Genetic Signatures

**ASX Code: GSS**
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# 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™* 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 *EasyScreen™* Respiratory Pathogen Detection Kit identifies 14 common respiratory pathogens, including Influenza A & B, Rhinovirus and *M. pneumonia*e. 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 *EasyScreen™* 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 *EasyScreen™* 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 (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 hospital and pathology laboratories undertaking infectious disease screening.

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