Nightingale Health reaches next milestone in the United States: first laboratory developed tests approved by New York State

Nightingale Health (Nasdaq Helsinki: HEALTH; OTCQX: NHLTY, NGHLF), a pioneer in disease risk detection and preventive health, has received the first approvals for its laboratory developed tests from the New York State Department of Health's Clinical Laboratory Evaluation Program (CLEP). Under the approvals, the company's New York laboratory, which holds a clinical laboratory permit from New York State, may offer the approved tests to healthcare customers.

For a new clinical laboratory in New York State, the CLEP process has two stages. First, the laboratory itself must hold a clinical laboratory permit. Second, the laboratory submits each laboratory developed test, meaning individual blood values in the Nightingale Health Check, to CLEP with the validation data for that test, and CLEP approves each test separately. The approvals now received are the first for Nightingale Health's tests in this second stage. Nightingale Health continues to submit its remaining laboratory developed tests for review under CLEP procedures.

Following a U.S. District Court ruling in 2025, laboratory developed tests remain regulated mainly under the CLIA/CLEP framework, the federal and New York State rules for clinical laboratories, rather than by the U.S. Food and Drug Administration (FDA). They do not require a separate FDA approval. For Nightingale Health, whose U.S. laboratory is in New York, test approvals under CLEP are therefore the regulatory route for its tests in the United States, the world's largest healthcare market.

"For a new measurement technology, the first test approvals are the most important ones. That is the first time that tests based on the measurement are reviewed against the validation requirements, and New York State has now approved the first tests based on our measurement technology. Every further test is submitted with its own validation data for CLEP's review, and our goal is unchanged: to make our technology available to healthcare in the United States," says Teemu Suna, CEO and Founder of Nightingale Health.

The Nightingale Health Check is approved for healthcare use in the European Economic Area, the United Kingdom, Japan, and Singapore. In the United States, Nightingale Health's tests are provided as laboratory developed tests from the company's own laboratory in New York.

For further information, please contact

Teemu Suna, CEO
ir@nightingalehealth.com

About Nightingale Health

Chronic diseases cause around 75% of deaths globally and place a growing burden on healthcare systems. The way to address this is preventive healthcare, but until recently the tools to detect disease risks at population scale have not existed. Nightingale Health has built them. The Nightingale Health Check is a blood-based risk detection test that identifies risks for multiple chronic diseases, including cardiovascular disease, type 2 diabetes, kidney disease, and fatty liver disease, from a single blood sample. It is designed to be applied population-wide, so healthcare systems can identify the people who would benefit most from preventive action before disease develops.

Nightingale Health's technology is validated in over 1,000 peer-reviewed scientific publications and is used in many of the world's leading health studies, including the UK Biobank. In Finland, the Nightingale Health Check is in nationwide healthcare use, and over 250,000 people have already received their results. Nightingale Health operates globally with a parent company in Finland and subsidiaries in countries such as Japan, the United States, Singapore, and the United Kingdom, and has customers in more than 34 countries across healthcare and medical research. The company's Series B shares are listed on the Main Market of Nasdaq Helsinki and on the OTCQX International market. Read more: https://nightingalehealth.com/