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Next-Generation Sequencing Tool Gets FDA Nod

Thermo Fisher Scientific Inc.'s (MA, USA) Ion PGM Dx next-generation sequencing system is now listed with the US Food and Drug Administration (FDA) as a class II medical device suitable for clinical use, according to a news report from *PharmaAsia*.

Next-generation sequencing (NGS) is a high-throughput DNA sequencing method that allows clinical professionals to simultaneously screen hundreds of genes from patient samples to provide key genetic information and enable patient enrollment within clinical trials. NGS is increasingly becoming an indispensable tool for clinical laboratories across the globe, as it provides accurate results at reduced costs compared to other genome sequencing technologies.

The new Ion PGM Dx System is specifically designed to meet the growing needs of the clinical laboratory. “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,” said Mark Stevenson, president of Life Science Solutions at Thermo Fisher Scientific.

Intended for targeted sequencing of human genomic DNA using peripheral whole blood samples, the Ion PGM Dx System supports reliable development and implementation of user-defined NGS diagnostic assays in a clinical laboratory and enables 21 CFR Part 11 compliance, *PharmaAsia* reported.

Integrated Data Analysis Software

The Ion PGM Dx 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 report said.

To test the new system's performance, the tool was validated using a large control panel containing an extensive number of germline variants that are representative of a range of human conditions and required in a clinical environment. When used for diagnostic assay development, users may define, validate, lock and publish protocols in a role-based workflow for implementation into routine use, from library construction to variant calling, Thermo Fisher Scientific explained.

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, Thermo Fisher Scientific said.

“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,” Stevenson said. “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."

Source: PharmaAsia.com
Image Credit: Thermo Fisher Scientific Inc.

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