FDA clearance for Roche analyzer, assay, 3/17

March 2017—Roche announced that its dedicated, high-throughput HbA1c testing solution, the Cobas c 513 analyzer, and HbA1c Gen. 3 assay have received 510(k) clearance from the Food and Drug Administration.

The Cobas c 513 analyzer has a test throughput of up to 400 patient results per hour with the same footprint as the Cobas Integra 800 CTS, which it replaces. The Cobas c 513 features direct results reporting, provides a high on-board test capacity of up to 18,000 tests, and features closed-tube sampling.

The analyzer runs the established Roche Tina-quant HbA1c Gen. 3 assay, which complies with current guidelines and recommendations for HbA1c testing and measures A1c as defined by IFCC/NGSP reference methods. With no interference by most known HbA1c variants, the Tina-quant HbA1c Gen. 3 assay aims to deliver accurate monitoring of HbA1c levels.

***Roche**, 317-521-2000*