MediaRoom

New Expanded Analytical Instrument Portfolio of U.S. FDA Class I Medical Devices for Clinical Diagnostic Laboratories

Thermo Scientific Medical Device portfolio provides an extensive range of chromatography and mass spectrometry instruments for performing laboratory developed tests

ANAHEIM, Calif., Aug. 6, 2019 /PRNewswire/ -- AACC 2019 – Thermo Fisher Scientific has expanded its portfolio of analytical instruments for clinical diagnostic laboratories with the addition of three systems now listed as Class I medical devices with the United States Food and Drug Administration (U.S. FDA). The portfolio enables clinical diagnostic laboratories to leverage a comprehensive platform for developing sensitive and reliable laboratory developed tests (LDTs).

The Thermo Scientific Medical Device (MD) portfolio of liquid chromatography-mass spectrometry (LC-MS) systems now includes the single-channel Thermo Scientific Vanquish MD High Performance Liquid Chromatography (HPLC) system, the enhanced sensitivity of the Thermo Scientific TSQ Altis MD Series mass spectrometer, and the Thermo Scientific Quantis MD Series mass spectrometer for routine testing.

The new systems join the existing dual-channel Thermo Scientific Prelude MD HPLC and four-channel Thermo Scientific Prelude LX-4 MD HPLC systems to form a more complete MD portfolio of analytical solutions. These comprehensive platforms enable clinical laboratories to achieve their desired sensitivity and throughput goals, while conforming to *in vitro* diagnostic (IVD) regulations. The analytical solutions are designed to ensure confidence in laboratory developed tests (LDTs) through a complete suite of LDT-enabled software with a laboratory information system (LIS) option. In addition, the enhanced product portfolio is designed to increase throughput of clinical diagnostic assays for the detection of small to large molecules within complex biological matrices.

Thermo Fisher is showcasing the MD portfolio during the 71st American Association for Clinical Chemistry Annual Scientific Meeting and Clinical Laboratory Exposition (AACC 2019), being held August 4–8, 2019, in Booth #2110 at the Anaheim Convention Center, Anaheim, California.

"Clinical laboratories need the ability to develop and optimize sensitive and reliable laboratory developed tests that are crucial in the diagnosis and monitoring of acute and chronic diseases," said Bradley Hart, senior director, clinical marketing, chromatography and mass spectrometry, Thermo Fisher Scientific. "With the new MD portfolio of Class I medical devices listed with the U.S. FDA, scientists in clinical diagnostic laboratories can now choose from a unique portfolio of liquid chromatography and mass spectrometry platforms to develop assays essential for clinical decision-making."

Designed to bring high-quality analytical performance for LDTs to clinical diagnostic laboratories, the TSQ Altis MD Series and TSQ Quantis MD Series mass spectrometers offer similar throughput for the analysis of human samples, but differ by sensitivity. The Vanquish MD HPLC system is the ideal chromatographic separations system for laboratories where analyte resolution is critical. The small, powerful single channel Vanquish MD HPLC instrument meets analytical needs, as well as space and resource limitations.

The MD portfolio is powered by Thermo Scientific TraceFinder LDT 1.0 Software. Included as standard, the software provides a workflow-oriented approach to high-throughput quantitation, including an administrator console for managing user-based permissions, data repositories, and auditing capabilities. In addition, an optional middleware solution is available to provide bidirectional communication between TraceFinder LDT Software and the LIS.

For more information on the Thermo Fisher solutions exhibited at AACC 2019, please visit www.thermofisher.com/AACC.

For in-vitro diagnostic use. Specifications subject to change. Not available in all countries.

About Thermo Fisher Scientific
Thermo Fisher Scientific Inc. is the world leader in serving science, with revenues of more than $24 billion and approximately 70,000 employees globally. 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, deliver medicines to market and increase laboratory productivity. Through our premier brands – Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific and Unity Lab Services – we offer an unmatched combination of innovative technologies, purchasing convenience and comprehensive services. For more information, please visit www.thermofisher.com.

Media Contact Information:

Laura Bright
Thermo Fisher Scientific
+1 562-335-8318
laura.bright@thermofisher.com

Ronan Muir
BioStrata
+44 (0) 1223 627133
rmuir@biostratamarketing.com

SOURCE Thermo Fisher Scientific

Additional assets available online: Photos (3)

https://thermofisher.mediaroom.com/2019-08-06-New-Expanded-Analytical-Instrument-Portfolio-of-U-S-FDA-Class-I-Medical-Devices-for-Clinical-Diagnostic-Laboratories