**Genetic Signatures gains FDA Listing for *EasyScreen™* Sample Processing Kit**

- **First regulatory step towards full product suite commercialisation in US**
- **Enables US sales of the kit to broad customer base**

**Sydney, Australia, 22 July 2015:** Molecular diagnostics company Genetic Signatures (ASX: GSS) today announced it has received a United States Food and Drug Administration (FDA) listing for it's clinical sample concentrator, the *EasyScreen*™ Sample Processing Kit (SP001). The FDA listing means that the company can legally sell it's *EasyScreen*™ Sample Processing Kit in the US, a first step in the further release of other *EasyScreen™* products planned for US markets.

Genetic Signatures proprietary *EasyScreen™* Sample Processing Kit rapidly isolates nucleic acids (DNA and RNA) from primary clinical specimens and is used with automated purification systems commonly found in diagnostic laboratories. The purified nucleic acids are compatible with our *EasyScreen™* Detection Kits, which facilitate rapid detection of common pathogens, such as those that cause gastroenteritis.

The FDA listing required a detailed revision of the Genetic Signatures' Quality Management System, to enable compliance with the FDA Quality System Regulation for Good Manufacturing Practice.

Genetic Signatures' Chief Executive Officer, John Melki, PhD said: "This is a significant first step forward along the path to commercialising our full product range in the US, the largest single diagnostics market in the world. The *EasyScreen*™ Sample Processing Kit easily integrates with existing diagnostic equipment allowing streamlined preparation of nucleic acids directly from a primary specimen, providing the customer with valuable workflow efficiencies. Importantly, it also provides for consistent results within and between laboratories inspiring confidence in the product and the *EasyScreen™* brand."

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

| **Company** | **Media and Investor Relations** |
|---|---|
| **John Melki, PhD**<br>**Chief Executive Officer**<br>john@geneticsignatures.com<br>T: +61 2 9870 7580<br><br>**Robert Birrell**<br>**Chief Financial Officer**<br>rob@geneticsignatures.com<br>T: +61 2 9870 7580 | **Peter Taylor**<br>**Investor Relations**<br>peter@nwrcommunications.com.au<br>T: +61 412 036 231 |

**About the EasyScreen™ Sample Processing Kit (SP001):** The EasyScreen™ Sample Processing Kit (SP001) is designed to rapidly isolate nucleic acids (DNA and RNA) from clinical samples (or bacterial culture), via an automated purification system. The nucleic acids are converted into 3base™ sequences prior to purification and are suitable for use with all *EasyScreen™* pathogen detection kits. The *EasyScreen™* Sample Processing Kit is currently optimised to isolate nucleic acids from stool samples, or bacterial culture. The kit is also being optimised for use with a range of other clinical sample types and diseases.

The *EasyScreen™* Sample Processing Kit is compatible with most commonly found automated nucleic acid purification systems. The *EasyScreen™* pathogen detection kit range incudes kits for comprehensive detection of bacterial, viral and protozoan causes of gastroenteritis, including hypervirulent *C. difficile* in stool specimens, and respiratory viruses from respiratory swabs in viral transport media. Kits for the detection of Respiratory Bacteria, MRSA, Viral & Bacterial Meningitis, Tuberculosis, and Sexually Transmitted Infections are also in development.

**About FDA Clinical Sample Concentrator Listing**: The US Food and Drug Administration (FDA) requires that sample preparation products used for clinical diagnostic applications from human samples be classified as clinical sample concentrators under the US Code of Federal Regulations pertaining to medical devices (21 CFR 862.2310). A clinical sample concentrator is a device intended to concentrate (by dialysis, evaporation, etc.) serum, urine, cerebrospinal fluid, and other body fluids before the fluids are analyzed, and is classified by the FDA as a class I device. The FDA requires registration and listing of sample preparation products that are part of systems for human diagnostics, if such products are used by a sponsor of a submission as front end and/or used by customers for clinical diagnostic use.[1]

**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™. Founded in 2001 by the late Dr Geoffrey Grigg, the former Chief of Molecular Biology at CSIRO, Genetic Signatures has released a suite of real-time Polymerase Chain Reaction (PCR) based products for the routine detection of infectious diseases under the EasyScreen™ brand. MDx is a modern technique increasingly used by hospitals and pathology laboratories to detect specific sequences of the genome, the DNA or RNA that define an organism. 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. As the spread of infectious diseases around the world continues to grow, the Company plans to launch additional products for the detection of pathogens associated with MRSA, sexual health infections, tuberculosis and meningitis.

[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=862.2310