Preliminary Results of Genetic Signatures' *EasyScreen™* Sexually Transmitted Infection Detection Kit Clinical Validation Trial to be Presented Today

- **Results show 100% concordance with traditional and confirmatory methods**
- ***EasyScreen*™ Sexually Transmitted Infection (STI) Detection Kit offers testing for an increased number of disease targets compared to traditional workflows**
- **Preliminary Results to be presented at the NRL molecular diagnostics workshop, which is an annual meeting of opinion leaders from pathology testing laboratories**
- **Further progress made toward market release of the *EasyScreen™* Sexually Transmitted Infection (STI) Detection Kit**

Sydney, Australia, 18 October 2016: Molecular diagnostics company Genetic Signatures Ltd (ASX: GSS) is pleased to announce that the preliminary results of a clinical validation trial of the Company's ***EasyScreen*™ Sexually Transmitted Infection (STI) Detection Kit** will be presented today at the NRL Molecular Diagnostics Workshop in Melbourne, Australia. The presentation, entitled "*Evaluation of a new 3Base™ Assay for Screening of Sexually Transmitted Infections*" will be given by Dr. Damien Stark of St. Vincent's Hospital (SydPath).

The NRL Molecular Diagnostics Workshop is a leading forum for scientists, regulators, test kit manufacturers and clinicians to meet and discuss current issues and new technologies occurring in the world of molecular pathology for infectious diseases.

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[1]. The ***EasyScreen*™ STI Detection Kit** was designed to cater for the large addressable STI testing market, estimated to be US $550M in 2017[2].

The clinical validation results have shown that the ***EasyScreen*™ STI Detection Kit** allowed the simultaneous identification of 12 of the most significant and commonly encountered STIs with 100% concordance with traditional and confirmatory methods. It was shown the assay offered improved accuracy and sensitivity (true positive detection), and additional STI pathogens were identified over existing testing techniques.

"*We are very pleased with these results.*" said John Melki PhD, CEO of Genetic Signatures. "*The rate of STI co-infection is high, and this trial showed that 25.9% of the patient samples had mixed infections (≥2 pathogens detected). These high rates of co- and mixed infections require an assay that can simultaneously screen for a large number of disease targets. As the assay performed so well in this trial we feel confident we have achieved this aim and can now progress toward regulatory approval and market release.*"

[1] http://www.who.int/mediacentre/factsheets/fs110/en/

[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

SydPath is a fully accredited registered pathology laboratory service located within the St Vincent's Hospital Campus, and an existing customer of the company's ***EasyScreen™*** **products** that screen for a wide range of infectious agents including viral, bacterial and protozoan agents.

SydPath Senior Hospital Scientist Dr Damien Stark commented on the results saying that: "*The* **EasyScreen™ *STI Detection Kit*** *allows simultaneous detection of more STIs than our current methodologies and algorithms. The Genetic Signatures STI test could be easily integrated into our current* EasyScreen™ *workflow and would allow us to consolidate our STI screening methods. We look forward to completing the study and publishing these results*."

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

Company	**Media and Investor Relations**
John Melki **Chief Executive Officer** john@geneticsignatures.com T: +61 2 9870 7580	**Peter Taylor** **Investor Relations** peter@nwrcommunications.com.au T: +61 412 036 231

About Sexually Transmitted Infections: The WHO has reported that each year, there are an estimated 357 million new infections with one of four 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

[3] 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 and research programs.

About NRL: NRL was established in 1985 as part of the Australian Government's HIV/AIDS Strategy, to evaluate HIV tests and adjudicate on the interpretation of HIV test results. Today, NRL remains a not-for-profit scientific organisation that exists for the benefit of the public. Its overall goal is to support laboratories, in Australia and internationally, that perform testing for the diagnosis and management of human infectious disease. NRL is designated a WHO Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections.