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Singapore Health approves Zika test by Vela Diagnostics

09 February 2018 | News

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Singapore Health Sciences Authority has recently given approval to the Real-Time PCR-based Sentosa SA ZIKV RT-PCR Test by Vela Diagnostics, for in vitro diagnostic use.

In August 2016, Vela's Zika panel received CE-IVD status, and then received Emergency Use Authorization from the US Food and Drug Administration (USFDA) in September 2016.

More recently, Vela received approval from the Taiwan Food and Drug Administration for its liquid handling platform.

The firm's test, which detects Zika in samples with a low viral load, can now be used in Singapore to identify and differentiate Zika in patients suspected to suffer from Zika infections. The test is validated for plasma, serum, and urine samples, alongside patient-matched serum or plasma.

The test can process 22 samples to detect up to 82 Zika virus strains in three hours using the firm's Sentosa SX Virus Total Nucleic Acid Kit v2.0. The test has a limit of detection of 3 x 103 copies/mL for the ZIKV PRAVBC59 gene and 6 x 103 copies/mL for the ZIKV MR-766 gene.