

**ASX Code: GSS**

15 May 2018

## TGA registration for superbug detection kits

- TGA registration has been received for Genetic Signatures' *EasyScreen™ ESBL & CPO ('antibiotic resistance') Detection Kit*
- *EasyScreen™ ESBL & CPO Detection Kit* is the second major TGA registered product group approved for sale in Australia
- Domestic registration follows its recent CE-IVD approval for sale of the Detection Kits in Europe in 2018

Genetic Signatures Limited (ASX: GSS, “**Genetic Signatures**” or the “**Company**”) is pleased to announce it has received Therapeutic Goods Administration (“**TGA**”) registration for the sale of its Extended Spectrum Beta-Lactamase and Carbapenemase Producing Organisms (“**ESBL & CPO**”) Detection Kit in Australia.

This follows the CE-IVD registration received in April 2018 allowing European sales to commence (refer to ASX announcement dated 20 April 2018, “*European approval expands product suite*”).

The ESBL & CPO Kit detects hospital ‘superbugs’ or ‘antibiotic resistant’ pathogens, which are a significant global concern in healthcare settings. According to a study by the Rand Corporation (2014), the estimated global cost of antimicrobial resistance is approximately US\$95bn per year<sup>1</sup> over the next 20 years. Given standard treatments may be rendered ineffective against superbugs, rapid identification of infected patients is important, so they can be isolated and treated before the infection spreads.

The *EasyScreen™ ESBL & CPO Kit* allows for rapid detection in less than 3 hours with minimal hands-on time for laboratory technicians. The Detection Kit has been designed to provide rapid and accurate detection of 16 Beta-lactam and Carbapenem resistant pathogen targets.

Genetic Signatures can now sell its *EasyScreen™ ESBL & CPO Detection Kit* across Australia in addition to its TGA registered Enteric range, to its existing customer base and new customers via its direct sales team already in place.

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

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

---

<sup>1</sup> Based on current infection rates. Taylor, Jirka, Marco Hafner, Erez Yerushalmi, Richard Smith, Jacopo Bellasio, Raffaele Vardavas, Teresa Bienkowska-Gibbs, and Jennifer Rubin, “*Estimating the economic costs of antimicrobial resistance: Model and Results*”. The Wellcome Trust, 2014. [https://www.rand.org/pubs/research\\_reports/RR911.html](https://www.rand.org/pubs/research_reports/RR911.html).

**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.