

TGA AUTHORISES SUPPLY OF UPDATED RESPIRATORY DETECTION KIT

Redesigned EasyScreen™ Respiratory Pathogen Detection Kit available in Australia

Genetic Signatures Limited (ASX:GSS), an Australian-based, global molecular diagnostics company (**Genetic Signatures** or the **Company**), is pleased to report that the Australian Therapeutic Goods Administration (TGA) has completed the review of the redesigned *EasyScreen™* Respiratory Pathogen Detection Kit and included the updated device within the ARTG to allow supply within Australia.

The updated kit has some minor modifications to the assay design which improved the detection of Influenza B in samples with low concentration of the virus. In December 2023 Genetic Signatures lodged an application to the TGA to cover the modifications that were made to the *EasyScreen™* Respiratory Detection Kit.

This application has now been reviewed by the TGA and after a favourable outcome the Company is ready to commence sale of this product to all its customers as the Australian influenza season commences. The modifications have also been cleared for sale in the United Kingdom & the European Union. The Company has remained in consistent close contact with its existing customers, and is fully expecting that revenue from its respiratory products will return in line with historical levels as a result of the TGA clearance for the redesigned product.

John Melki, CEO and Managing Director of Genetic Signatures said *“We are delighted to have secured TGA authorisation for sales of our modified EasyScreen™ Respiratory Detection Kit in time for the upcoming Australian influenza season. While this process did have a material impact on our sales revenue during the 2023 influenza season, we have maintained strong relationships with our customers throughout this time. We fully expect that the modified 3base™ assay for Influenza B will enable them to adopt our EasyScreen™ Respiratory Detection Kit in line with their usage in previous influenza seasons.”*

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Authorisation and Additional Information

This announcement was authorised by the Board of Directors of Genetic Signatures Limited.

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

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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 hospitals and pathology laboratories undertaking infectious disease screening. Genetic Signatures is leveraging strong COVID-19 related sales of its *EasyScreen™* respiratory kits and the growing interest in its gastroenteritis products to further commercialise its **3base®** technology to rapidly and cost effectively screen for a wide array of infectious pathogens including antibiotic resistant bacteria, sexually transmitted infections, meningitis and mosquito borne viral diseases.