



Lucira Health's At-Home COVID-19 Test Granted Full Exemption by New Zealand Ministry of Health

July 4, 2022

New Zealanders can now get fast, accurate COVID-19 test results without leaving home and unnecessarily exposing themselves or others to the virus.

The Lucira COVID-19 molecular test:

- Displays a positive result in as little as 11 minutes, negative in 30 minutes
- Provides 98% accuracy as compared to gold standard PCR tests ¹
- Can detect the SARS-CoV-2 virus earlier than antigen tests ²
- Detects all known variants of the SARS-Cov-2 virus ¹
- Option to generate a verified test record of results ¹

New Zealand, July 4, 2022 (EIN Presswire.com) -- Lucira Health, Inc. (Nasdaq: LHDX) ("Lucira Health," or "Lucira"), a medical technology company focused on the development and commercialization of transformative and innovative infectious disease tests, today reported that the New Zealand Ministry of Health granted [Lucira Health's Check-It COVID-19 test a full exemption for use in New Zealand](#), ³ heralding a new era in Test-to-Treat in the region.

Lucira's test is the [first molecular at-home test for COVID-19, as reported by the US FDA](#). ⁴

The Lucira test uses nucleic acid amplification technology to deliver PCR-quality results in as little as 11 minutes for a positive result, 30 minutes for a negative result. ¹ The test is completely untethered, requiring no additional equipment typically required with conventional PCR testing. The test's ability to detect the SARS-CoV-2 virus is comparable to high-sensitivity PCR laboratory tests, ¹ but Lucira's test fits right in the palm of your hand and comes with everything needed in one box, allowing New Zealanders to test anywhere at any time.

For every test, users have the option of generating a verified test record using LUCI Pass, an easy-to-use, web-based platform made available by Lucira Health.

At present, Air New Zealand is completing a 3-month trial of Lucira Check-It tests at Auckland Airport with airline staff to gather data on local use of the test. ⁵

New Zealand's response to the pandemic has received wide recognition and brought the country global attention for its decisiveness, nimbleness, and innovative approaches. For over two years and through multiple variants, New Zealand has been valiantly fighting to keep SARS-CoV-2 at bay. Now, with at-home molecular testing, New Zealanders can get fast, accurate results without leaving home and unnecessarily exposing themselves or others to the virus.

Lucira Health is proud to partner with Device Technologies NZ to introduce this innovative testing technology in New Zealand. The tests are currently available for purchase through Device Technologies NZ via phone 0508 DEVICE (338 423); or email customers@device.co.nz

About the Lucira COVID-19 & Flu Test

The Lucira COVID-19 & Flu test is a NAAT test utilizing the same platform and device design as Lucira's commercialized EUA authorized COVID-19 tests to provide independent diagnoses for COVID-19, Flu A, and Flu B. The single-use test fits in the palm of your hand, runs on 2 AA batteries, and with one nasal swab provides a positive or negative result for COVID-19, Flu A, and Flu B in less than 30 minutes. Each Lucira test contains everything needed to run a single COVID-19 test: the test device, two AA batteries, sample vial, swab, and simple instructions. There is no separate reader or instrument to purchase and maintain. Lucira is seeking an EUA for prescription at-home use of the test.

About Lucira Health

Lucira is a medical technology company focused on the development and commercialization of innovative infectious disease tests to make lab-quality diagnostics more accessible. Lucira designed its test platform to provide accurate, reliable, PCR-quality test results anywhere and at any time. Beyond its already commercialized COVID-19 tests, Lucira is working on new diagnostic tests including a single test for COVID-19 & Flu, additional respiratory infections, and for other categories including Sexually Transmitted Infections (STIs). For more information, visit www.lucirahealth.com.

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Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "can," "seek," "toward," "plans," "may," "anticipates," "expects," and similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements regarding, among others, the timing and availability, if approved, of Lucira's COVID-19 & Flu test available throughout the United States. These forward-looking statements are based upon Lucira's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including Lucira's ability to increase production, streamline operations and increase product availability; the success of Lucira's test platform with COVID-19 including its variants, Flu A and Flu B; the extent and duration of the COVID-19 pandemic and Lucira's expectations regarding customer and user demand for its COVID-19 test and the COVID-19 and Flu test; Lucira's ability to obtain and maintain regulatory approval for its tests, including Lucira's existing Emergency Use

Authorization for its COVID-19 test and LUCI Pass; Lucira's expectations around the timing of submission and receipt of regulatory approval for its tests; the performance of, and Lucira's reliance on, third parties in connection with the commercialization of its tests, including Jabil Inc., Switch Health and Lucira's single-source suppliers; Lucira's ability to successfully continue to expand internationally; any impact on Lucira's ability to market its tests; demand for Lucira's tests due to deferral of procedures using its tests or disruption in its supply chain; Lucira's ability to achieve or sustain profitability; Lucira's ability to gain market acceptance for its tests and to accurately forecast and meet customer demand; Lucira's ability to compete successfully; Lucira's ability to enhance and expand its product offerings; Lucira's ability to accurately predict continued expansion; Lucira's ability to accurately forecast revenue; development and manufacturing problems; capacity constraints or delays in production of Lucira's tests; maintenance of coverage and adequate reimbursement for procedures using Lucira's tests; and test defects or failures. These and other risks and uncertainties are described more fully in the "Risk Factors" section and elsewhere in Lucira's filings with the Securities and Exchange Commission and available at www.sec.gov, including in its most recent Annual Report on Form 10-K and subsequently filed reports. Any forward-looking statements that Lucira makes in this announcement speak only as of the date of this press release, and Lucira assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise after the date of this press release, except as required under applicable law.

References:

1. [Lucira Check-It Test Kit Instructions for Use](#)
2. Coronavirus Disease 2019 Testing Basics (fda.gov)
3. [New Zealand Gazette. Full Exemption of Certain COVID-19 Point-of-care Tests Under the COVID-19 Public Health Response Order 2021. 8 June 2022](#)
4. [US Food & Drug Administration. Coronavirus Update: FDA Authorizes First COVID-19 Test of Self-Testing at Home. 17 November 2020](#)
5. Covid-19 Omicron outbreak: New 'Lamp' tests trial at Auckland Airport - NZ Herald

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