

Clinical IVD LC-MS/MS Systems

Class I Medical Devices and CE-marked
LC-MS/MS *In Vitro* Diagnostic Systems



Capitalize on the Benefits of Mass Spectrometry for Your Clinical Laboratory

Mass spec offers clinical labs many advantages over traditional tests. It sets the benchmark for mass accuracy, precision, robustness and sensitivity, giving you data that delivers specificity and sensitivity that simply isn't achievable with most other analytic techniques.

It also facilitates considerable workflow efficiencies – allowing multi-analyte panels, compatibility with generic sample prep, versatility in allowing the addition of new compounds, requires less preparation of samples and has a lower cost-per-sample than other methods.

Tandem mass spec medical devices from SCIEX can also generate a structural analysis of target compounds.

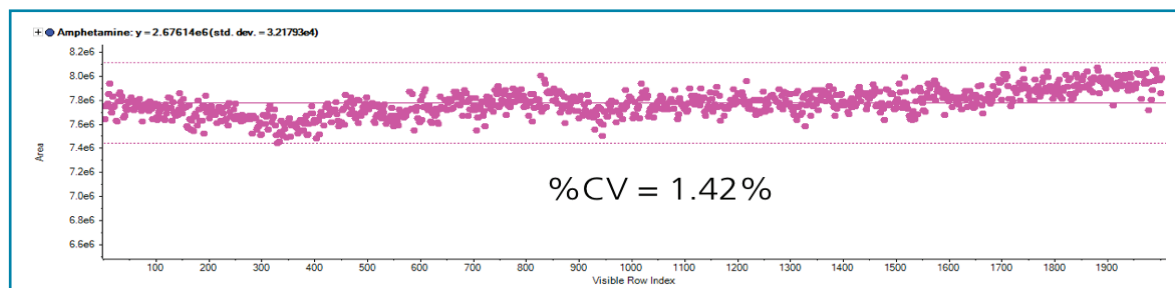
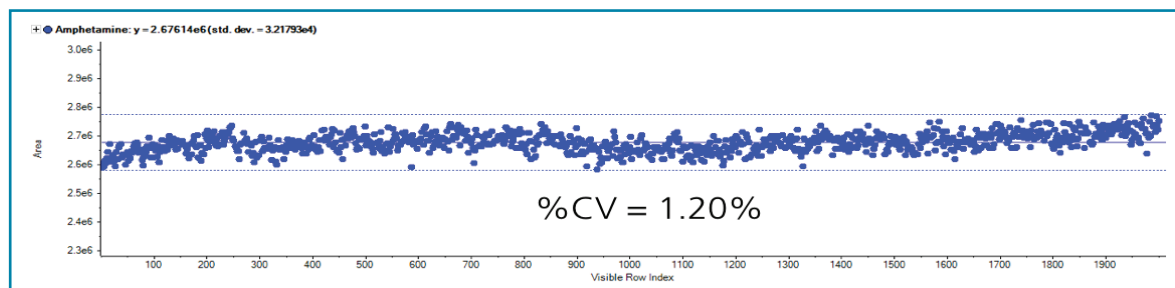
- SCIEX LC-MS/MS systems give you a unique level of performance and application versatility
- Sensitivity to detect low concentrations in biological matrices
- Dynamic range to see low to high concentrations
- Scan speed to clearly resolve similar analytes
- Ionization source flow ranges for LC flexibility
- Compact to fit your valuable bench space
- SCIEX *in vitro* medical device MS systems and software meet the requirements for compliance and tracking

Powerful, Robust SCIEX IVD LC-MS/MS Systems

As scientific understanding evolves into improved clinical diagnostic testing, customers who develop their own assays are turning to fast, sensitive instruments to perform routine tests with high efficiency and cost savings. SCIEX IVD LC and mass spec systems provide rock solid, robust performance for biological compounds minimizing maintenance and maximizing uptime. Our IVD mass spec systems feature the Turbo V™ ion source and Curtain Gas™ interface for unequaled reliability, sensitivity and reproducibility.

The patented Turbo V ion source is made for demanding applications and considered the gold standard for LC-MS/MS ionization. The ion source delivers highly efficient desolvation for stable, sensitive performance; virtually eliminating cross contamination— even large sample loads, across a wide range of flow rates.

The Curtain Gas interface provides a wall of clean nitrogen to help prevent neutral components from entering the mass spec, so the system is more robust, requires less maintenance, and delivers increased uptime for your lab.



Measured peak areas for 1000 consecutive injections of a sample containing Methamphetamine (top) and Amphetamine (bottom), over a period of 5 consecutive days on SCIEX 4500MD Mass Spectrometry System.

IVD Systems to Meet Your Lab Requirements

| Specifications | Citrine™ System | Topaz™ System | 4500MD Systems | 3200MD Systems | Importance |
|------------------------------|---|------------------------------------|---|---|---|
| Recommended for | Highest sensitivity | Higher sensitivity and ease of use | Assays requiring higher sensitivity and higher throughput | Standard assays not requiring lowest level of quantitation | Choice of options to meet your lab needs and budget. |
| MRM mode sensitivity | 100x | 10x | 10x | 1x | Higher sensitivity means less sample prep may be required, and enables the detection of trace levels of compounds in biological matrices. |
| QTRAP® sensitivity* | 500-1000x | NA | 50-100x | 1x | Higher sensitivity means less sample prep may be required, and enables the detection of trace levels of compounds in biological matrices. |
| Polarity switching time | 5 msec | NA | 50 msec | 700 msec | Faster polarity switching allows monitoring positive and negative ions in a single method. No need to perform 2 analyses per sample. |
| Minimum MRM dwell time | 1 msec | 1 msec | 1 msec | 5 msec | Smaller MRM dwell times allow you to monitor more analytes in a single method. You can further improve throughput by switching to fast UHPLC methods. |
| Triple quadrupole scan speed | 12,000 Da/sec | 12,000 Da/sec | 12,000 Da/sec | 24,000 Da/sec | Faster scanning speeds allow you to acquire more information about your sample, in each run. Throughput can be improved by switching to fast UHPLC methods. |
| QTRAP scan speed* | 20,000 Da/sec | NA | 20,000 Da/sec | 4,000 Da/sec | Faster scanning speeds allow you to acquire more information about your sample, in each run. Throughput can be improved by switching to fast UHPLC methods. |
| FDA cleared kits | - | Vit D** | - | - | FDA cleared Vitamin D 200M Assay Kit for reduced method development time. |
| User methods | Yes | Yes | Yes | Yes | Expand your menu and increase ROI. |
| Software | Analyst® MD Software, MultiQuant™ MD Software | ClearCore™ MD Software | Analyst MD Software, Cliquant MD Software, MultiQuant MD Software | Analyst MD Software, Cliquant MD Software, MultiQuant MD Software | Powerful, intuitive software to meet your needs. |
| Dynamic range | 5.5 | 4 | 4 | 4 | Allows quantitation across a broad concentration range. |
| LC system | Jasper™ LC | Topaz LC | Jasper LC | Jasper LC | Systems optimized for optimal performance, one vendor for service and support. |

*Only applicable to Citrine QTRAP®, 3200MD QTRAP, and 4500MD QTRAP systems

**Only available in the US at this time

Explore IVD LC-MS/MS System Choices

SCIEX offers a range of CE-marked, Class I Medical Device options designed to meet the needs of the clinical diagnostic lab.



The **Citrine MS/MS⁺ System** – our fastest, most sensitive IVD mass spectrometer yet, provides you with the ultimate performance and reliability to tackle today's difficult assays, and the versatility to address tomorrow's challenges.

- Highly multiplexed panels – Monitor 100's of MRM transitions per analysis with uncompromised accuracy, precision and sensitivity
- Rapid polarity switching – Faster than ever data acquisition with 5 msec polarity switching
- Utmost reliability – Accurately detect at picomole levels for clinically relevant biomarkers and metabolites
- Unique workflows – Perform qualitative and quantitative analysis in a single injection available with QTRAP Technology

The **Topaz System** is an integrated design of LC, mass spec and software designed to accelerate adoption.

- Quantitate multiple compounds in a single run
- Capture highly accurate results in weeks not months with SCIEX assay kit
- Easy navigation with ClearCore MD Software
- 1D/2D LC capability for on line sample clean up
- Flexibility to implement lab developed tests





The **4500MD Systems*** are flexible LC-MS/MS platforms that offer high performance, increased sensitivity and fast data acquisition. Ideal for labs that develop their own applications to validate methods and that require lower detection limits or higher throughput, it offers the peace of mind afforded by a regulatory compliant solution.

- Automated method development
- Quick, simple ion source changes
- Minimum maintenance requirements
- 4500MD mass spectrometers are available in both triple quadrupole and QTRAP

The **3200MD Systems*** are affordable bench top platforms that give you a unique level of performance and application versatility. The high sensitivity, low detection limits, and high specificity lead to better data compared to traditional technologies, so you can support physicians with high confidence and reliable results. With the ability to perform multiple types of assays on a single platform, and analyze multiple compounds simultaneously, you'll benefit from significant time and cost-savings for your routine clinical diagnostic assays.

- Confident quantitative analysis
- Flexibility through simultaneous, sensitive quantitation
- Library searching workflows for quantitative and qualitative analysis in a single run
- 3200MD mass spectrometers are available in both triple quadrupole and QTRAP



The **Jasper HPLC System** is a fixed-configuration higher pressure LC medical device specifically designed for SCIEX medical device mass spectrometers.

Built to meet the robustness and high throughput needs of the clinical diagnostic laboratory.

- Robust and reliable for optimal performance with your SCIEX MS/MS
- An FDA Class I and CE-marked *in vitro* diagnostic HPLC system
- Supports a wide range of applications with HPLC/UHPLC flow rates maximizing throughput
- Service contract and phone support from a single vendor
- Powerful software optimized for new and experienced users

Multi-Targeted Screening + Confirmation

Exclusive QTRAP technology in a medical device for clinical toxicology.

QTRAP technology delivers equivalent or better data, and more of it, than you can capture on an ordinary triple quadrupole system. You can combine all the MRM sensitivity of a triple quad, with a multi-functional linear ion trap (LIT), for unique and powerful workflows.

The SCIEX Citrine, 4500MD and 3200MD MS/MS systems are available in a QTRAP configuration. As a result you can reliably screen more compounds in a one system without compromising data quality.

- MRM detection provides sensitivity and selectivity
- MS/MS library searching for unambiguous confirmation
- Screen for hundreds of compounds

QTRAP System – Two Instruments in One

The QTRAP system is a hybrid triple quadrupole/linear ion trap mass spectrometer - a unique, flexible MS/MS system that can accommodate a wide variety of both quantitative and qualitative LC-MS/MS workflows.

It is the ability to use both triple quadrupole and linear ion trap scan functions on a single platform – and even within a single LC-MS/MS run – that makes the QTRAP system adaptable to a wide variety of both screening and quantitative tests.

Unambiguous Compound ID Using QTRAP Technology

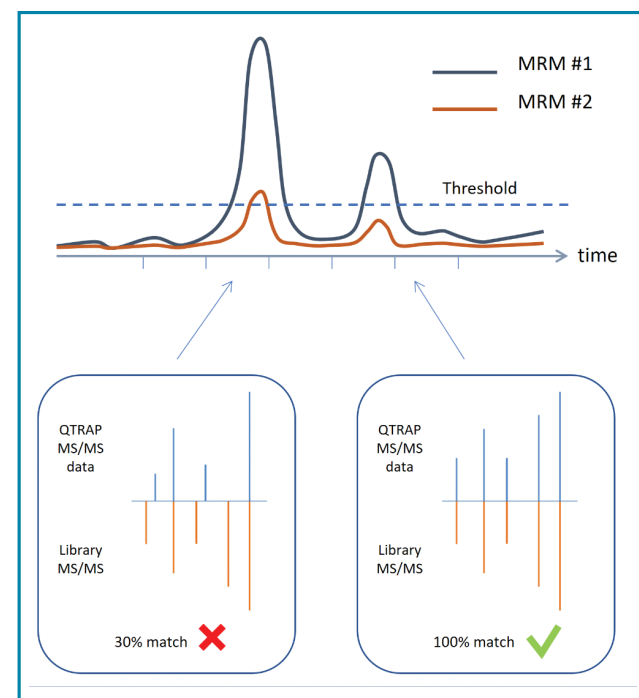
Leverage the scanning speed and sensitivity of the QTRAP system to automatically acquire full-scan MS/MS spectra for every detected compound during a targeted MRM experiment – quant and qual in a single injection!

In a typical LC-MS/MS chromatogram, there may be numerous peaks observed. If several peaks elute at a similar retention time, it can be difficult to correctly identify the target compound.

Compound ID using MS/MS library searching

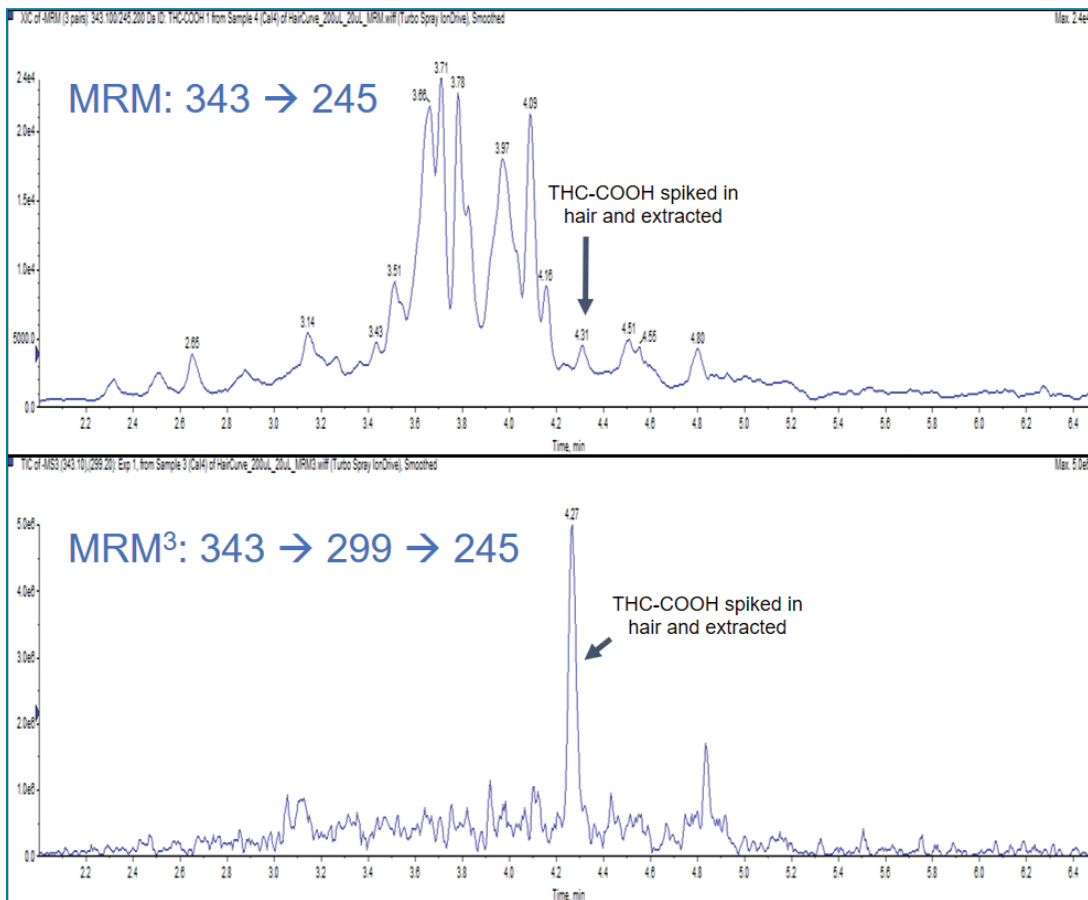
The QTRAP system can be used to rapidly acquire MS/MS spectra for every detected peak that exceeds a threshold. Library searching of MS/MS spectra allows the unambiguous identification of chromatographic peaks.

While screening by LC-MS/MS for 100s of target compounds in a single method, numerous peaks may be observed for every target mass, owing to the presence of interference ions having common fragment ions and MRM transitions. Using the Citrine QTRAP system, LC peaks can be unambiguously identified based on library searching of the full-scan MS/MS spectra that are automatically acquired for every peak that exceeds a predetermined threshold.



Improve your Limit of Detection using MRM³ Scanning on the QTRAP System

In some cases isobaric interferences cannot be differentiated using high-resolution mass spectrometry, since the interferences may have the same exact mass as the target compound. In these cases, the ability to use second-order fragmentation (MS/MS/MS) provides highly specific measurements, and can remove chromatographic interferences caused by isomers and background ions.



Use MRM³ scanning on the Citrine QTRAP system to enhance selectivity, and to improve limits of detection in complex sample matrices. For the measurement of THC-COOH in hair samples, the sample matrix produces numerous interferences that cannot be resolved using traditional MRM (top pane). With MRM³ (bottom pane), the interferences are removed and the THC-COOH metabolite is clearly differentiated from background ions.



Easy-To-Use Workflow Driven IVD Software

Expert results, even for non mass spec experts.

SCIEX offers complete LC-MS/MS system solutions designed to transform your approach to clinical testing. From automation systems to complementary software, our growing range of enhancements and options will accelerate your workflows, deliver more timely and reliable results, and keep your clinical lab performing at its peak.

The screenshot displays the 'SCIEX DX SMPLR' software interface. It features a top navigation bar with tabs for 'Isocratic', 'Autosampler', 'Column Oven', and 'System Controller'. The main area is divided into several sections: 'Injection settings' (with checkboxes for 'Autosampler', 'Injection settings', and 'Cooler temperature'), 'Sample rack settings' (with a 'Specify rack' checkbox and a 'Sample rack' dropdown), 'Rinse settings' (with a 'Rinse mode' dropdown), 'Acquisition cycle time optimization' (with 'Pretreatment start timing' and 'Pretreatment overlap time' fields), 'Rinse settings' (with 'Rinsing speed' and 'Rinse volume' fields), 'Purge settings' (with 'Purge time' field), and 'Autopurge settings' (with an 'Execute sampler purge' checkbox). A 'Time program' sidebar is visible on the right.



Analyst MD Software provides LC-MS/MS data acquisition for your Citrine MS/MS, 4500MD and 3200MD systems.

Analyst MD Software provides functionality for instrument control, data analysis, reporting, and audit trail. The latest version of Analyst MD Software builds on this legacy by providing new features that enhance performance, as well as ease-of-use



Cliquid MD Software for routine diagnostic screening and quantitation is designed to work in conjunction with Analyst MD Software to provide a simple, four-step workflow

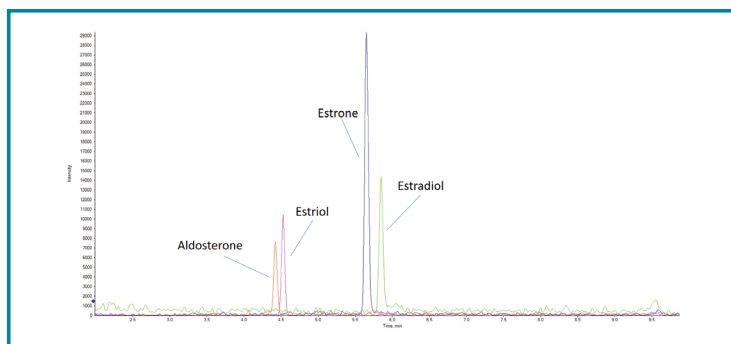
by LC-MS/MS. The software can be used with any SCIEX Triple Quad MD or QTRAP MD LC-MS/MS system. From assay menu selection to customized reports, Cliquid MD Software provides a step-by-step intuitive, user interface for quick adoption of LC-MS/MS in your lab.

The screenshot displays the 'Cliquid MD Software' interface. It features a top navigation bar with tabs for 'Home', 'Help', 'Method', 'Queue', and 'Log Off'. The main area is divided into a 'Run Samples' section with a 'Choose test' dropdown, a 'Step 1 Choose test' section, a 'Step 2 Build sample list' section, a 'Step 3 Set report options' section, and a 'Step 4 Submit samples' section. At the bottom, there is an 'Instrument Panel' with a 'Ready' status and a 'Queue' section showing 'Sample Name', 'Sample Type', and 'Sample Status'.

Speed and Sensitivity to Address a Broad Range of Analytical Challenges

Trace Level Compounds

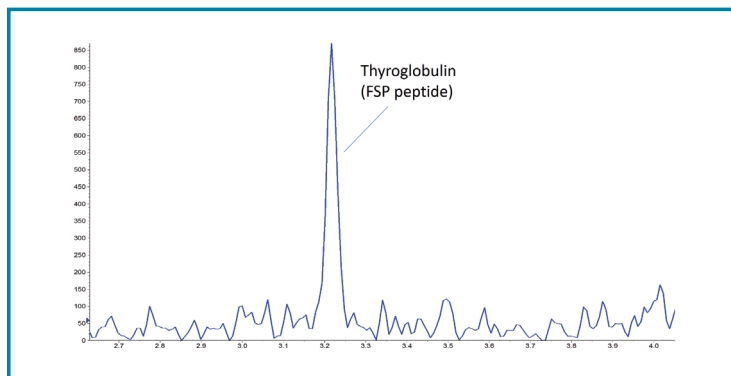
The Citrine System — our most sensitive tandem mass spectrometer ever, provides the lowest possible limits of quantification, enabling the measurement of trace levels of biomarkers and metabolites at sub-pg/mL concentrations.



Sensitive detection of estrogens and aldosterone in BSA extract, at 1 pg/mL, using negative electrospray ionization (ESI).

Proteins and Peptides

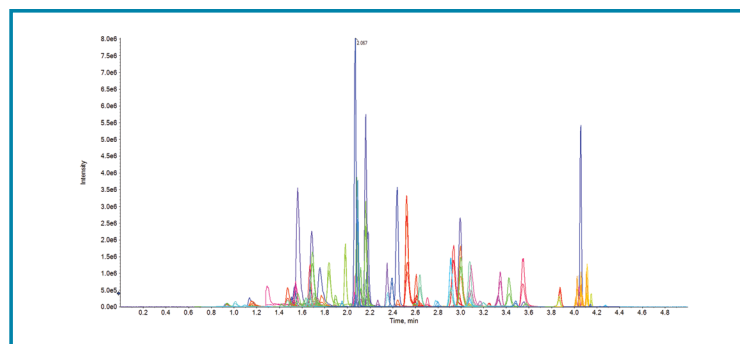
Citrine System provides accurate, sensitive quantitation of compounds with masses up to m/z 2000, allowing the measurement of large molecules such as peptides, protein digests and multiply-charged proteins.



Quantitation of thyroglobulin at a concentration of 0.06 ng/mL. Sample preparation consisted of trypsin digestion followed by SISCAPA immunopurification of the FSP peptide, prior to LC-MS/MS analysis.

Comprehensive Multi Analyte Panels

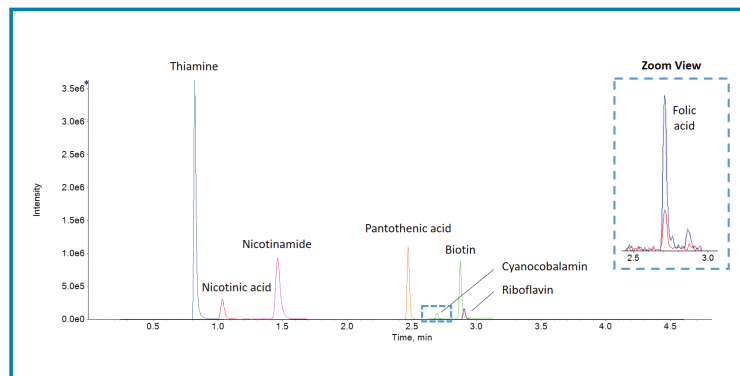
Fast MRM scanning (1 msec dwell times) and fast polarity switching (5 msec) between positive and negative ionization modes on the Citrine System enable the measurement of very large panels of compounds, across multiple compound classes.



Quantitative analysis of 93 compounds (212 MRMs) in a run-time of 5 minutes, using rapid polarity switching between positive and negative electrospray ionization (ESI) modes.

Small Molecule Quantitation

The versatile Citrine System offers ESI and APCI ionization options, an extended mass range up to m/z 2000, and a large linear dynamic range, making this the perfect tool for the measurement of a large variety of polar and non-polar biomarkers and metabolites in biological fluids, over a large range of concentrations.



Measurement of the water-soluble vitamins thiamine, riboflavin, nicotinic acid, nicotinamide, pantothenic acid, biotin, cyanocobalamin and folic acid, in serum.

An Unrivalled Level of Performance and Applications Versatility

Increasing sensitivity & speed

| Compound Class | Limit of Quantitation | Family of Compounds | 3200MD | 3200MD QTRAP | Topaz | 4500MD | 4500MD QTRAP | Citrine | Citrine QTRAP |
|---|-----------------------|---|-------------|--------------|-------|--------|--------------|---------|---------------|
| Small Molecule Drugs and Drug Metabolites | 1-100ng/ml | Amphetamines | • | • | • | • | • | • | • |
| | | Antidepressants and Neuroleptics | • | • | • | • | • | • | • |
| | | Antiretrovirals | • | • | • | • | • | • | • |
| | | Benzodiazepines | • | • | • | • | • | • | • |
| | | EtG and EtS | • | • | • | • | • | • | • |
| | | Cyclosporine, Tacrolimus, Everolimus, Sirolimus | • | • | • | • | • | • | • |
| | | Nicotine and Metabolites | • | • | • | • | • | • | • |
| | | Opiates | • | • | • | • | • | • | • |
| | | Phencyclidine | • | • | • | • | • | • | • |
| | | Cocaine Metabolites | • | • | • | • | • | • | • |
| | | Heroin Metabolite, 6-MAM | • | • | • | • | • | • | • |
| | | Large Pain Panel | | | | • | • | • | • |
| | | Drugs of Abuse Screen (library search) | | • | | | • | | • |
| | | Small Molecule Biomarkers | 1-100 ng/ml | Testosterone | • | • | • | • | • |
| Amino Acids | • | | | • | • | • | • | • | • |
| Homocysteine | • | | | • | • | • | • | • | • |
| Homovanillic Acid | • | | | • | • | • | • | • | • |
| Amino Acids & Acylcamitines in DBS | • | | | • | • | • | • | • | • |
| Metanephrines, Urine | • | | | • | • | • | • | • | • |
| 25-OH Vitamin D2 and D3 | • | | | • | • | • | • | • | • |
| Small Molecule Biomarkers | 0.01-100 ng/ml | Metanephrines, Plasma | | | • | • | • | • | • |
| | | Testosterone | | | • | • | • | • | • |
| | | 17-OH-Progesterone | | | • | • | • | • | • |
| | | Cortisol | | | • | • | • | • | • |
| Small Molecule Drug Metabolites | 0.01-100 ng/ml | THC Metabolite THC-COOH | | | • | • | • | • | • |
| Small Molecule Biomarkers | 1-100 pg/ml | Estradiol, Estrone, Estriol | | | | | | • | • |
| | | Free T3 and Free T4 | | | | | | • | • |
| | | Steroid Panels | | | | | | • | • |
| | | Testosterone, Low-Level | | | | | | • | • |
| | | 1-25 Dihydroxyvitamin D2 and D3 | | | | | | • | • |
| | | Aldosterone | | | | | | • | • |
| | | Metanephrines in Plasma, MRM ³ | | | | | | | • |
| Small Molecule Drug Metabolites | 1-100 pg/ml | THC-COOH in Hair, MRM ³ | | | | | | | • |
| Large Molecule Biomarkers | | Thyroglobulin | | | | | | • | • |
| | | Insulin and Insulin Analogues | | | | | | • | • |

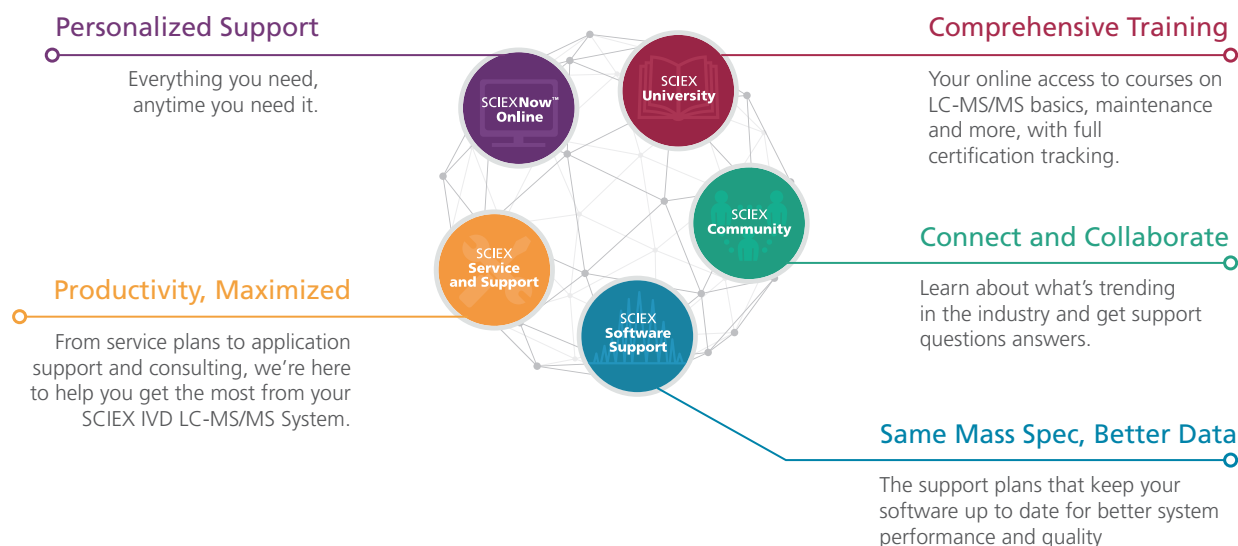
Your Success is Our Success

We take it personally

As a SCIEX user you have access to a world-class customer support organization in the SCIEX Success Network. Wherever you are, we're there with you as a trusted partner to answer questions, provide solutions, and maximize lab productivity.

Superior patient care is a click away.

Learn more at sciex.com/diagnostics



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