

# GEMINA LABORATORIES LTD.

## News Release

May 5, 2022

### GEMINA LABS COMPLETES SUCCESSFUL HUMAN CLINICAL PERFORMANCE EVALUATION ON ITS LEGIO X™ COVID-19 RAPID ANTIGEN TEST

**May 5, 2022, Vancouver, British Columbia: Gemina Laboratories Ltd.** (CSE: GLAB) (FRA:8I7) (the “Company” or “Gemina”) is pleased to announce the successful completion of its human performance study for the Gemina Legio X™ COVID-19 Rapid Antigen test, a significant development milestone demonstrating the power of Gemina’s novel patented chemistry.

Gemina Labs initiated human clinical performance studies which began in early April 2022 at the Centro Diagnostico Buonarroti (Buonarroti Diagnostic Center - “CDB”) in Civitavecchia, Italy. CDB is a leading health facility with expertise in the provision of diagnostic testing and clinical analysis for Italy’s general population, with a specific expertise in COVID-19 testing. After four weeks of patient testing and the administration of more than 500 Gemina Legio X™ COVID-19 Rapid Antigen Tests, the real-world data has revealed exceptionally strong performance results. The performance data benchmarked against the gold standard of PCR test results continues to exceed expectations and further supports upcoming regulatory submissions.

Importantly, the Gemina Legio X™ COVID-19 test was administered with a shallow (anterior) nasal swab, which showed comparable sensitivity and specificity to one of the most widely distributed and best performing rapid COVID tests in Europe and the United Kingdom. To achieve the performance demonstrated by Gemina’s Legio X™ test, the comparator test was required to be administered using the much more invasive nasopharyngeal (deep nasal) swab, which can only safely be administered by a healthcare professional. This important ‘form of administration’ advantage suggests that the Gemina Legio X™ test has the potential to deliver clinical performance results using a much less invasive sampling method that can be performed without the assistance of a healthcare professional.

“During the first waves of the COVID pandemic, when the wild-type and Alpha variants were circulating, our preferred CE-marked rapid test performed sufficiently well with shallow nasal swabs to show correlation with PCR in the high 90<sup>th</sup> percentile,” commented Dr. Carlo Tarantino, the lead clinician at Centro Diagnostico Buonarroti. “However, because of the way the Delta and Omicron variants have evolved, we were compelled to switch to nasopharyngeal swabs to provide sufficient sensitivity. When the Gemina team proposed to evaluate the performance of the Legio X™ test using shallow nasal swabs, I cautioned them not to be disappointed if their test did not perform well in comparison. However, after the first week of testing, I was very impressed to see the Gemina test providing equivalent sensitivity with a shallow swab as the comparator test was generating with a deep nasopharyngeal swab. This high performance of the Gemina Legio X™ test persisted throughout the study and as soon as it becomes commercially available, I would add the Gemina Legio X™ test to our inventory. Patients, especially children, much prefer the less invasive sample method.”

The successful completion of the clinical performance study provides Gemina with the sensitivity and specificity data required to support its regulatory submissions in advance of the commercial rollout of the

Gemina Legio X™ COVID-19 Rapid Antigen Test. In addition to moving the COVID test one step closer to commercialization, the superb performance of the test in such a clinical setting validates the Gemina chemistry platform that lies at the heart of the diagnostic device. The Company has proven that its novel chemistry can be used to design and build a very high-quality point-of-care assay that can be manufactured at scale and reliably used for patient diagnosis. This gives Gemina the confidence to expand its development program beyond COVID to new respiratory infection targets and beyond, which will further demonstrate the universal applicability of the Gemina chemistry platform.

Robert Greene, CTO of Gemina Labs stated, “We are extremely pleased by the consistently strong performance of our Legio-X™ COVID test. The independent data collected to date shows that we not only can exceed the performance of leading shallow nasal swab rapid antigen tests currently on the market, but also meet or exceed leading deep nasal swabs as administered by healthcare professionals. This provides us with great confidence that our chemistry platform is very robust, and has the ability to power the next generation of point of care testing, whether in the clinic or at home.”

The Company is not making any express or implied claims that its product has the ability to eliminate, cure or contain the COVID-19 virus. The Company will be seeking regulatory approval for our product(s) before sales and clinical use are permitted.

On Behalf of the Board of Directors

John Davies  
CEO  
Gemina Laboratories Ltd.

#### **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](http://www.geminalabs.com).

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