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FDA Grants De Novo Designation to Vela Diagnostics' NGS HIV-1 Genotyping Assay

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Vela Diagnostics' Sentosa® SQ HIV-1 Genotyping Assay is the first FDA De Novo designated Next Generation Sequencing (NGS) assay for detecting HIV-1 drug resistance mutations (DRMs).

Vela Diagnostics announced on 5 Nov 2019, that it has received FDA authorization to market its *in vitro* diagnostic test for the detection of HIV-1 genomic drug resistance mutations (DRMs). The *Sentosa*® SQ HIV-1 Genotyping Assay uses the plasma of patients infected with HIV-1 to detect HIV-1 Group M DRMs in the protease, reverse transcriptase, and integrase regions of the *pol* gene, in a single test. It is the first and only HIV-1 genotyping NGS assay currently available on the market to receive marketing authorization from the FDA.

"The granting of the De Novo designation of our NGS assay by the U.S. FDA is a major milestone in HIV diagnostics. VELA strives to bring relevant products to clinicians to help patients around the world. With the *Sentosa*® SQ HIV-1 Genotyping Assay, laboratories will now have a sample-to-report solution to aid in monitoring and treating HIV-1 infection," said Sam Dajani, acting CEO & Chairman of the Board.

The *Sentosa*® SQ HIV-1 Genotyping Assay is validated on the *Sentosa*® NGS workflow that enables automated RNA extraction, PCR setup, library construction, template preparation, sequencing, data analysis, and automated reporting. The workflow also offers clear sample traceability, with seamless LIS integration and connectivity.

Using a standalone version of the curated Stanford University HIV Drug Resistance Database to ensure traceability of the DRM interpretation report, the system generates a clinical interpretation report that provides information on drug resistances associated with the detected mutations.

Compared to Sanger bi-directional sequencing and other non-automated NGS alternatives, the *Sentosa*® SQ HIV-1 Genotyping Assay utilizing the *Sentosa*® NGS workflow is highly sensitive and delivers clinically relevant results with reduced hands-on time (<2 hours combined), and turnaround time (2 days).

The resistance of HIV-1 to antiretroviral drugs as a result of DRMs is the most common cause of therapeutic failure in patients with HIV-1 infection. The detection and reporting of DRMs are crucial for optimal selection of Highly Active Antiretroviral Therapy (HAART) regimens and can prevent or minimize the development of resistance to antiviral drugs. The World Health Organization (WHO) recommends monitoring and reporting early warning indicators (EWI) of HIV drug resistance as a key component of public health strategy when scaling up antiretroviral therapy.

In 2017, an earlier version of the *Sentosa*® SQ HIV Genotyping Assay received the CE mark and was approved by the TGA (Australian Therapeutic Goods Administration) and HSA (Singapore Health Sciences Authority). In August 2019, the assay received approval from the Thai FDA. In addition to receiving the FDA De Novo designation, the current configuration of the assay is pending review for the CE mark and from the HSA.