

ASX Code: GSS 17 December 2018

CE-IVD Mark for Respiratory Pathogen Detection Kit

- CE-IVD registration has been confirmed for Genetic Signatures' EasyScreen™ Respiratory Pathogen Detection Kit
- European registration of Respiratory Pathogen Detection Kit provides an opportunity to market into the Northern Hemisphere winter flu season
- TGA registration anticipated in the coming months to accelerate domestic sales with large customers already secured
- Three product ranges have now successfully achieved European registration over the last 18 months
- The EasyScreen[™] Pathogen Detection Kits improve diagnostic times, fast-tracking treatment and thereby saving lives

Genetic Signatures Limited (ASX: GSS, "Genetic Signatures" or the "Company") is pleased to announce that it has received CE-IVD registration permitting the sale of its $EasyScreen^{TM}$ Respiratory Pathogen Detection Kit in Europe.

Rapid identification of viral respiratory infections is critical in initiating antiviral treatment and limiting the spread of the infection. The *EasyScreenTM* Respiratory Pathogen Detection Kit identifies 14 common respiratory pathogens, including Influenza A & B, Rhinovirus and *M. pneumoniae*. It allows for rapid detection of pathogens in up to 94 specimens per batch in approximately 4.5 hours with minimal hands-on time for laboratory technicians, allowing a rapid high-throughput workflow.

The Detection Kit has broad market appeal in that it can be adopted in most testing laboratories with existing equipment.

This is the third *EasyScreenTM* product to receive the CE Mark, having previously received approvals for its Enteric range (including Protozoan, Viral and Bacterial targets) as well as its ESBL & CPO Antibiotic resistant 'Superbug' Detection Kit.

Simultaneously, Genetic Signatures has been progressing market entry of the *EasyScreenTM* Respiratory Pathogen Detection Kit in Australia. In August 2018, Genetic Signatures announced it had secured a major new domestic customer for the Respiratory Pathogen Detection Kit. TGA registration is expected in the coming months.

Genetic Signatures CEO, Dr. John Melki commented:

"The registration of our Respiratory Kit is an important achievement within our European commercialisation efforts. Our Regulatory and Product Development teams have a proven track record of taking product through the regulatory process with three product ranges achieving full CE-IVD registration in the last 18 months. Our expanding European team now has a suite of products to advance sales in 2019 and beyond."



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

Dr John Melki Chief Executive Officerjohn@geneticsignatures.com
T: +61 (0)2 9870 7580

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.

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