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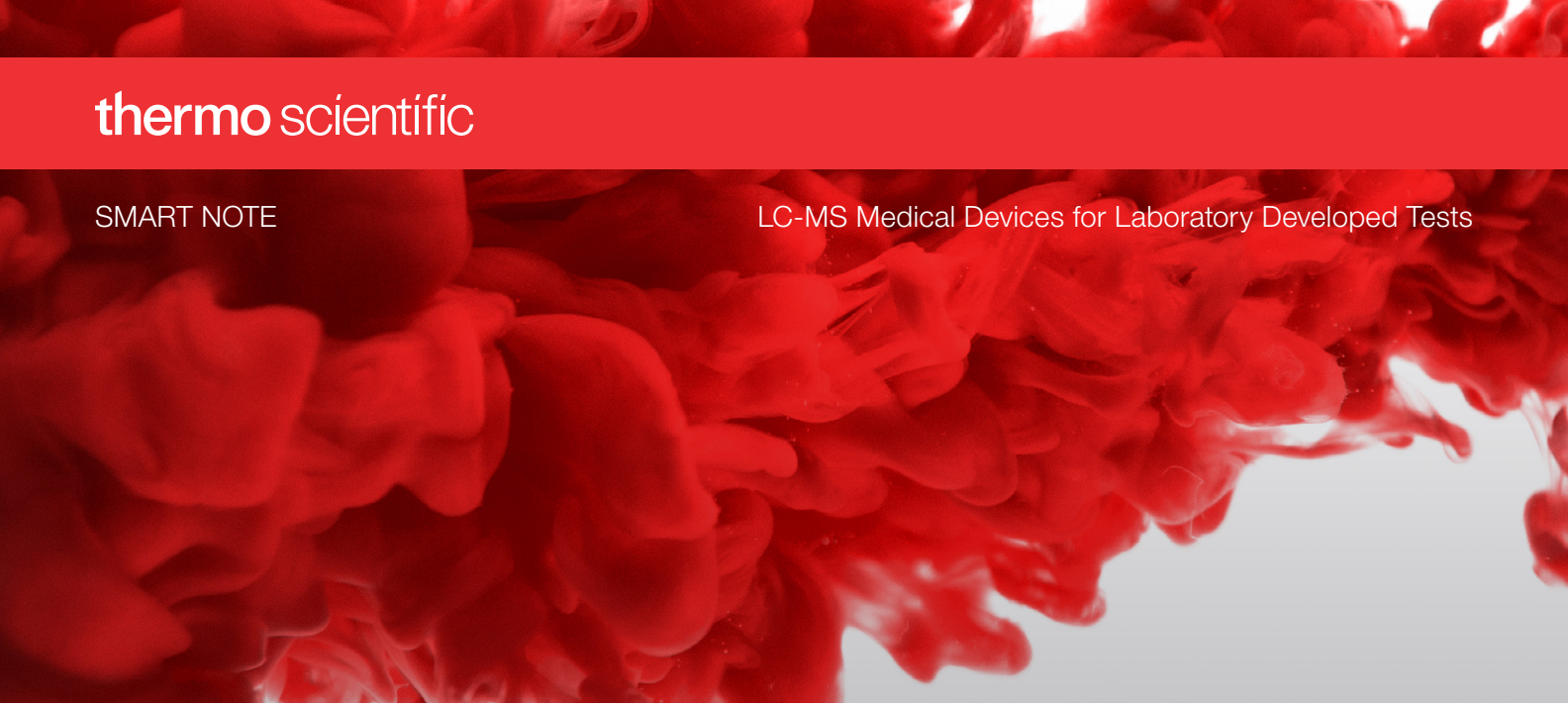
SMART NOTE

LC-MS Medical Devices for Laboratory Developed Tests



5 REASONS

Five reasons to implement LC-MS platforms for your laboratory developed tests

Technological advancements in Liquid Chromatography (LC) coupled to Mass Spectrometry (MS) technology, especially in the last decade, have opened several options to leverage this technology in the clinical diagnostic laboratory arena. Hence, from the analysis of acylcarnitines and amino acids in neonatal blood spots during the early 90s, LC-MS technology is now being used for other applications, such as endocrinology, toxicology, pharmacology, and therapeutic drug monitoring. The use of LC-MS for laboratory developed tests (LDTs) is gaining interest as the need for fast, accurate analyses is on the rise.

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LC-MS for lab developed tests

LC-MS offers several benefits over traditionally used technologies. However, most clinical diagnostic laboratories that are using LC-MS in today's world face some daunting challenges from development, optimization, and implementation of methods to meet the daily requirements of their routine assays to achieving their scientific and business goals. Clinical diagnostic laboratories have very few options when it comes to instruments that are in vitro diagnostic (IVD) compliant and can be used for development and optimization of LDTs.

If an LC offered enough separation capability, it might lack the desired speed or throughput. Similarly, if a certain MS offered enough robustness, it might not deliver the desired sensitivity for every analyte.

In addition, the lack of comprehensive software for method development to report generation, and lack of connectivity to the preferred laboratory information management system (LIMS) can create some additional challenges. The new portfolio of Class I medical devices[1] from Thermo Fisher Scientific aims to bridge these gaps and enable every clinical diagnostic laboratory to achieve their desired success with their LDTs. A lot can be said about this portfolio, however, its critical features and their benefits are summarized below in five concise points.

Time to change—five by five!

1. **Specificity, selectivity, sensitivity:** Compared to traditional immunoassays, LC-MS offers significantly higher specificity and selectivity enabling increased confidence in data accuracy and quantitative efficiency. However, the growing complexities of analytes and matrices demand mass spectrometers to demonstrate i) higher speed (for increased throughput); ii) sufficient sensitivity for everyday routine assays; and iii) enhanced sensitivity for more demanding tests.

   The new portfolio of Class I medical devices offers a choice of triple quadrupole MS with the Thermo Scientific™ TSQ Altis™ MD Series and the Thermo Scientific™ TSQ Quantis™ MD Series. While the TSQ Altis MD Series MS addresses critical sensitivity for challenging analytes, the TSQ Quantis MD Series MS enables achievement of sensitivity necessary for everyday routine clinical assays.

2. **Speed and high throughput capability for increased productivity:** The TSQ Altis MD Series and TSQ Quantis MD Series are fast and they offer selected-reaction monitoring (SRM) with up to 30,000 SRMs definable and up to 600 SRMs/sec. With Increased analytical speed and reliability, the Thermo Scientific(TM) Vanquish(TM) UHPLC system is the ideal chromatographic separations system for laboratories where analyte resolution is critical. The small, powerful system meets analytical needs, as well as space and budget limitations with the throughput, speed and sample capacity to boost workflow productivity for laboratory developed tests.

3. **Comprehensive and flexible platform options:** As described above, clinical diagnostic laboratories face critical challenges where they cannot receive the best of all options (for IVD compliant devices) that can help them achieve their desired goals with their LDTs. In other words, lack of options often coerce users to rely upon the traditional technologies, even though they may not achieve the desired quality of data. The new Class I IVD-compliant medical devices portfolio from Thermo Fisher Scientific aims to bridge this gap—by providing laboratories with a comprehensive and flexible choice of platforms suited to sensitivity and productivity needs, powered by a complete software suite enabling confident results and data integrity.

   Software is the conduit that enables communication between the operator and the LC-MS platform. But having to work with multiple programs, can become extremely challenging, especially so, in a regulated environment.

   The new portfolio of Class I medical devices from Thermo Fisher Scientific is powered by the integral Thermo Scientific™ TraceFinder™ LDT software, which provides a seamless approach to robust, reliable, high-throughput quantitation. TraceFinder LDT software does so by automating and accelerating the processes of creating methods, loading samples, generating data, manually reviewing and editing results, and finalizing the data review and reporting process.

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The B-link LIS/LIMS Connector enables the exchange of compliant LIS system file formats commonly used for test requests and reports.

4. **Connectivity:** A middleware software solution that can facilitate bidirectional communication between acquisition/data processing software and the Laboratory Information System (LIS) is considered to be a must in today's clinical laboratories.

   An optional middleware solution is available as a part of this comprehensive suite of Class I medical devices for LDTs. The B-Link® LIS/LIMS CONNECTOR offers bidirectional communication between TraceFinder LDT software and the LIS.

   The B-link LIS/LIMS Connector enables the exchange of compliant LIS system file formats commonly used for test requests and reports. In this manner, laboratories can manage their data seamlessly while continuing the use of existing LIS/LIMS systems and reporting infrastructures.

5. **Eliminating costs/increasing productivity:** The cost of the antibodies and associated reagents can make performing LDTs by immunoassay expensive. And the more tests performed, the greater the sum of the variable costs. In contrast, the more tests run on an LC-MS system, the lower the fixed cost/test. The question becomes how many tests can be run on an LC-MS system in a given time.

   The Class I IVD-compliant LC-MS instruments from Thermo Fisher Scientific offer the unique ability to not only conduct high throughput LC separation of samples, but also optimize the extent of high throughput MS analysis. The ultra-fast selected reaction monitoring offered by the TSQ Altis MD Series MS and TSQ Quantis MD Series MS (600 SRMs/sec) can enable detection and quantitation of increased number of analytes without increasing the run times.

Conclusion

Analytical results and their quality have an extremely high impact—from understanding the nature and type of disease to deciding the course of treatment. Hence, implementation of a completely new analytical approach to LDTs may not be easy for clinical diagnostic laboratories. Implementing LC-MS requires sufficient justification and commitment of resources but can have a very positive impact on clinical and business goals. It is time to Be Sure of your LC-MS platforms for your LDTs—"with so much riding on something so small, why would you choose anything else?"

Reference

1. Listed with U.S. FDA

Find out more at **thermofisher.com/BeSure**

IVD In Vitro Diagnostic Medical Device

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