

Be sure

LC-MS Medical Devices
for Laboratory Developed Tests

For In Vitro Diagnostic Use



ThermoFisher
SCIENTIFIC

Increase efficiency, productivity, and cost savings

Performing laboratory developed tests by liquid chromatography-mass spectrometry

Comprehensive and reliable LC-MS systems powered by a complete suite of software conforming to in vitro diagnostic (IVD) requirements with an optional laboratory information system (LIS) connection enabling clinical diagnostic laboratories to fulfill scientific and operational needs based on clinical relevance.

Liquid Chromatography-Mass Spectrometry (LC-MS) represents a complementary technology to typically used chemistry and immunoassay and offers greater specificity, speed, and analyte range coupled with a lower cost per sample and reduced sample volumes.

Performing laboratory developed tests (LDTs) by LC-MS enables clinical diagnostic laboratories to replace expensive chemistry or immunoassays run on random-access automated lines with more economic batch testing.

Positive immunoassay screens are typically followed by LC-MS confirmation and quantitation. But where positive rates are high, switching solely to identification and quantitation by LC-MS often makes economic and operational sense.

The need remains for LC-MS medical devices that can meet a range of sensitivity needs along with a need for “middleware” capable of providing bidirectional communication with the Laboratory Information System (LIS).

The portfolio of Thermo Scientific™ LC-MS Medical Devices provides laboratories with a comprehensive and flexible choice of platforms suited to sensitivity requirements, powered by a complete software suite, to ensure confident results and data integrity.

Ease, efficiency, and flexibility for laboratory developed tests

Flexible options to meet sensitivity and throughput needs

The comprehensive portfolio of Thermo Scientific LC-MS Medical Devices for laboratory developed tests offers the clinical diagnostic laboratory a unique choices to address sensitivity needs. This portfolio consists of a High Pressure Liquid Chromatography (HPLC) system and two Mass Spectrometers (MS) differentiated by *sensitivity*:

HPLC system

- Thermo Scientific™ Vanquish™ MD HPLC system

Mass spectrometer options

- Thermo Scientific™ TSQ Quantis™ MD Series triple-stage quadrupole mass spectrometer
- Thermo Scientific™ TSQ Altis™ MD Series triple-stage quadrupole mass spectrometer

In addition, the new portfolio of Thermo Scientific LC-MS Medical Devices for LDTs enables laboratories to:

- Protect investments by addressing *in vitro* diagnostic requirements
- Eliminate the need to purchase additional software by including Thermo Scientific™ TraceFinder™ LDT software
- Overcome the limitation of manual data entry with an *optional* bi-directional LIS connection



Thermo Scientific LC-MS Sensitivity	Vanquish MD HPLC System
TSQ Altis MD Series Mass Spectrometer	Enhanced sensitivity with good throughput
TSQ Quantis MD Series Mass Spectrometer	Outstanding separation and good throughput meeting sensitive requirements for everyday use

Addressing *in vitro* diagnostic requirements

Protecting today's investment for tomorrow's testing



LC-MS Medical Device Usage	Liquid Chromatography System	Mass Spectrometers	
	Vanquish MD HPLC System	TSQ Altis MD Series Mass Spectrometer	TSQ Quantis MD Series Mass Spectrometer
Intended Use	General purpose laboratory instruments intended to separate drugs or compounds in human specimens. For <i>in vitro</i> diagnostic use only by trained, qualified laboratory personnel.	Intended to identify and quantify inorganic and organic compound in human specimens. For <i>in vitro</i> diagnostic use only by trained, qualified laboratory personnel.	
Indications for Use	Used by clinical diagnostic laboratories as a component of a LDT method or workflow.	Used by clinical diagnostic laboratories as a component of a LDT method or workflow.	
Contraindications of Use	For <i>in vitro</i> diagnostic tests only. The Vanquish MD HPLC is to be operated only with hardware or software approved for <i>in vitro</i> diagnostic application.	For <i>in vitro</i> diagnostic applications only. The TSQ Altis MD Series and TSQ Quantis MD Series mass spectrometers are to be operated only with hardware or software labeled for <i>in vitro</i> diagnostic use.	
Limitations of Use	Compatible with the following instruments from Thermo Fisher Scientific: TSQ Altis MD Series mass spectrometer and TSQ Quantis MD Series mass spectrometer.	Compatible with the following instrument from Thermo Fisher Scientific: Vanquish MD HPLC.	

As a component of an LDT method or workflow, validation of the LDT method or workflow is the responsibility of the clinical laboratory.

Benefits of choosing LC-MS for laboratory developed tests

Superior specificity, selectivity, sensitivity: Compared to traditional immunoassays, LC-MS enables accurate results, thus reducing false positives or negatives

Fast speed and high throughput capability: Enable faster turnaround time in clinical laboratories

Comprehensive and flexible: Allows spontaneous detection of multiple analytes in the same run

Cost Savings and increased productivity: Compared with immunoassay, LC-MS methodology reduces costs associated with testing kits and consumables and sample and potential labor costs


Reasons to choose Class I medical devices

Compliance: Hardware manufactured follows ISO 13485 and FDA 21 CFR 820 standards; dedicated, integral LDT software for clinical workflow and auditing capability


Regulatory trends: Global clinical diagnostics market is trending towards LC-MS devices conforming to FDA and EU regulation to perform LDTs

Connectivity: A middleware software (B-Link® Universal LIS/LIMS Connector) for bidirectional communication between acquisition/data processing software and the Laboratory Information System (LIS)

Risk control: Thorough validation and verification process; Medical device-certified engineer for service; quality tracking in place to ensure the highest instrument performance



Our family of liquid chromatography-mass spectrometry (LC-MS) instruments for *in vitro* diagnostics provides clinical labs with consistent reliable results, and faster turn around time. These comprehensive LC-MS platform solutions enable accurate results, facilitate cost savings, and allow clinical laboratories to achieve organizational and scientific goals while ensuring confidence in results of LDTs.



Choose from a unique portfolio of compatible LC-MS medical devices for LDTs

A unique choice of flexible options to meet a wide range of sensitivity and productivity needs for LDTs

Vanquish MD HPLC System

The powerful, robust single channel Vanquish MD HPLC system, with a smaller footprint and excellent reproducibility, meets analytical needs, as well as space and budget limitations.

TSQ Series II Altis MD and TSQ Series II Quantis MD Software

An integral component of the TSQ Altis MD Series and TSQ Quantis MD Series mass spectrometers, which is used to “tune” the mass spectrometer, enable diagnostic capabilities, and develop test methods.



TSQ Altis MD Series Mass Spectrometer

Provides enhanced sensitivity for demanding quantitative analyses with remarkable speed and robustness. The TSQ Altis MD Series mass spectrometer is used by clinical diagnostic laboratories to address their more sensitive requirements for laboratory developed tests.



TSQ Quantis MD Series Mass Spectrometer

Provides the sensitivity needed for routine quantitative analyses with remarkable speed and robustness. The TSQ Quantis MD Series mass spectrometer is used by clinical diagnostic laboratories to meet their routine requirements for laboratory developed tests.

TraceFinder LDT Software

An integral component of the TSQ Altis MD Series mass spectrometer and TSQ Quantis MD Series mass spectrometer, which is used to run samples, acquire and process data, as well as generate reports.



LINK B

The B-Link Connector

Optional downloadable software package capable of providing bi-directional communication between TraceFinder LDT software and the preferred LIS or other middleware. Installed on the same computer as TraceFinder LDT software.



Vanquish MD HPLC System

Better separation, accuracy, and ease-of-use

The Vanquish MD HPLC 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.

- Increased analytical speed and reliability—necessary for targeted quantitation analyses performed by clinical laboratories focused on laboratory developed tests
- Increased flexibility—industry leading 2×3 solvent channels for maximized method flexibility
- Increased confidence—excellent flow accuracy and precision by ultra-precise piston drives
- Outstanding robustness—enabled by highest system up-time and low total cost of ownership



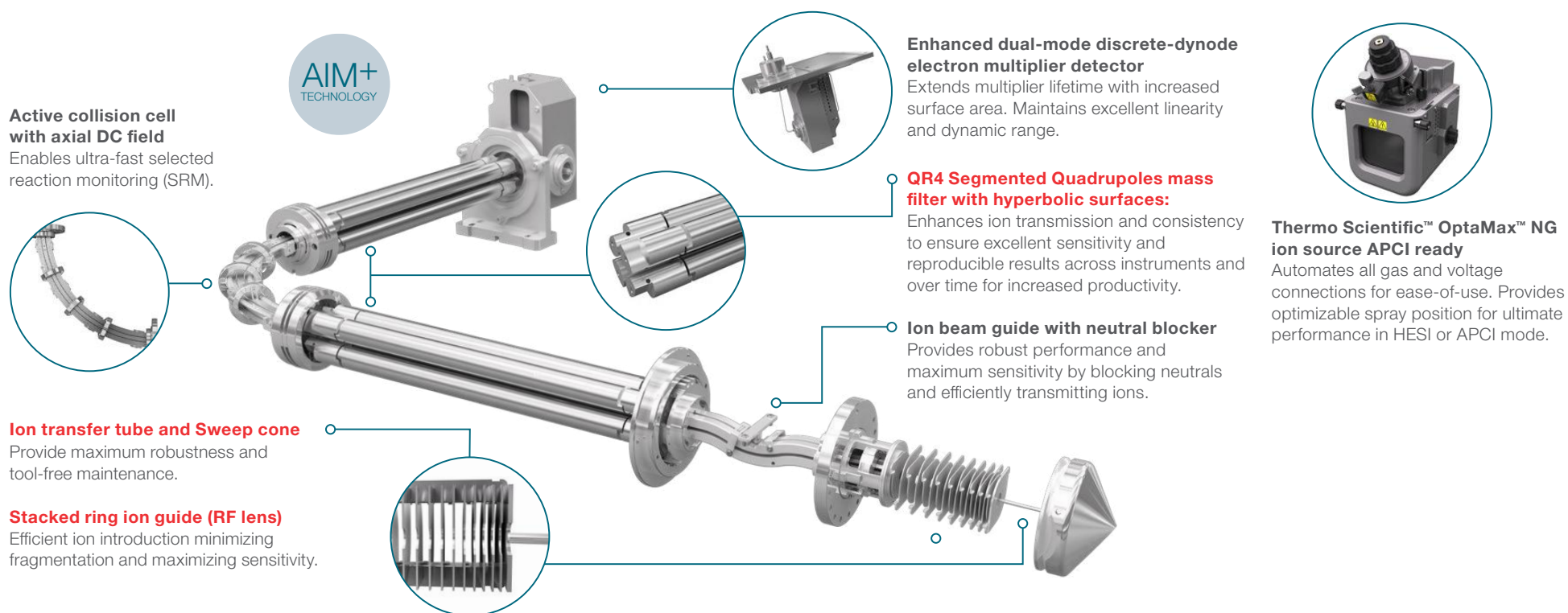


TSQ Quantis MD Series mass spectrometer

IVD compliance with sensitivity, remarkable speed,
and robustness for routine laboratory developed tests

The TSQ Quantis MD Series triple-stage quadrupole mass spectrometer offers the sensitivity needed for routine, everyday quantitative analyses together with remarkable speed and robustness. The TSQ Quantis MD Series mass spectrometer will be used by clinical diagnostic laboratories to meet their routine requirements for laboratory developed tests.

With Thermo Scientific™ Active Ion Management (AIM+) technology, the TSQ Quantis MD Series confidently delivers routine analyses day after day.



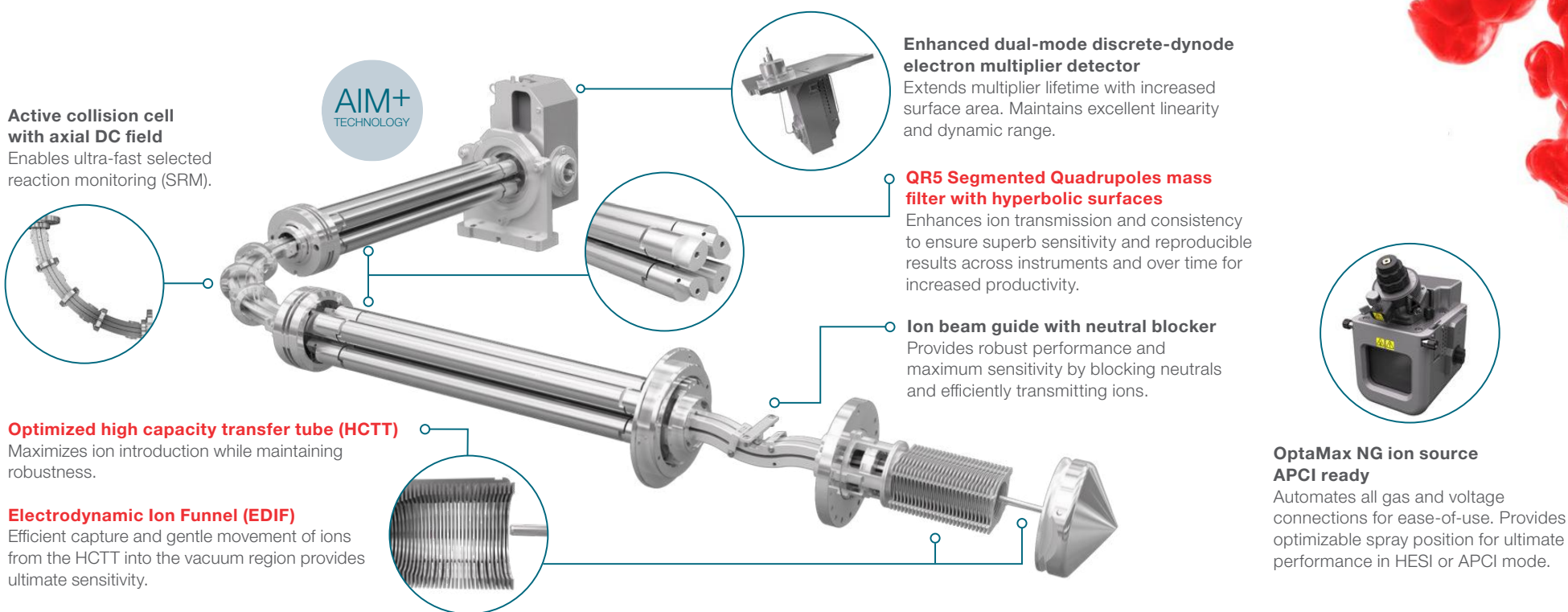


TSQ Altis MD Series mass spectrometer

Enhanced sensitivity with remarkable speed and robustness for laboratory developed tests

The TSQ Altis MD Series triple-stage quadrupole mass spectrometer offers enhanced sensitivity for demanding quantitative analyses together with remarkable speed and robustness. The TSQ Altis MD Series will be used by clinical diagnostic laboratories to address their more sensitive requirements for laboratory developed tests.

With AIM⁺ technology, the TSQ Altis MD Series confidently delivers ultimate performance in human specimens at low levels of analyte.

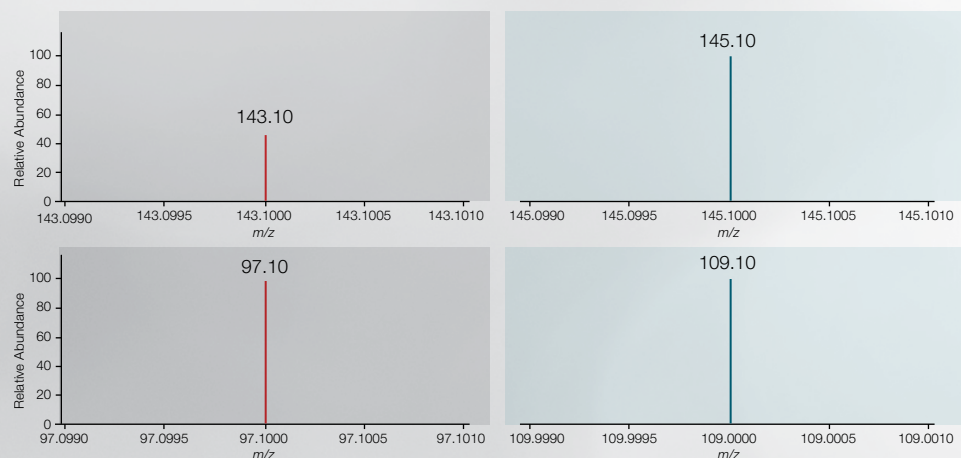


Critical features enabling every laboratory developed test

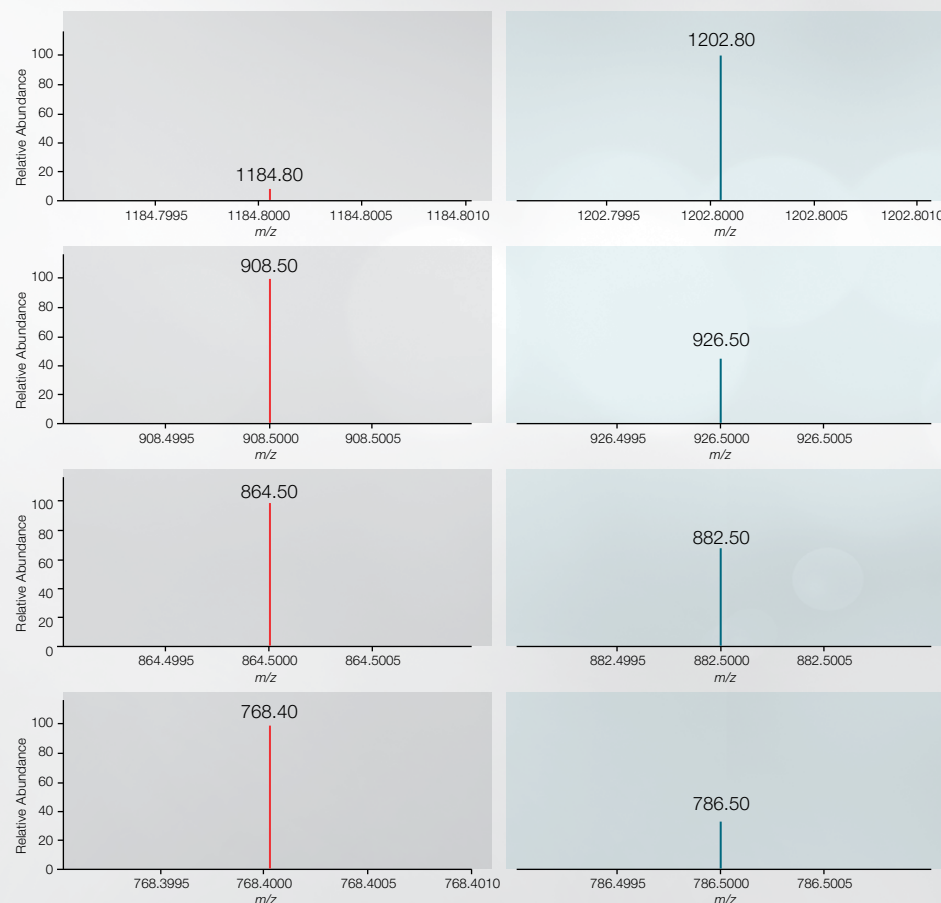
IVD compliance with sensitive, fast, and robust mass spectrometers

The Vanquish MD HPLC System, along with TSQ Quantis MD Series mass spectrometers, enables sensitive quantitative data for everyday analysis of clinically relevant analytes. The performance data shown in here are for illustrative purposes only and may not represent the performance that laboratories will obtain. Thermo Fisher Scientific does not recommend or suggest analysis of the analytes described herein using its systems. Performance in an individual laboratory may differ from what is presented in this document due to factors, including but not limited to laboratory methods, materials used, operator technique, and system conditions. It is the laboratory's responsibility to validate performance of any assay it intends to utilize in its facility and to comply with all applicable laws and policies.

Analytical performance of clinically relevant compounds



From top to bottom: Estrone, greater relative abundance quantifier ion and lesser relative abundance confirming ion. Testosterone, quantifier ion and confirming ion.



From top to bottom: Cyclosporin A, Everolimus, Sirolimus and Tacrolimus. Greater relative abundance quantifier ion. Lesser relative abundance confirming ion.

Comprehensive software for performing LDTs with confidence

Easy to use, built-in mass spectrometry software

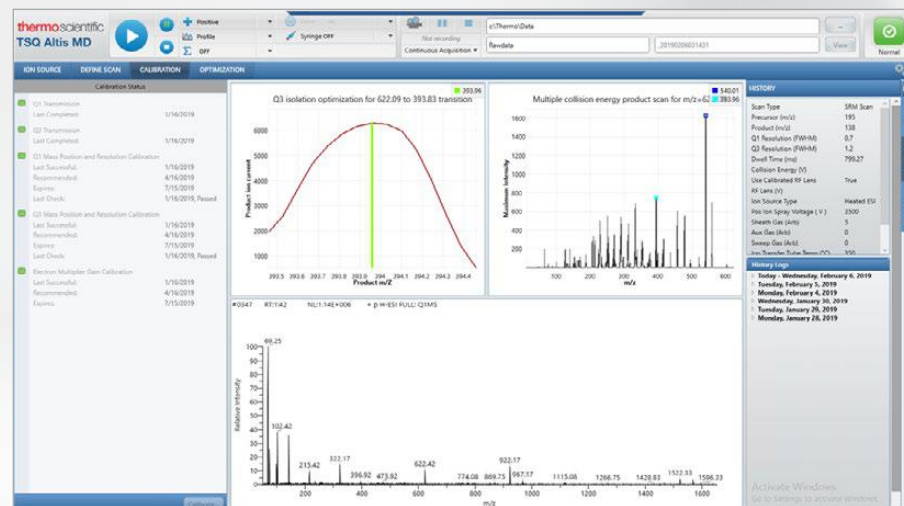
“Tune” the mass spectrometer and develop test methods with the integral TSQ Series II Altis MD and Quantis MD Software. Control of the mass spectrometer is conveniently provided through two application packages: **Tune** and **Method Editor**.

Tune features:

- Constantly monitor instrument parameters and operating status
- Tune and calibrate critical features for maximum performance
- Easily troubleshoot using diagnostic functions
- Generate reports for diagnostic purposes

Method Editor features:

- Set up and run experiments using optimized scan types established in Tune mode
- Design customized sequences of scans for complicated samples
- Specify peripheral device controls as part of an experiment



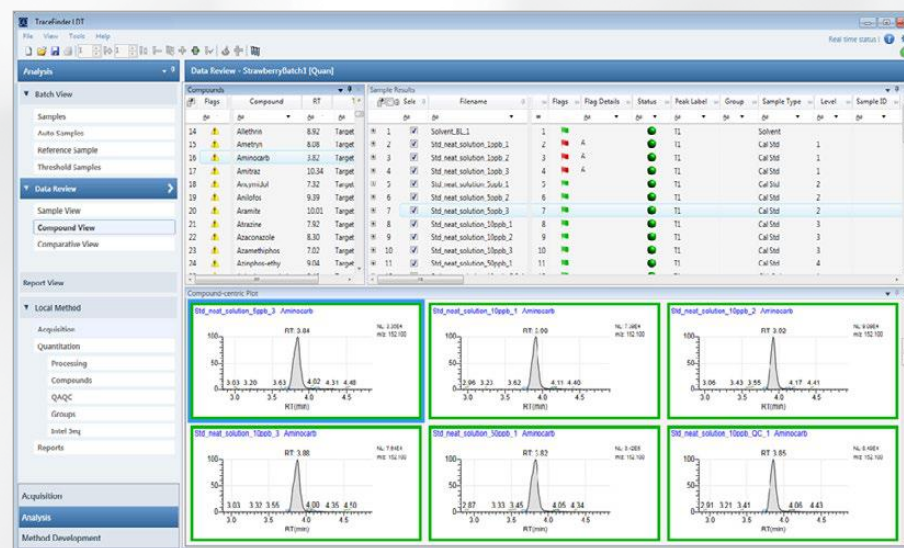
Calibrate the instrument for maximum performance with a variety of scan types, scan modes, ion polarities, scan rates, and resolution settings.

Quantitate with the integral TraceFinder LDT software

TraceFinder LDT software provides a seamless approach to high-throughput quantitation. Automate and accelerate the processes of creating methods, loading samples, generating data, manually reviewing and editing results, and finalizing the data review and reporting process for a quick start-up. Comprehensive processing methods provide improved handling of ion ratio calculations, reviewing, reporting, and comparison of mass spectra and data integration.

Key features:

- Manage user-based permissions, data repositories, and auditing
- Acquisition mode for creating and submitting samples
- Configure reports, detection and acquisition defaults, and customize columns and flags
- Results mode with batch views, data review, local method views, and report views
- Develop instrument methods, and set processing, error flag parameters, and report options



Comprehensive processing methods provide improved handling of ion ratio calculations, reviewing, reporting, comparison of mass spectra and data integration.

Bi-Directional LIS Connection

Expedited by the optional B-Link LIS/LIMS Connector

B-Link® is a Universal LIS/LIMS Connector validated for TraceFinder LDT software. Comprised of a downloadable software package of “middleware” capable of providing bidirectional communication between TraceFinder software and the LIS, the B-Link LIS/LIMS Connector software is installed on the TSQ Altis MD Series data system or TSQ Quantis MD Series data system—there is no need for any additional hardware.

This turnkey middleware solution facilitates data-sharing between:

- The LIS/LIMS and B-Link (ASTM-1394-91 and ASTM 1381-95); and,
- B-Link and TraceFinder LDT software (.csv)



Learn about fully-automated LC-MS/MS testing for clinical labs, visit thermofisher.com/cascadion



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Find out more at thermofisher.com/BeSure

IVD In Vitro Diagnostic Medical Device

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Since the .csv input and output of the mass spectrometer do not conform to the requirements of the typical Laboratory Information System, laboratories performing LC-MS are often challenged by data management issues, such as:

- Downloading test requests to the mass spectrometer
- Uploading test reports to the Laboratory Information System

The B-Link LIS/LIMS Connector resolves these data management issues by converting data to the appropriate format and providing bi-directional communication:

- Between LIS/LIMS and B-Link Connector
- Between B-Link Connector and TraceFinder LDT software