

ABBOTT LAUNCHES FIRST-EVER RAPID POINT-OF-CARE HbA1c TEST TO AID IN THE DIAGNOSIS OF DIABETES

- Afinion™ HbA1c Dx test provides results in three minutes, enabling clinicians to develop informed, individualized care plans during patient consultation

- Assay is the first and only rapid point-of-care test cleared by the U.S. Food and Drug Administration (FDA) to aid healthcare professionals in the diagnosis of diabetes

ABBOTT PARK, Ill., June 17, 2019 / [PRNewswire](#)/ -- Abbott (NYSE: ABT) today announced that its Afinion™ HbA1c Dx assay is now available for use on the Afinion 2 Analyzer, as well as the Afinion AS100 Analyzer. The Afinion HbA1c Dx assay is the first and only rapid point-of-care test cleared by the U.S. Food and Drug Administration (FDA) to aid healthcare professionals in the diagnosis of diabetes and the assessment of patients' risk of developing the condition.

The Afinion HbA1c Dx meets FDA's stringent requirements for performance testing for diagnostic use claims. The test delivers accurate and precise^{1, 2} glycated hemoglobin (HbA1c) results in only three minutes, enabling clinicians to diagnose patients and help them formulate individualized care plans during a single doctor's office visit. The Afinion HbA1c Dx assay (approved for monitoring and diagnosis) complements the Afinion HbA1c assay (approved for monitoring only), the number one point-of-care HbA1c test in the U.S. for monitoring long-term glycemic control in diabetes.³

"As diagnostics continue to move to point-of-care settings such as physician office labs, the Afinion HbA1c Dx rapid assay shows how Abbott is once again setting new standards for innovation in the diagnosis and monitoring of diabetes," said Elizabeth Balthrop, divisional vice president, Cardiometabolic and Informatics, Rapid Diagnostics, Abbott. "In addition to giving physicians the certainty of diagnosis they need to make informed decisions during a patient visit, the HbA1c Dx assay gives people living with diabetes near real-time results, so that in consultation with their doctor they can make adjustments to their lifestyle and better manage their condition."

"Rapid, reliable diabetes screening at the point of care enables healthcare providers to immediately link patients to comprehensive care that can help prevent the serious consequences of the disease," said Richard Kahn, Ph.D., former chief scientific and medical officer of the American Diabetes Association. "In addition, point-of-care diagnosis can enhance clinical efficiencies for busy practices and, at a population level, help stem the massive economic and societal impacts of diabetes in the U.S."

ABOUT DIABETES

Diabetes is a chronic metabolic condition that occurs when the body cannot produce insulin or use it efficiently, causing sugar (glucose) to build up in the bloodstream. The Centers for Disease Control and Prevention (CDC) estimates that 7.2 million people in the United States have diabetes but are as yet unaware of this diagnosis. Another 84.1 million have prediabetes.⁴ Diabetes can cause serious consequences, including problems with blood vessels, heart, nerves, kidneys, mouth, eyes and feet.⁵

ABOUT THE AFINION HbA1c Dx ASSAY

The Afinion HbA1c Dx assay is FDA-cleared as a moderate complexity test for quantitative determination of HbA1c in human whole blood, used to aid in the diagnosis of diabetes and assessment of patients' risk of developing the disease. It is also cleared for use in monitoring long-term glycemic control. The assay received FDA clearance for use on the Afinion AS100 Analyzer in May 2018.

ABOUT THE AFINION 2 ANALYZER

The Afinion 2 Analyzer is a state-of-the-art multi-assay platform that streamlines and simplifies the delivery of actionable, accurate measurements of HbA1c and ACR (albumin-to-creatinine ratio) results at the point of care. The system arms healthcare professionals with the information needed to make fast and accurate medical decisions. The Afinion 2 platform, which offers all-in-one connectivity to LIS/HIS (laboratory and hospital information systems) and a sleeker, quieter experience for clinicians and patients, was launched in May 2018 for patient management of diabetes through whole blood HbA1c testing and ACR testing in urine.

ABOUT ABBOTT

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 103,000 colleagues serve people in more than 160 countries.

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¹ Arnold, W et. al. Fingerstick Precision and Total Error of a Point-of-Care HbA1c Test. J Diab Sci Technol 2019; Mar [Epub ahead of print]. <https://doi.org/10.1177/1932296819831273>

² Arnold, W et. al. Accuracy and Precision of a Point-of-Care HbA1c Test. J Diab Sci Technol 2019; Mar [Epub ahead of print]. <https://journals.sagepub.com/doi/full/10.1177/1932296819831292>

³ Market share data reflects Q1-4 2018 & Q1-2019 GHX data for distributor product sales in US.

⁴ Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Available at <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

⁵ National Institutes of Health, the National Institute of Diabetes and Digestive and Kidney Diseases. Types of diabetes. Available at <https://www.niddk.nih.gov/health-information/diabetes/types>.

SOURCE Abbott

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