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Thermo Fisher Scientific Announces Its Ion PGM Dx Next Generation Sequencing System is Now CE-Marked for In Vitro Diagnostic (IVD) Use

CARLSBAD, Calif.--(BUSINESS WIRE)--Thermo Fisher Scientific today announced the successful CE-IVD registration of its new Ion PGM Dx System for sale in European countries. The Ion PGM Dx System was developed using the proven Ion Torrent next generation sequencing (NGS) technology, currently used to produce hundreds of thousands of tests in clinical research laboratories each year to uncover meaningful genetic information for a range of human conditions.

> “Providing accurate and reliable genetic variant analysis with as little as 10ng of sample DNA, and with the rapid turnaround times required in clinical settings, we anticipate the Ion PGM Dx will bring many benefits to the European clinical and diagnostic communities.”
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“The CE-IVD registration of the Ion PGM Dx System will enable European clinical laboratories to more easily develop and implement new next-generation sequencing diagnostic assays in accordance with the European Directive on In Vitro Diagnostic Medical Devices,” said Mark Stevenson, President of Life Sciences Solutions at Thermo Fisher Scientific. “Providing accurate and reliable genetic variant analysis with as little as 10ng of sample DNA, and with the rapid turnaround times required in clinical settings, we anticipate the Ion PGM Dx will bring many benefits to the European clinical and diagnostic communities.”

The Ion PGM Dx System was validated using a number of challenging germline variants with library kits based on the trusted Ion AmpliSeq technology. To support the accuracy and reproducibility performance requirements of clinical laboratories, the complete Ion PGM Dx System includes the instruments, GMP reagents, and software controls necessary to establish high-performing next-generation clinical sequencing workflows.

The company is prepared to accept orders for the system in Europe and plans to begin fulfilling orders this calendar year.

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Thermo Fisher Scientific Inc. is the world leader in serving science, with revenues of $17 billion and 50,000 employees in 50 countries. Our mission is to enable our customers to make the world healthier, cleaner and safer. We help our customers accelerate life sciences research, solve complex analytical challenges, improve patient diagnostics and increase laboratory productivity. Through our four premier brands – Thermo Scientific, Life Technologies, Fisher Scientific and Unity Lab Services – we offer an unmatched combination of innovative technologies, purchasing convenience and comprehensive support. For more information, please visit www.thermofisher.com.

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