-quality results, and simplified workflow for A1c testing. The system delivers rapid results without sacrificing the ability to detect hemoglobin variants, which can interfere with the interpretation of test results. Earlier this year, Bio-Rad obtained CE marking and released the D-100 System in Europe, Canada, and several countries in Asia-Pacific.

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