

READYGO DIAGNOSTICS AND GEMINA LABORATORIES ANNOUNCE THE FEASIBILITY OF MYCOBACTERIUM TUBERCULOSIS (MTB) DIAGNOSIS IN SALIVA

Monday 5 June, 2023

The feasibility of utilising saliva as a sample for the detection of Mycobacterium tuberculosis (MTB) through a molecular diagnostic test has been successfully demonstrated.

Press Release: June 5th, 2023, Bath, United Kingdom: ReadyGo Diagnostics Ltd. (ReadyGo), a developer of isothermal molecular diagnostics, and Gemina Laboratories Ltd. (CSE: GLAB) (FRA:817), a specialist in fast, affordable, and accurate diagnostic tests, are thrilled to announce a significant milestone in their collaboration.

ReadyGo and Gemina began a partnership in January 2023 to develop a saliva-based test for Mycobacterium Tuberculosis (MTB). We are delighted to announce the successful feasibility of this, using contrived samples to confirm analytical performance against the WHO Target Product Profile for a triage test. A saliva triage test for MTB would be a breakthrough product and would have a profound impact on how TB could be detected as part of the eradication efforts, particularly in countries like India, Indonesia, and other affected regions around the world.

MTB, a highly contagious airborne disease, caused over 10 million infections worldwide in 2021, resulting in 1.6 million deaths. Alarming, an estimated 4 million infections (40% of all cases) remain undiagnosed and untreated, posing significant challenges to disease control initiatives. Diagnosis in low- to middle-income countries, where MTB is most prevalent, often relies on smear microscopy using sputum samples. However, these tests have limitations, especially in remote areas and when diagnosing certain patient populations such as children and the elderly, who may have difficulty producing sputum.

Consequently, the diagnosis of MTB presents a serious and complex healthcare challenge. In response, the World Health Organization (WHO) has recommended the use of molecular diagnostic tests that can utilize alternative sample types like saliva, thereby improving testing accessibility.

The ReadyGo and Gemina collaboration will now proceed to full product development, leveraging the Geo platform. Geo is a low-cost fluorescence device that can deliver sophisticated molecular diagnostics at a very low price point outside of the laboratory. The objective is to launch an MTB Screening Test in 2024, which can replace smear microscopy with a simple saliva sample. This innovative solution will provide results within 30 minutes, making it accessible anywhere and at an affordable cost. Building upon the successful feasibility stage, the team plans to introduce a compact laboratory instrument that will retail for under \$1000, with a per-test cost of \$5, enabling field testing near patients.

Ben Cobb, CEO of ReadyGo Diagnostics, added:

"I'm thrilled about our continued progress and partnership with Gemina to establish a tuberculosis diagnostic platform that can use saliva as the primary sample. We understand the pressing need for a triaging test that can replace smear microscopy at an affordable price point, particularly in resource-constrained settings. Using our collective experience and the platforms we've developed it has been immensely beneficial in developing this kind of test and I'm pleased with the progress we've achieved in such a short period of time. We see Geo as both an open platform that can be used for rapid molecular diagnostics by research groups, but we also want to become the preferred partner for companies seeking to create cost-effective solutions for molecular diagnostics for patients across diverse healthcare environments by utilising our platforms."

Brian Firth, CEO of Gemina, commented:

"I'm delighted to be seeing such significant results so quickly from our partnership with ReadyGo Diagnostics so quickly. Our goal is to create better diagnostic tests for managing patients with tuberculosis, the fact that we have proven feasibility of detecting TB in saliva opens the door to a fundamental improvement in human health and a significant contribution to eradicating TB worldwide."

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Contacts

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Scan Me:



ReadyGo Diagnostics Ltd

Ben Cobb, Chief Executive Officer

Ben Reed, Chief Commercial Officer

Email: info@readygotest.com

Gemina Laboratories Ltd

Brian Firth, Chief Executive Officer

Email: investor@geminalabs.com

About ReadyGo Diagnostics Ltd.

ReadyGo Diagnostics is a rapidly growing diagnostics company that designs, develops and commercialises novel sample collection devices and diagnostic platforms. Our proprietary technology molecular diagnostic platform, GEO™, permits low cost decentralised testing in under 30 minutes. Our Sampler transforms diagnostic testing by elegantly combining sample collection and processing into a single, user-friendly disposable and provides optimal and reproducible samples for testing using molecular, biochemical and lateral flow tests.

For more information please refer to the website: www.readygotest.com

About Gemina Laboratories Ltd.

Gemina Labs is a biosensor and diagnostic company with a transformative, patented, proprietary chemistry that powers next-generation testing platforms for a wide range of pathogens that affect human health and wellness. Our technology drives testing platforms that are fast, affordable and accurate, and easily self-administered. Our development pipeline includes platforms for the rapid testing of COVID-19, influenza and other viruses.

Additional information on the Company can be found at www.geminalabs.com.

Company Contact:

ReadyGo Diagnostics Limited

T. 07881660737

E. info@readygotest.com

W. <https://www.readygotest.com>

Additional Contact(s):

Dr Ben Reed- benreed@readygotest.com

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