

## 510(k) clearance for diabetes testing assay, 8/15

**August 2015—The FDA has cleared Ortho-Clinical Diagnostics' Vitros Chemistry Products** HbA1c Reagent Kit for use on the Vitros 5600 Integrated System, Vitros 4600 Chemistry System, and the Vitros 5,1 FS Chemistry System. The test can be used for the quantitative determination of percent glycated hemoglobin A1c and mmol/mol hemoglobin A1c in human whole blood. The test is to be used as an aid in the diagnosis of diabetes, as an aid in identifying patients who may be at risk for developing diabetes mellitus, and for the monitoring of long-term blood glucose control in individuals with diabetes mellitus. The design of the Vitros HbA1c assay allows its use in patients with hemoglobin variants S, C, D, and E traits. The new assay will replace the Vitros Chemistry Products d%A1c Reagent Kit, which will eventually be discontinued.

The kit uses Vitros MicroTip Technology, which offers a special chemistry menu and user-defined assays in a cost-effective, easily implemented format. Single-use disposable tips and closed reagent packs are designed to eliminate the risk of sample carryover or reagent-to-reagent contamination and to extend onboard reagent stability. This test is performed without the need for water.

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