

TGA registration for SARS-CoV-2 Detection Kit

- Genetic Signatures' *EasyScreen*TM SARS-CoV-2 Detection Kit (the virus that causes COVID-19) has been approved for inclusion in the Australian Register of Therapeutic Goods (ARTG)
- Registration provides an opportunity for greater market access during the COVID-19 pandemic and the upcoming domestic flu season

Genetic Signatures Limited (ASX: GSS, "Genetic Signatures" or the "Company") today announced that it has received notice from the Therapeutic Goods Administration ("TGA") that its *EasyScreen*TM SARS-CoV-2 Detection Kit has been approved to be listed on the ARTG in Australia. Local registration follows formal European authorisation which was announced on 4 April 2020.

Genetic Signatures CEO, Dr John Melki said "We thank the TGA for moving so quickly and the opportunity to support the important national and international effort to rapidly and accurately test, treat and contain the spread of coronavirus throughout the community. This registration comes at an important time with the onset of the domestic flu season approaching."

Interest in the new kit is growing within Australian laboratories. Several domestic private and public testing laboratories are already using the *EasyScreen*TM Respiratory Pathogen Detection Kit and this new kit can be used alone or alongside the broader respiratory kit which detects 14 common respiratory pathogens. Genetic Signatures' current customers have already incorporated the new *EasyScreen*TM SARS-CoV-2 Detection Kit into their testing programs as have several new customers, and discussions are underway with other domestic laboratories who have expressed interest in the kits.

The *EasyScreen*TM SARS-CoV-2 Detection Kit in conjunction with the Company's highest throughput instrument, GS-1000, provides laboratories the ability to process approximately 1,500 samples per instrument in a 24-hour period.

As more sequencing of the SARS-CoV-2 virus is published it is apparent that the viral mutations are occurring and there are at least 8 different strains already identified¹. Genetic Signatures' **3base**TM platform technology was invented in order to recognise common nucleic acid mutations.

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¹ <https://nextstrain.org/ncov/global>

For further information, see our website (www.geneticsignatures.com) or contact us:

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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.