# GEMINA LABORATORIES LTD.

## **News Release**

### May 17, 2022

## GEMINA LABS ANNOUNCES CE MARK FOR ITS FIRST PRODUCT – THE BEST IN CLASS LEGIO-X<sup>™</sup> COVID RAPID ANTIGEN TEST

- Less than two weeks after announcing the highly successful completion of human trials, Gemina has secured a European Union ("EU") CE Mark, which accelerates commercialization of the breakthrough product into the EU.
- In trials, the CE-marked Legio-X<sup>™</sup> COVID-19 Rapid Antigen Test, using shallow nasal swabs, correlated with PCR testing in the high 90th percentile.

May 17, 2022, Vancouver, British Columbia: Gemina Laboratories Ltd. (CSE: GLAB) (FRA:817) (the "Company" or "Gemina") is pleased to announce that its inaugural product – the Gemina Legio X<sup>TM</sup> COVID-19 Rapid Antigen Test – has been awarded an EU CE Mark under the EU's In Vitro Diagnostic Medical Device Directive ("IVDD"). The CE Mark signifies that a product sold in the European Union has been assessed to meet high safety, health, and environmental protection requirements, and for businesses, the CE Mark indicates that the product can be traded in the EU without restrictions. Achieving the CE Mark provides the Company with a strong foundation for bringing the Gemina Legio X<sup>TM</sup> COVID-19 Rapid Antigen Test to market within the European Union member countries. Gemina is actively engaged with its Canadian manufacturing partner, International Point of Care, to manufacture and achieve commercialization for the Legio-X<sup>TM</sup> COVID test in the second half of 2022.

The award of the CE mark is Gemina's first regulatory approval, and marks a major milestone for the Company, as it executes its strategy, leveraging its breakthrough chemistry platform to power a family of rapid tests for medical diagnosis and human wellness monitoring. Today's news follows the recent announcement of the completion of the patient study announced May 5, 2022, where the Company reported exceptionally strong performance results for the Gemina Legio X<sup>™</sup> COVID-19 Rapid Antigen Test in a 500-subject trial in Italy.

The award of a CE Mark opens the door to subsequent regulatory approvals for the test. The Company is actively exploring pathways for additional approvals in Europe and beyond. While the world is learning to live with COVID as the pandemic evolves from a pandemic to an endemic phase, market analysis suggests that rapid testing will remain a core response throughout 2027, with the COVID-19 antigen test market size surpassing USD \$8 billion<sup>1</sup>.

Commenting on today's announcement, John Davies, CEO stated, "This is a fantastic achievement for the Company and a great vindication of the strength of Gemina's chemistry platform. We're building a company of enormous potential in the point of care testing space. As we do so, it's absolutely essential that we achieve visible successes along the way. Today's result is precisely that – a measurable point of success on the road to many more in the future."

Rob Greene, CTO, added "Often, bioscience can take years to productise. But within 2 years, we've developed an incredibly powerful biosensing chemistry platform, and developed our first regulated product based on the strength of that platform. We've formulated a great set of targets for our successor products over the next three years, including our previously announced Flu A/B rapid test, which leverages the experience we've already developed in the COVID space."

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.

1. Market Study Report, LLC July 26, 2021 www.marketstudyreport.com/reports/global-covid-19-antigen-test-market-size-research

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.

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### **Forward Looking Statements**

This news release includes forward-looking information and statements, which may include, but are not limited to, information and statements regarding or inferring the future business, operations, financial performance, prospects, and other plans, intentions, expectations, estimates, and beliefs of the Company. Such statements include statements regarding the anticipated terms of any proposed transaction or engagement. Information and statements which are not purely historical fact are forward-looking statements. Forward-looking information and statements involve and are subject to assumptions and known and unknown risks, uncertainties, and other factors which may cause actual events, results, performance, or achievements of the Company to be materially different from future events, results, performance, and achievements expressed or implied by forward-looking information and statements herein. Although the Company believes that any forward-looking information and statements herein are reasonable, in light of the use of assumptions and the significant risks and uncertainties inherent in such information and statements, there can be no assurance that any such forward-looking information and statements will prove to be accurate, and accordingly readers are advised to rely on their own evaluation of such risks and uncertainties and should not place undue reliance upon such forward-looking information and statements. Furthermore, the Company is presently unable to fully quantify the impact that the Covid-19 pandemic will have on its operations and recognizes that certain eventualities may affect planned or assumed performance moving forward. As such, any forward-looking information and statements herein are made as of the date hereof, and except as required by applicable laws, the Company assumes no obligation and disclaims any intention to update or revise any forward-looking information and statements herein or to update the reasons that actual events or results could or do differ from those projected in any forward looking information and statements herein, whether as a result of new information, future events or results, or otherwise, except as required by applicable laws.

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