FDA approves A1c test for diabetes diagnosis

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Many health care providers already use A1c tests, which are FDA cleared only for monitoring glucose control, to diagnose diabetes. In an analysis of 141 blood samples, however, researchers found this particular A1c test, the COBAS INTEGRA 800 Tina-quant HbA1cDx assay, yielded a difference of less than 6 percent compared with the standard reference for hemoglobin analysis.

The agency stressed that over-the-counter A1c assays should not be used to diagnose diabetes. The Tina-quant HbA1cDx assay is available only by prescription for use by health care professionals in clinical laboratories.

"As the Tina-quant HbA1cDx assay was designed for diabetes diagnosis and has been reviewed by the FDA, physicians can have confidence that this test is reasonably safe and effective when used for its intended purposes of monitoring and diagnosing diabetes," Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics and Radiological Devices in the FDA's Center for Devices and Radiological Health, said in a statement.

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