

## Supply agreement with major US customer

### Highlights

- Genetic Signatures secures new North American customer for its *EasyScreen™* SARS-CoV-2 Detection Kit
- The two-year supply agreement is for reagents to meet demand for estimated 1,000 tests per day
- First order received, to be invoiced in December
- Warehouse facility established in Los Angeles, California to support customer supply across North America

Genetic Signatures Limited (ASX: GSS, “Genetic Signatures” or the “Company”) is pleased to announce it has acquired a new North American customer, Boston Medical Center (BMC) of Boston, Massachusetts, to supply *EasyScreen™* SARS-CoV-2 Detection Kits.

The new supply agreement will provide BMC with an expanded testing capability and has been signed during a particularly challenging phase of the COVID-19 pandemic in the US. Target volumes are for 1,000 patient samples per day over the next 2 years, however there is no minimum purchase quantity. Genetic Signatures is also providing instruments for testing.

The duration and severity of the COVID-19 pandemic is uncertain and may influence the number of *EasyScreen™* SARS-CoV-2 Detection Kits purchased although if target volumes are achieved this will contribute significant revenue to Genetic Signatures over the life of the agreement. Broader utilisation of *EasyScreen™* for other indications are also under consideration by BMC. The first order for US\$227,000 has been received and will be invoiced this month.

### Genetic Signatures CEO, Dr John Melki commented:

*“The new supply agreement and first North American customer marks a major milestone for Genetic Signatures. We are pleased to be working with the Boston Medical Center, a highly regarded hospital and medical center in the US. As COVID-19 remains a challenge in North America, wide-spread testing remains key to managing the spread of the disease. Genetic Signatures remains focused on both growing its global reputation as a leading molecular diagnostics company, and the provision of reliable and accurate diagnostic solutions. While securing new customers across North America and EMEA is a near-term focus, the Company is continuing to market the benefits of more comprehensive screening with our EasyScreen™ Detection Kit range.”*

The USA is the largest diagnostics market globally and Genetic Signatures is positioned to grow its presence under the FDA Section IV.c exemption<sup>1</sup>. Sales and field teams are actively engaged with multiple sales leads. A new warehouse facility has been established in Los Angeles, California with an international third-party logistics group to supply kits to BMC and other potential new customers in the region. The Company has continued to invest and build inventory in North America.

#### About Boston Medical Center (BMC)

Boston Medical Center is a highly regarded academic medical center and hospital in Boston, Massachusetts. It is the largest safety-net hospital and busiest trauma and emergency services center in the New England region. The hospital sees more than one million patient visits per year who are cared for by close to 1,500 physicians including residents and fellows.

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For further information, see [www.geneticsignatures.com](http://www.geneticsignatures.com) or contact:

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#### Announcement authorised by Genetic Signatures' Board of Directors

**About Genetic Signatures Limited:** Genetic Signatures is a specialist molecular diagnostics (MDx) company focused on the development and commercialisation of its proprietary platform technology, **3base™**. Genetic Signatures designs and manufactures a suite of real-time Polymerase Chain Reaction (PCR) based products for the routine detection of infectious diseases under the **EasyScreen™** brand. Genetic Signatures' proprietary MDx **3base™** platform technology provides high-volume hospital and pathology laboratories the ability to screen for a wide array of infectious pathogens, with a high degree of specificity, in a rapid throughput (time-to-result) environment. Genetic Signatures' current target markets are major hospital and pathology laboratories undertaking infectious disease screening.

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<sup>1</sup> The FDA is permitting manufacturers that have or will submit an EUA for a SARS-CoV-2 test to supply their test prior to receiving the EUA. The FDA describes this marketing route in Section IV.C. of their Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)<sup>2</sup> Under the exemption the manufacturer must have validated the kit and is required to notify the FDA of their intent to supply the test. The use of the test is limited to laboratories that have been certified under CLIA (Clinical Laboratory Improvement Amendments) to perform high complexity testing and the laboratory is required to disclaim the status of the test on all results that are issued using the test. (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>)