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Thermo Fisher next gen sequencing system is for clinical use'

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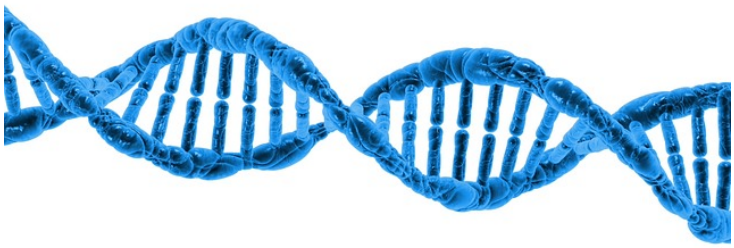

Singapore: Thermo Fisher Scientific's Ion PGM Dx next generation sequencing system has been listed with the US Food and Drug Administration (FDA) for clinical use as a class II medical device.

"Next generation sequencing is rapidly becoming an indispensable tool for clinical laboratories around the world, allowing clinical professionals to simultaneously screen hundreds of genes from patient samples to provide key genetic information and enable patient enrollment within clinical trials," said Mr Mark Stevenson, president, Life Science Solutions at Thermo Fisher Scientific. "The Ion Torrent platform and accompanying reagents provide a number of unique advantages to clinical customers, enabling accurate and reliable genetic variant analysis from more samples due to low DNA input requirements (10ng) and faster turnaround times that reduce the time of sample to result."

The new Ion PGM Dx System is intended for targeted sequencing of human genomic DNA using peripheral whole blood samples, the Ion PGM Dx System supports development and implementation of user defined NGS diagnostic assays in a clinical laboratory and enables 21 CFR Part 11 compliance. The System was validated using a large control panel that contains an extensive number of germline variants that are representative of a range of human conditions, demonstrating the high level of performance achieved by the platform, and required in a clinical environment. When used for diagnostic assay development, customers may define, validate, lock and publish protocols in a role-based workflow for implementation into routine use, from library construction to variant calling.

The Ion PGM Dx System will include the instrument specific library kit, template kit, sequencing kit, and 318 chip, all manufactured under GMP. Based on 200bp chemistry, the library kit will also include barcodes to enable cost effective and flexible processing of up to 16 samples within a single run. The System provides integrated data analysis software for sample and reagent tracking capability, QC metrics, audit trails, and a suite of software controls to aid clinical laboratories in maintaining high performance standards with the implementation of each new assay.

"The development of the Ion PGM Dx System is representative of our continued commitment to enable our clinical customers to develop new molecular diagnostic assays within the rapidly changing regulatory environment," said Mr Stevenson. "This new addition builds upon our growing line of Thermo Fisher Scientific's diagnostic platforms for genetic analysis including the Applied Biosystems 3500 Dx Series Genetic Analyzers and Applied Biosystems QuantStudio Dx Real-Time PCR instrument. As we look to the future, we plan to continue investing in our Ion PGM Dx System by enhancing user defined NGS diagnostic assay capabilities and by providing an expanded menu of clinically focused IVD diagnostic NGS assays for our customers, with an emphasis on oncology."