

Genetic Signatures Presents Results of Flavivirus Clinical Trial at ECCMID 2017: New Detection Kit Addresses Complex Global Challenge

- **GSS' Chief Scientific Officer presents clinical trial results following 2016 dengue outbreak study to help address complex global challenge**
- **Successful trial uses new pathogen detection kit prototype that simultaneously screens for a variety of Flavivirus/Alphavirus viral families including Zika and West Nile virus**
- **Unique 3base™ technology delivers more accurate detection in hours versus weeks compared with conventional methods**

Sydney, Australia, 24 April 2017: Molecular diagnostics company Genetic Signatures Ltd (ASX: GSS) has presented the clinical trial results of its new Flavivirus detection kit at the prestigious **27th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID)** in Vienna overnight. The trial, which was conducted in partnership with Port Vila Central Hospital, used patient clinical samples following Vanuatu's 2016 dengue outbreak and successfully demonstrates the global potential of the Flavivirus pathogen detection kit, which is in advanced stages of development, in helping prevent the spread of serious infectious diseases such as Zika and West Nile virus.

The *Flaviviridae* are a family of viruses that are found primarily in ticks and mosquitoes and can infect humans, causing widespread morbidity and mortality throughout the developed and developing world. Some of the mosquito-transmitted viruses include: **Yellow Fever, Dengue Fever, Japanese encephalitis, West Nile viruses, and Zika virus**. Other Flaviviruses are transmitted by ticks and are responsible for encephalitis and haemorrhagic diseases¹. Hampering the efforts of the international health community, this complex viral family has many similar variants, making conventional detection methods labour intensive.

Whilst Yellow Fever, Zika and Dengue are more commonly associated with developing parts of the world, other strains of this family are found within the developed regions of Asia, Europe and North America. For example, Murray Valley Encephalitis, Ross River and Barmah Forest are all local Australian variants, whilst the West Nile virus is regularly found in parts of Europe and resulted in 286 deaths following the 2012 Texas epidemic in the US².

To help address this global challenge, Genetic Signatures' Flavivirus pathogen detection kit prototype leverages the company's unique **3base™** technology that is also found in Genetic Signatures' enteric, respiratory and STI product suite currently used by customers around the world.

¹ <https://www.cdc.gov/vhf/virus-families/flaviviridae.html>

² <http://www.austintexas.gov/westnile>

Using existing compatible nucleic acid extraction equipment (or a low cost, easy to install and use robot equivalent) hospital and pathology labs will be able to test for 15 of the most common variants of the Flaviviruses and Alphaviruses, including all four dengue serotypes, in a single real-time polymerase chain reaction (PCR) primer test.

Once the virus family type is determined, a second regional test has been designed for Australia, Asia, Africa, Latin America, America or Europe to then determine the specific viral infection.

“Mosquito and tick borne illnesses are complex and certainly not unique to the developing world,” said John Melki PhD, CEO of Genetic Signatures. “As awareness for Flavivirus related diseases grows, the Genetic Signatures Flavivirus pathogen detection kit, which benefits from the simpler and more effective capabilities of 3base™ technology, will help address this complex global challenge head-on.”

Vanuatu, a South Pacific island nation and international tourism destination, experienced a significant outbreak of dengue fever late last year. With dengue hemorrhagic fever (DHF) having a more than a 20% mortality rate if left untreated³, diagnosis was difficult and time consuming as most samples had to be sent to New Zealand for detection analysis.

“In a 187 patient cohort, our new screening kit detected 123 cases of dengue, of which 116 were confirmed to be serotype 2,” said Dr Doug Millar, Chief Scientific Officer of Genetic Signatures, who presented the promising trial results at ECCMID.

“Furthermore our real-time PCR assay was able to deliver faster results with a high degree of accuracy,” continued Dr Millar. “This provides a high degree of confidence in the results obtained, much quicker patient outcomes and valuable population infection data for future location-based planning and mitigation.”

“Along with the ability to screen for multiple Flavivirus and Alphavirus pathogens in a short space of time, the practical benefits of this new detection kit include saved resources and the opportunity to more rapidly help millions of people around the world and prevent the wider spread of these serious infectious diseases,” said Dr Melki.

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

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About the EasyScreen™ Flavivirus/Alphavirus Pathogen Detection Kit: The *EasyScreen*™ Flavivirus and Alphavirus Detection Kit includes targets for Pan-flavivirus, Pan-alphavirus, Pan-dengue 1-4 (DENV), Zika virus (ZIKV), West Nile virus (WNV), yellow fever virus (YFV), St Louis encephalitis virus (SLEV), tick borne encephalitis virus (TBEV), and Japanese encephalitis virus (JEV) and chikungunya (CHIKV). The *EasyScreen*™ Flavivirus and Alphavirus Detection Kit is currently for Research Use Only (RUO).

³ <http://www.who.int/mediacentre/factsheets/fs117/en/>

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 Flavivirus/Alphavirus: Flavivirus is a genus in the family *Flaviviridae* that contains a large number of viral agents capable of causing encephalitis and jaundice⁴. Most flaviviruses are arboviruses and transmitted to the human population by a bite from infected mosquitoes or ticks. Flaviviruses typically contain a positive sense single-stranded RNA genome of approximately 10-11kb in length. The genome encodes 3 structural proteins (Capsid, prM, and Envelope) and 8 non-structural proteins (NS1, NS2A, NS2B, NS3, NS4A, NS4B, NS5 and NS5B)⁵. The viruses are enveloped and have a diameter of around 50nm that appear icosahedral or spherical when observed under the electron microscope⁶. Individual members such as dengue, yellow-fever virus, Japanese encephalitis virus, tick-borne encephalitis virus and West Nile virus cause significant morbidity and mortality worldwide.

About Port Vila Central Hospital: Port Vila Central Hospital is the principal hospital serving Efate, Vanuatu, near the capital of Port Vila. Situated on a hillside overlooking the lagoon, it has over 200 beds and six full-time doctors, with four wards (medical, surgical, paediatric and maternity), two theatres, a radiology department (with ultrasound) and a busy outpatients unit.

About ECCMID: The 27th European Congress of Clinical Microbiology and Infectious Diseases takes place in Vienna, Austria, from 22 - 25 April 2017. The annual congress brings together the world's leading experts to discuss the latest developments in infectious diseases, infection control and clinical microbiology.

⁴ Shi, P-Y (editor) (2012). *Molecular Virology and Control of Flaviviruses*. Caister Academic Press. ISBN 978-1-904455-92-9

⁵ Quantitative real-time PCR detection of Zika virus and evaluation with field-caught Mosquitoes. Oumar Faye, Ousmane Faye, Diawo Diallo, Mawlouth Diallo, Manfred Weidmann and Amadou Alpha Sall. *Virology Journal* 2013, 10:311.

⁶ http://viralzone.expasy.org/all_by_species/24.html

EasyScreen™ Flavivirus/Alphavirus Detection Kit

Multiplex Pathogen Screening of Flavivirus and Alphavirus Infections



Dengue (DENV): 400m infections/100m clinical cases in 2010* (>20% mortality rate if dengue hemorrhagic fever untreated**)

West Nile virus (WNV): 286 Deaths in USA following 2012 Texas epidemic^

Yellow Fever Virus (YFV): 29,000–60,000 deaths in Africa in 2013^^

Zika (ZIKV): 2016 South American outbreak linked to microcephaly in newborns

Murray Valley encephalitis (MVE), Ross River (RRV) and Barmah Forest viruses (BFV): Commonly detected in Australia

Overview

- Global challenge: infection from mosquitoes and ticks causes morbidity and death
- Complexity and similarities of Flavivirus and Alphavirus make conventional detection difficult and labour intensive
- New EasyScreen™ Flavivirus/Alphavirus Detection Kit screens for 15 species of Flavivirus and Alphavirus in a single assay
- Joint Flavivirus and Alphavirus detection research conducted with Vila Central Hospital (Vanuatu) in March, 2017

EasyScreen™ Flavivirus/Alphavirus Detection Kit

Pan-Flavivirus		Pan-Alphavirus			Pan-Dengue	
Secondary regional specific test						
Australia	Asia	Africa	Latin America	America	Europe	

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



Results from 187 Vanuatu Specimens Tested



Virus Detected	Results	% of specimen
Pan-Flavivirus	116	62
Pan-Alphavirus	0	0
Pan-Dengue	123	66
Dengue 2	116	62
Dengue not typed* (weak positives)	7	3.2
Negative	64	34

EasyScreen™ Flavivirus/Alphavirus Detection Kit is currently for Research Use Only (RUO)

Outcomes



Screening for a range of Flavivirus and Alphavirus Viral Families

EasyScreen™ Flavivirus/Alphavirus Detection Kit simultaneously screens for 15 species of Flavivirus and Alphavirus (including four dengue serotypes) in single assay using 3base™ extraction



123 Cases Detected

EasyScreen™ Flavivirus/Alphavirus assay detected 123 pan-dengue infections delivering results in 2-4 hours versus 2-4 weeks of conventional methods



Single Simplified Approach

Single primer test detects all members of the Flavivirus/Alphavirus viral family saving time and money



Faster results drive health system value and improve patient outcomes

Faster results drive health system value and improve patient outcomes



Rapid Detection

New outbreak strains can be monitored and population infection data collected for global epidemic planning and mitigation

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

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* <http://www.cdc.gov/nndss/conditions/dengue-virus-infections/case-definition/2015/> ** <http://www.who.int/mediacentre/factsheets/fs117/en/> ^ <http://www.austintexas.gov/westnile>

^^ <http://www.who.int/mediacentre/factsheets/fs100/en/>