

**ASX Code: GSS**

27 May 2019

## **TGA registration for Respiratory Pathogen Detection Kit**

- **TGA registration has been received for Genetic Signatures' *EasyScreen*<sup>TM</sup> Respiratory Pathogen Detection Kit**
- **Registration provides an opportunity for increased market access during the domestic flu season, improving diagnostic outcomes and ultimately saving lives**
- **Domestic registration follows the CE-IVD registration in December 2018 permitting the sale of the Detection Kit in Europe**

Genetic Signatures Limited (ASX: GSS, "**Genetic Signatures**" or the "**Company**") is pleased to announce it has received Therapeutic Goods Administration ("**TGA**") registration for its *EasyScreen*<sup>TM</sup> Respiratory Pathogen Detection Kit in Australia.

TGA registration of the *EasyScreen*<sup>TM</sup> Respiratory Pathogen Detection Kit follows the CE-IVD registration in late 2018 (refer to ASX announcement dated 17 December 2018, "*CE-IVD Mark for Respiratory Pathogen Detection Kit*").

The *EasyScreen*<sup>TM</sup> Respiratory Pathogen Detection Kit identifies 14 common respiratory pathogens including Influenza A & B, Rhinovirus and *M. pneumoniae*. The kits allow a large number of samples to be simultaneously tested for a broad range of organisms with very high accuracy. This is beneficial for potential customers, particularly as Australia is experiencing an early start to the 'flu season with almost as many cases already reported in 2019 as were identified for the whole of 2018<sup>1</sup>.

Genetic Signatures now has 3 product groups successfully registered with the TGA, including the Enteric range, ESBL & CPO ("antibiotic resistance"), and the Respiratory Pathogen Detection Kits.

For further information, see our website ([www.geneticsignatures.com](http://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**<sup>TM</sup>. 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*<sup>TM</sup> brand. Genetic Signatures' proprietary MDx **3base**<sup>TM</sup> 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> <https://www.immunisationcoalition.org.au/news-media/2019-influenza-statistics/>