

Genetic Signatures Launches 3base™ *EasyScreen*™ Sexually Transmitted Infection (STI) Genital Pathogen Detection Kit

- **New *EasyScreen*™ STI Kit simultaneously detects the 12 most commonly encountered STIs and has superior multiple infection detection over traditional methods**
- **World Health Organisation: 1 Million people contracting an STI daily**
- **First sales of new STI Detection Kit follows successful validation trials**
- **SydPath (part of St. Vincent's Hospital in Sydney) is first commercial customer**
- **Global addressable STI testing market estimated at US\$550M in 2017**

Sydney, Australia, 31 March 2017: Molecular diagnostics company Genetic Signatures Ltd (ASX: GSS) has today launched and commenced the first sales of its *EasyScreen*™ Sexually Transmitted Infection (STI) Genital Pathogen Detection Kit. The availability of the newest member of Genetic Signatures' product offering follows a highly successful clinical trial and validation period that demonstrated the kit's superior capability over traditional methods to simultaneously and more effectively detect 12 of the world's most commonly encountered STIs including chlamydia, gonorrhoea and syphilis.

With the World Health Organisation recently reporting that there are globally more than one million sexually transmitted infections contracted daily¹, STIs have a profound impact on sexual and reproductive health, particularly as many offer no, or few, clear symptoms that may be recognised as an STI.

To address this Genetic Signatures' 15 month product development, clinical trial and validation have demonstrated that the "***EasyScreen*™ STI/Genital Pathogen Detection Kit**" offers improved accuracy, sensitivity and detection of additional STI pathogens over existing techniques (ASX Announcement 18 October 2016 and refer to results provided below). This outcome is thanks largely to Genetic Signatures' unique 3base™ platform, which reduces genetic information complexity and delivers more accurate results in hours versus days when using conventional methods..

SydPath, the fully accredited private Pathology Laboratory of St. Vincent's hospital and an existing customer of the Genetic Signatures' *EasyScreen*™ Enteric and Respiratory Pathogen Detection Assays, will be the first customer to use the company's new STI kit on an ongoing basis.

Commenting on this decision, SydPath Senior Hospital Scientist Dr Damien Stark said "The *EasyScreen*™ STI Detection Kit allows my team to simultaneously detect more STIs than our current molecular methodology whilst easily integrating into our consolidated *EasyScreen*™ testing workflow, helping us to more readily and rapidly address a serious growing health problem."

¹ Source: <http://www.who.int/mediacentre/factsheets/fs110/en/>

“Key to the future success of our new STI detection kit is its ability to screen for multiple pathogens in a rapid and common process using existing laboratory equipment,” said John Melki PhD, CEO of Genetic Signatures. “This saves both time and money, but most significantly provides more effective patient results and far better health outcomes.”

The “EasyScreen™ STI/Genital Pathogen Detection Kit” will initially be available in *Research Use Only* until regulatory approvals are gained in Australia and the EU. The 12 targets detected by the kit will also be available as Analyte Specific Reagents in the USA. Further regulatory approvals will enable Genetic Signatures to continue expanding into a \$550m addressable STI testing market².

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

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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)³.

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.

About SydPath: SydPath is a fully accredited NATA/RCPA/TGA registered laboratory offering a wide range of pathology services. As a teaching hospital laboratory located within

² 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

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

the St Vincent's Hospital Campus, SydPath offers a market-leading range of onsite testing and expert consultative support. Extensive experience at the forefront of diagnostic pathology and ongoing commitment to research and scientific development enables SydPath to provide a service based on the most recent advances in scientific pathology and laboratory technology. SydPath offers services to St. Vincent's Hospital and St Vincent's Private Hospital, General practitioners, Specialists, Private and Public sector laboratories and Hospital research programs. SydPath also provides specialised services tailored to the needs of the pharmaceutical and biotechnology industries for their clinical trial & research programs.

EasyScreen™ STI Genital Pathogen Detection Kit

Multiplex Pathogen Screening of Sexually Transmitted Infections



**1 MILLION+ STIs
CONTRACTED DAILY***

Overview

- STIs impact sexual and reproductive health
- New EasyScreen™ STI Genital Pathogen Detection Kit screens **12 causes** of STI infections
- **Multiple targets detected** in one workflow solution
- Unique **3base™** platform delivers **results in hours**, not days
- Joint STI detection research conducted with **St Vincent's Pathology** in 2016

EasyScreen™ STI Genital Pathogen Detection Kit

<i>C. trachomatis</i> <i>N. gonorrhoeae</i> LGV	<i>M. genitalium</i> <i>T. vaginalis</i> <i>Ureaplasma spp.</i>	<i>Candida spp.</i> <i>M. hominis</i> <i>S. agalactiae</i>	<i>T. pallidum</i> HSV-1 HSV-2
Panel A	Panel B	Panel C	Panel D

3base™ technology reduces complexity and enhances detection using standard procedures

Results from 846 Specimens Tested

Pathogen Detected	EasyScreen™	Conventional Methods
<i>C. trachomatis</i>	48	42
<i>N. gonorrhoeae</i>	17~	17~
LGV	1	Not tested
<i>M. genitalium</i>	10	Not tested
<i>T. vaginalis</i>	8	4
<i>Ureaplasma spp.</i>	296	Not tested
<i>Candida spp.</i>	153	95
<i>M. hominis</i>	71	Not tested
<i>S. agalactiae</i>	98	51
<i>T. pallidum</i>	2	Confirmed by reference lab
HSV-1	32	25
HSV-2	19	15
Total	755	249

~Excluding Throat Swabs

Outcomes

Screening for 12 STIs

EasyScreen™ STI Genital Pathogen Detection simultaneously screens for 12 common STIs using 3base™ extraction

755 vs 249

EasyScreen™ STI Genital Pathogen Detection vs conventional methods

25.1% Mixed Infection

>2 Pathogens detected in 25.1% of samples

Multiple Health Benefits

Faster results, drives health system value and improves patient outcomes

US\$550M

Addressable STI detection market (2017)^

EasyScreen™ STI Genital Pathogen Detection Kit is currently for Research Use Only (RUO)

For more information on the Genetic Signatures product range, or the underlying 3base™ technology please contact us:

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

^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.