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US FDA gives clearance to Australia's gastrointestinal parasite detection kit

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Australia-based Genetic Signatures has announced that the US Food & Drug Administration has cleared the company's *EasyScreen* Gastrointestinal Parasite Detection Kit and GS1 automated workflow for marketing and sale in the US.

Genetic Signatures' *EasyScreen* Gastrointestinal Parasite Detection Kit has the broadest coverage of the FDA cleared molecular tests and is able to identify 8 of the most common and clinically relevant gastrointestinal parasites in a single test, representing approximately 90% of all gastrointestinal Parasitic infections in the US.

Gastrointestinal Parasite Detection Kit is highly automated and is able to provide a result for all 8 targets in approximately 5 hours.

The current practice for gastrointestinal parasite testing is predominantly microscopic examination using O&P testing (stool ova and parasite), that is time-consuming, labour intensive, slow to provide a result, of variable sensitivity and frequently has poor patient compliance across multi sample protocols. It is estimated there are approximately 65 million annual cases of parasitic gastrointestinal infections in the US which result in approximately 5.5 million O&P tests each year.

Genetic Signatures is well-prepared for the commercial launch of its *EasyScreen* Gastrointestinal Parasite Detection Kit. The company has installed instruments and completed training at nine customerÃ¢â?¬â??experience sites which span a range of customer groups including hospitals, health departments and corporate pathology providers under a customer-experience programme.

The company has received positive feedback from these sites and expects some will become the initial commercial customers. Genetic Signatures expects first commercial sale of the kit in the US within 60 – 90 days of this clearance once appropriately packaged and labelled product is available and the company's pathology provider customers have completed their internal technology evaluation and approval process.