

## Clinical Validation of Genetic Signatures *EasyScreen*™ Sexual Health Detection Kit Commenced

- Key step in progress toward clinical validation, regulatory approval, and market release of the *EasyScreen*™ Sexually Transmitted Infection (STI) Detection Kit
- Next step in Genetic Signatures product range expansion
- Large addressable STI testing market estimated at US\$550M globally in 2017<sup>1</sup>
- Preliminary results anticipated Q2 FY17

**Sydney, Australia, 27 September 2016:** Molecular diagnostics company Genetic Signatures Ltd (ASX: GSS) is pleased to announce that a trial of the *EasyScreen*™ Sexually Transmitted Infection (STI) Detection Kit has commenced with a clinical partner. The trial will examine clinical patient specimens and compare the *EasyScreen*™ results with those obtained via current testing standards.

Sexually Transmitted Infections (STIs) have a significant impact on sexual and reproductive health with the World Health Organisation (WHO) reporting that more than 1 million STIs are contracted on a daily basis<sup>2</sup>.

The *EasyScreen*™ STI Detection Kit was developed over fifteen months and leverages the company's proprietary molecular diagnostic (MDx) 3Base™ platform technology. The *EasyScreen*™ STI Detection Kit can simultaneously identify twelve of the most significant and commonly encountered STIs. The trial data will be used to support full regulatory approvals.

"This is an important step in our *EasyScreen*™ product range expansion strategy. Clinical validation data will allow us to progress toward market release and regulatory approval for this product," said Genetic Signatures' Chief Executive Officer, John Melki PhD. "Our 3base™ technology allowed us to develop a panel that covers a broad range of significant pathogens for genuine STI screening. As many STIs are asymptomatic and require screening for diagnosis, our test will allow clinicians to detect a broad range of STIs with a single molecular diagnostic assay."

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

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<sup>1</sup> Source: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 168

<sup>2</sup> <http://www.who.int/mediacentre/factsheets/fs110/en/>

**About Sexually Transmitted Infections:** The WHO has reported that each year, there are an estimated 357 million new infections with 1 of 4 STIs: chlamydia, gonorrhoea, syphilis and trichomoniasis. More than 500 million people are estimated to have genital infection with herpes simplex virus (HSV) and more than 290 million women have a human papillomavirus (HPV) infection. The majority of STIs have no symptoms or only mild symptoms that may not be recognized as an STI. STIs such as HSV type 2 and syphilis can increase the risk of HIV acquisition. Over 900,000 pregnant women were infected with syphilis resulting in approximately 350,000 adverse birth outcomes including stillbirth in 2012. In some cases, STIs can have serious reproductive health consequences beyond the immediate impact of the infection itself (e.g., infertility or mother-to-child transmission)<sup>3</sup>.

**About the *EasyScreen*™ STI Detection Kit:** The STIs detected by the *EasyScreen*™ STI Detection Kit are *Chlamydia trachomatis* (Chlamydia), *Neisseria gonorrhoeae* (Gonorrhoea), *Lymphogranuloma venereum* (LGV), *Mycoplasma Genitalium*, *Trichomonas vaginalis*, *Ureaplasma* spp. *Candida* spp. (Thrush), *Mycoplasma hominis*, *Streptococcus agalactiae* (Group B Streptococcus), *Treponema pallidum* (Syphilis), Herpes Simplex Virus 1 (HSV1) and Herpes Simplex Virus 2 (HSV2).

**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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<sup>3</sup> <http://www.who.int/mediacentre/factsheets/fs110/en/>