



LumiraDx Continues Commercial Expansion of its Rapid Microfluidic Immunoassay HbA1c Test

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Now Available in Europe, parts of the Middle East, Asia, Latin America, and Africa

- Early customers include GP offices and other community-based healthcare settings
- Latest figures, released as part of World Diabetes Day, reveal that 1 in 10 adults are now living with diabetes and nearly half are undiagnosed¹
- The LumiraDx HbA1c test is designed to address the growing clinical need for accessible and reliable HbA1c testing in community-based healthcare settings such as primary care, diabetes clinics, rural clinics, retail pharmacy & other decentralised healthcare settings
- The actively controlled microfluidic immunoassay is run on the highly portable LumiraDx Platform and designed for near-patient testing with connected results in under seven minutes
- The addition of HbA1c to the rapidly growing LumiraDx test menu, enables the consolidation of multiple instruments to a single, next-generation point of care Platform; all with a common workflow

LONDON, Nov. 14, 2022 (GLOBE NEWSWIRE) -- **LumiraDx Limited (Nasdaq: LMDX)**, a next-generation point of care diagnostics company, today announced the continued commercial expansion of its [HbA1c test](#), for professional use across multiple care settings. Used alongside the LumiraDx Platform, the test monitors known diabetic patients' HbA1c levels and also serves as an aid in screening and identifying patients who may be at risk for developing diabetes. Providing results in under seven minutes from sample application, the test allows improved efficiency and convenience with on-the-spot diabetes screening and monitoring at the patient's side. The company announced the assay had achieved CE marking in late May of this year.

Today's announcement comes on the heels of today's World Diabetes Day which called attention to recent figures from the IDF Diabetes Atlas that 1 in 10 adults now have diabetes and nearly 1 in 2 are undiagnosed. ¹ The portability and flexibility of the LumiraDx Platform enables the LumiraDx HbA1c test to address the growing clinical need for accessible and reliable HbA1c testing in the community healthcare setting to aid in quicker clinical decision making. The LumiraDx HbA1c test has a reportable range of 20 - 130 mmol/mol HbA1c (4.0 - 14.0% HbA1c). In an external, multi-site clinical study, the test achieved precision, expressed as mean paired replicate %CV, of $\leq 2.50\%$ (NGSP) in both capillary and venous whole blood.

David Walton, LumiraDx's Chief Commercial Officer commented, "As the global prevalence of diabetes is increasing, it's critical for healthcare professionals to have access to rapid and reliable HbA1c results. The availability of an immediate, lab-comparable HbA1c test has been shown to improve patient outcomes through improved diabetes management. ^{2,3} In addition, there are a number of well-known comorbidities associated with diabetes. These are supported through our multi-assay testing Platform - including tests for cardiac biomarkers, coagulation, and inflammation-making the LumiraDx Platform an ideal tool for improving patient outcomes within the community healthcare setting."

Professor Garry John, Consultant Clinical Biochemist, Norfolk and Norwich University Hospital, current Secretary of the IFCC Executive Committee of the Scientific Division (SD) and former Chairperson of the IFCC Working Group for the Global Standardisation of HbA1c, Honorary Professor, Norwich Medical School (UEA), explained, "Decentralised diabetes testing allows people to go to their GP or pharmacy and have these tests done there. This is important because it allows individuals to see their results immediately and therefore encourages them to achieve the target set out for them. It also enables the healthcare provider to be reassured that the level of improvement or control is a true representation of the metabolic situation." He continued, "Basic laboratory support for clinical colleagues providing healthcare is fundamental; anything that allows our clinical teams to gather the complete information they need on the patient they are dealing with at that point in time is central to good metabolic control."

Johannes Pachler, Managing Director of Leupamed Medizintechnik GmbH, a leading medical equipment supplier in Austria, commented, "The HbA1c test is a welcome addition to the LumiraDx Platform for our customers, which includes more than 100 LumiraDx Platforms used by GPs and internal medicine groups. We know there is tremendous value for clinicians being able to share immediate results with patients - this is particularly true for the monitoring and screening of diabetes. The intuitive nature of the Platform and the accurate results of the HbA1c test make it an important tool for diabetes management and clinicians are already seeing the positive impact the test can make on patient care."

About LumiraDx

LumiraDx Limited (Nasdaq: LMDX) is next-generation point of care diagnostics company that is transforming community-based healthcare. Its actively controlled microfluidic technology provides fast, high performance and accessible diagnostic solutions wherever the patient is for nearly any testing scenario, creating unique testing options at the point of need.

The company offers a broad menu of lab comparable tests on a single portable Platform, with more than 30 assays on the market and in the pipeline, covering infectious diseases, cardiovascular diseases, diabetes, and coagulation disorders. The company also supports high-complexity laboratory testing in an accessible high-throughput format to leverage current molecular laboratory operations.

Founded in 2014 and based in the UK, LumiraDx's diagnostic testing solutions are being deployed globally by governments and leading healthcare institutions across laboratories, urgent care, physician offices, pharmacies, schools, and workplaces to help screen, diagnose, and monitor wellness as well as disease.

More information on LumiraDx is available at www.lumiradx.com.

References:

- 1: worlddiabetesday.org/about/facts-figures/
- 2: diabetesjournals.org/care/article/22/11/1785/19794/Immediate-feedback-of-HbA1c-levels-improves
- 3: www.ncbi.nlm.nih.gov/pmc/articles/PMC4933534/

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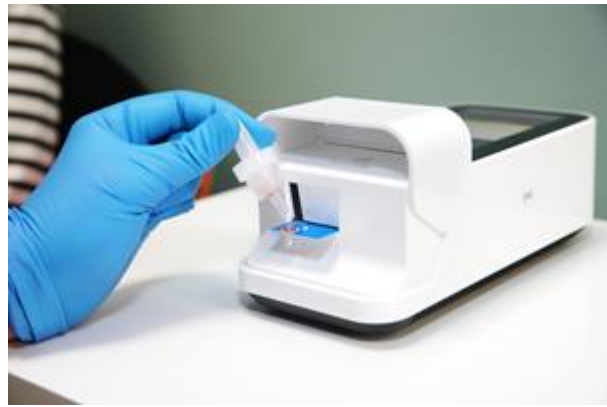
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A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/e24265c7-f665-478a-92bd-b0f8f1bf9b53>



Source: LumiraDx Inc

LumiraDx HbA1c Test



LumiraDx Rapid Microfluidic Immunoassay HbA1c Test and Point of Care Platform