SCIEX

Clinical IVD LC-MS/MS devices

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The power of precision

Explore our IVD LC-MS/MS devices

Unveil the benefits of mass spectrometry for your most challenging clinical assays with our portfolio of robust and sensitive IVD LC-MS/MS solutions.

SCIEX offers best-in-class LC-MS/MS solutions that are registered as in vitro diagnostic (IVD) devices with a Class I designation from the US Food and Drug Administration (FDA) and a Class A designation under the EU In Vitro Diagnostics Regulation (IVDR). Our IVD LC-MS/MS systems are designed to meet the needs of the clinical diagnostic lab. Capitalize on the benefits of mass spectrometry for your clinical laboratory.

Mass spectrometry 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 any other analytic techniques. Capitalize on the benefits of mass spectrometry for your clinical laboratory, which include:

- **Workflow efficiencies** – 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 costper-sample than other methods
- **Qualitative information** – QTRAP Technology available on SCIEX IVD LC-MS/MS systems can also generate structural analysis of target analytes
- **Versatility** – SCIEX IVD LC-MS/MS systems provide a unique level of performance for a wide range of clinically relevant analytes
- **Sensitivity** – Reliably quantify low-levels biomarkers and metabolites from human
- **Dynamic range** – Detect biomarkers at a wide range of concentrations
- **Rapid scan speed** – Resolve similar analytes with fast quadrupole scanning
- **Flow range flexibility** – Ionize analytes across a wide range of flow ranges
- **Data integrity and compliance** – Meet your compliance and tracking requirements with SCIEX IVD LC-MS/MS systems and software solutions

Citrine system

The Citrine system – our fastest and 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. Harness the benefits of the Citrine system to meet the demands of your clinical laboratory.

Unparalleled sensitivity

Reliably measure clinically relevant biomarkers and metabolites at picomole levels

Highly multiplexed panels

Monitor hundreds of MRM transitions per run with uncompromised accuracy and precision

Rapid polarity switching

Get faster than ever data acquisition with 5 ms polarity switching

Wide dynamic range

Detect biomarkers from human specimens at a wide range of concentrations

Unique workflows

Perform qualitative and quantitative analysis in a single injection (available withthe QTRAP system version)

Learn more

4500MD system

The 4500MD system – our workhorse and most flexible IVD mass spectrometer, provides you the level of performance required for routine clinical assays. Ideal for labs that develop their own applications to validate methods and that need lower detection limits or higher throughput. Elevate your diagnostic testing capabilities with peace of mind with the 4500MD system and meet the daily needs of your clinical laboratory.

Workflow productivity

Accurately detect and quantify hundreds of analytes in a single injection

Polarity switching

Data acquisition of both positive and negative ions within a single run with 50 ms polarity switching

Ultimate robustness

Reliably quantify hundreds of analytes across thousands of injections

Unique quant/ qual workflows

Confidently identify low levels of analytes in complex biological matrices

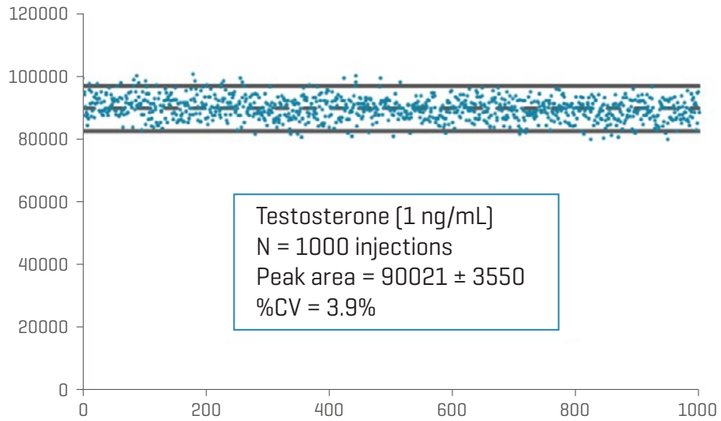
Learn more

Powerful and robust SCIEX IVD LC-MS/MS systems powered by the Turbo V Ion Source

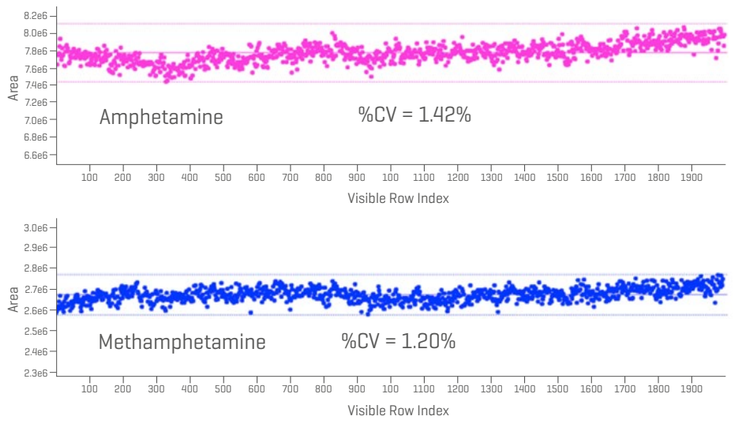
As scientific understanding evolves into improved clinical diagnostic testing, customers who develop their own assays are turning to fast, sensitive instruments to perform routine tests with high efficiency and cost savings. SCIEX IVD LC and MS devices provide rock solid, robust performance for biological compounds minimizing maintenance and maximizing uptime. Our IVD mass spectrometry 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 on the Citrine system system of a 1 ng/mL testosterone sample acquired over a 48-hour period of continuous instrument operation without operator intervention.



Measured peak areas for 2000 consecutive injections on the 4500MD system of a sample containing methamphetamine (top) and amphetamine (bottom) acquired over a period of 5 consecutive days of continuous instrument operation without operator intervention.

IVD systems to meet your lab requirements

Specifications	Citrine system	4500MD system	Importance
Recommended for	Highest sensitivity	Assays requiring higher sensitivity and higher throughput	lowest level of quantitation Choice of options to meet your lab needs and budget
MRM mode sensitivity	100x	10x	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	50-100x	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	50 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	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	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	20,000 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
Software	Analyst® MD Software, MultiQuant™ MD Software	Analyst MD Software, Cliquid MD Software, MultiQuant MD Software	Powerful, intuitive software to meet your needs
Dynamic range	5.5	4	Allows quantitation across a broad concentration range

*Only applicable to Citrine QTRAP and 4500MD QTRAP system

QTRAP MS/MS – 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.

Which of these peaks is the target compound?

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.

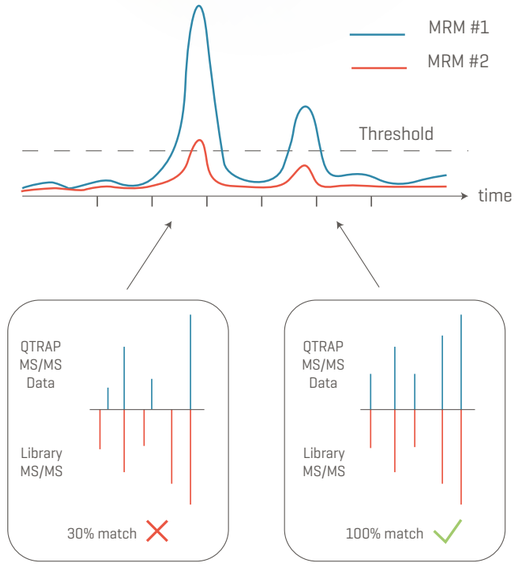
Compound ID using MS/MS library searching

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

While screening by LC-MS/MS for 100's 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 QTRAP MS/MS, 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.

Unambiguous compound ID using SCIEX QTRAP systemsy

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!



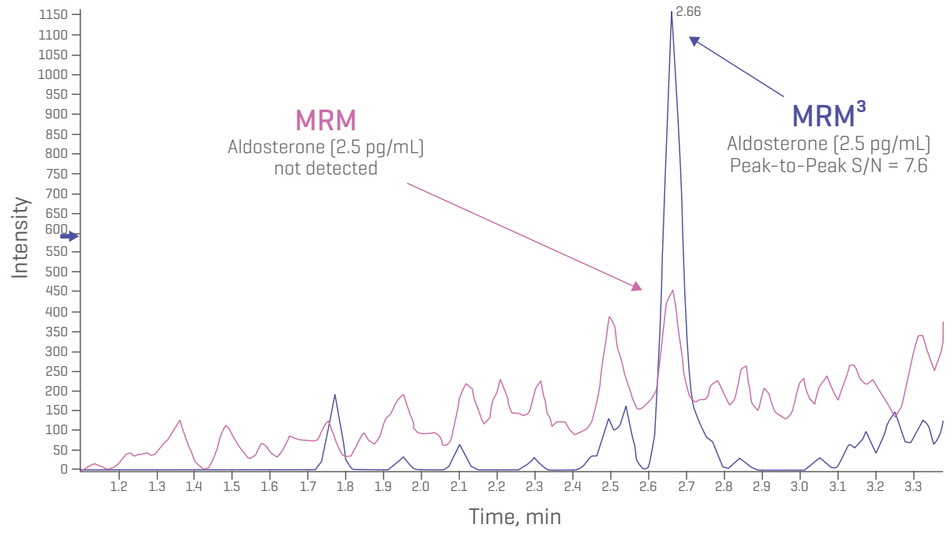
Improve your limit of detection using MRM^3 scanning on the QTRAP systems

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 MRM^3 scanning on the QTRAP systems to enhance selectivity, specificity, and sensitivity to improve limits of detection in complex matrices.

Extracted ion chromatograms (XICs) of extracted human serum calibrator standard for aldosterone at 2.5 pg/mL using Citrine QTRAP system

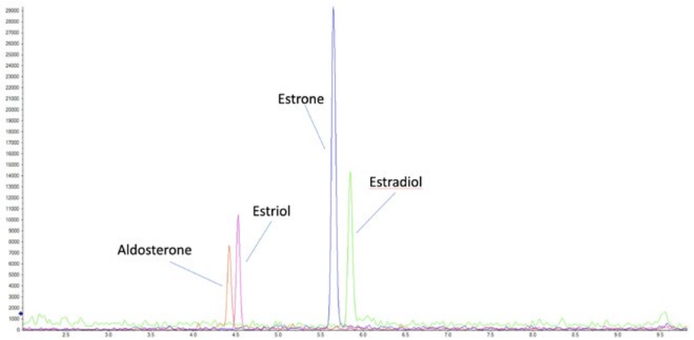


The use of the MRM workflow (pink) did not resolve aldosterone at 2.5 pg mL from the background due to numerous matrix interferences. The use of the MRM^3 workflow (blue) provided much higher sensitivity compared to MRM alone due to the additional level of selectivity obtained by monitoring secondary product ions for aldosterone in extracted human serum in oral fluid. The MRM^3 workflow was shown to increase selectivity by significantly reducing background and matrix interference, resulting in a 3- fold improvement in S/N compared to the MRM approach.

Speed and sensitivity to address a broad range of analytical challenges

Trace level compounds

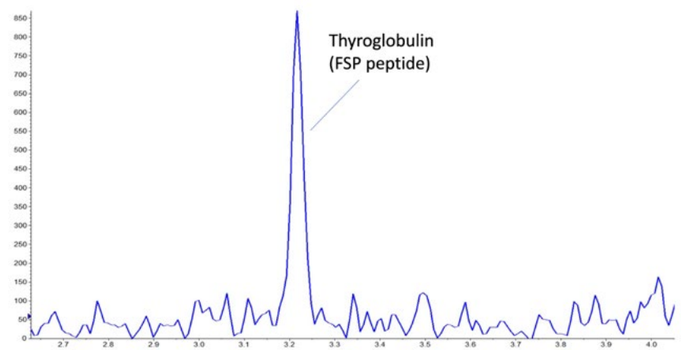
The Citrine system — our most sensitive tandem mass spectrometer ever, provides the lowest possible limits of quantification, enabling the measurement of trace levels of biomarkers and metabolites at sub-pg/mL concentrations.



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

Proteins and peptides

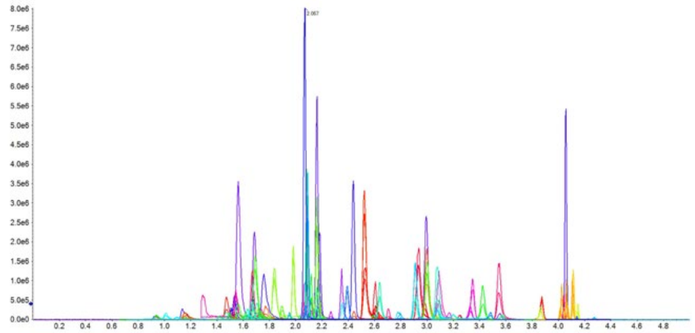
Citrine system provides accurate, sensitive quantitation of compounds with masses up to m/z 2000, allowing the measurement of large molecules such as peptides, protein digests and multiply-charged proteins.



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

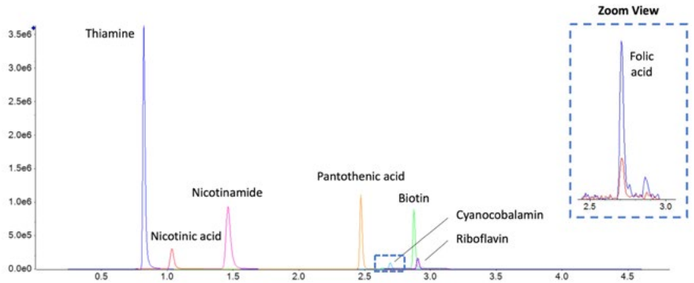
Fast MRM scanning (1 msec dwell times) and fast polarity switching (5 msec) between positive and negative ionization modes on the Citrine system enable the measurement of very large panels of compounds, across multiple compound classes.



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

Compound class	Limit of quantitation	Family of compounds	4500MD	4500MD QTRAP	Citrine	Citrine QTRAP
Small molecule drugs and drug metabolites	1-100 ng/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			✓	✓

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.

Intuitive software for IVD systems

ransform LC-MS/MS data into meaningful and actionable results to improve patient care with our suite of software solutions tailored to your clinical diagnostics applications.

Analyst MD software

Powerful LC-MS/MS control, streamlined data management and compliance for your SCIEX devices.

You're in control

Analyst MD software delivers full-system integration and enables LC and MS method development, all from a single point of control. Additionally, Analyst MD software acts as the central integration software platform for add-on packages such as MultiQuant and Cliquid MS software, providing you with additional analysis and processing options.

Screen, verify and quantify with confidence

Spend more time understanding your data and less time running your samples. Analyst MD software was designed to maximize the performance of your LC-MS/MS system so you can acquire data with high accuracy and precision. Easily schedule up to 4000 individual MRM transitions within a single run with Scheduled MRM Algorithm Pro so you can detect and quantify analytes with confidence.

Reveal hidden compounds, instantly

Don't wait to uncover underlying peaks. The Dynamic Background Subtraction (DBS) algorithm allows you to subtract background ions and uncover underlying analytes dynamically throughout a run.

Quality with less effort

Forget the endless scrolls through each chromatogram to view your peaks. With the integration quality index, you get instant information with less information. Our unique hybrid QTRAP technology enables you to obtain quantitative and qualitative information in the form of structural information in a single injection using the Information-Dependent Acquisition (IDA) mode, providing you added confidence for your most challenging assays.

Compliance at heart

Analyst MD software makes compliance less cumbersome, incorporating comprehensive security and audit trail features and functionalities that provide the documentation and electronic records required for GLP compliance. Maintain your laboratory standards by relying on Analyst MD software, designed to support 21 CFR Part 11 compliance regulations.

Learn more

MultiQuant MD software

Seamlessly process and accurately quantify multiple analytes across numerous samples with flexible software.

Minimize mouse clicks and reduce data bottlenecks

Whether you need to review all analytes at once or narrow them down by classes, MultiQuant MD software gives you complete control over how you want to process your data and review your results. The flexibility of MultiQuant MD software enables you to customize displays and let you sort through MRM data by any attribute to streamline data processing and reviewing, giving you the flexibility and the productivity you need to improve laboratory results turnaround time.

Do more with large, complex data sets

Manage large datasets with multiple data processing options that can process MRM data for quantitation as well as full scan data for qualitative analysis. The advanced SignalFinder algorithm feature generates results faster, while customizable flagging rules allow rapid visualization of results outside their desired ranges. MultiQuant MD software also lets you set concentration thresholds and sample tolerance standards so you can rapidly identify outliers in the results.

Flexible result reporting options

With hard-copy and digital report exporting options, MultiQuant MD software provides the flexibility to choose your preferred format for reporting and exporting results. Output formats include Word, HTML, PDF, CSV or TXT files, with multiple options to report sample results. In addition, MultiQuant MD software is compatible with direct export to your preferred Laboratory Information System (LIS).

Quantitative flexibility

Choose how quantitation is performed. MultiQuant MD software supports both relative and absolute quantitation experiments as well as unlabeled or stable isotope-labeled internal standards.

Multiple applications, one terminal

Multiple applications, but one terminal connecting to WATSON LIMS (with GLB/CFT compliant link), UV/DAD and ADC with MultiQuant MD software. Experience usability features that also speed up data review and comparison for quality assessment and interrogation — a valuable feature for protein/peptide quantitative workflows and multi-analyte panels.

Compliance at heart

Designed to support regulatory compliance, MultiQuant MD software incorporates a suite of robust audit trail features such as a Grouped Audit Event, for repeated auditing eventualities, and the Audit Map Editor, so lab administrators have full control of the audit trail functionality. Seamless integration with WATSON LIMS enables easy results transfer within a secure, compliant environment.

Learn more

Easy-to-use workflow driven IVD software

Cliquid MD software

Streamline your LC-MS/MS clinical diagnostic testing with a simple 4-step workflow and intuitive point-and-click interface.

Easy operation

A streamlined user experience, from the assay selection menu to customized reports, Cliquid MD software's intuitive user interface makes routine IVD mass spectrometry analysis simple and straightforward. The step-by-step, workflow-driven analysis tools support simple and accessible operations to reduce training needs for routine quantitation, as well as targeted and unknown screening workflows.

Intelligently effective

Cliquid MD Software intelligently reads and processes barcode data. Read and compare barcode data based on sample number or name, and automatically flag any mismatched barcodes. Selecting and releasing your samples to a LIMS or LIS for analysis has never been simpler and can now be achieved with a single click of a button.

Simple yet customizable

Setting up and running samples is straightforward with the ability to customize your simple four-step workflow. Choose your reporting and exporting formats, including Word, Excel, PDF or other text-based documents – all of which can be tailored to your laboratory's specific style.

Secure yet flexible

Secure user log-in functionality links the identity of operators to the tasks they are allowed to perform. Assign user permission privileges, whether it's limited access to purely run samples and generate reports or extensive rights to create and activate tests and report styles.

Pre-configured testing

Cliquid MD software allows administrators to pre-configure and customize LC-MS/MS assays, for easy deployment to routine clinical testing.

Learn more

ChemoView MD software

Effortlessly process batch sample screening results with user-friendly and personalized reports.

Easy operation

A simple interface enabling users to relate the method process and method test details with tests results and the associated audit trail history. This enables users to quickly review the analysis to increase confidence and data processing and reporting.

Effective reporting

Automatically batch process results across different sample types to increase the speed and efficiency of reporting. This functionality streamlines data processing and provides quick report turnaround time.

Searchable archival

Archive results and search by report name, date, Wiff file, or sample name. This functionality enables users to quickly go back at previously acquired and processed data sets, should they need to, providing an added layer of confidence.

Classify and highlight samples

Specify sample composition type (i.e: blood, bile) in each sample ID and associate this information with report limits and user-defined calculations. If the acceptance limits for the compounds are outside the range, the program will highlight the samples having results outside of the limits.

Flexible data review

Specify test limits for each analyte, view and automatically flag the results that fall outside of user-defined limits. This functionality enables users to quickly identify the compounds whose concentrations fall outside the user-defined limits.

Customizable reporting

Designate a specific report template by processing method from a wide range of standard reports that can also be easily customized according to specific test requirements. This level of customization ensures that clinical laboratories can process and report data the way you want, giving your laboratory full control over how sample results are reported and presented to clinicians.

Learn more

SCIEX Now support network

SCIEX Now

- Manage your instruments
- Submit and manage support cases, track status and view history
- Access online training courses and articles.
- Manage software licenses linked to your registered instruments
- View and report critical instrument statistics when connected to StatusScope remote monitoring service
- Be a part of the SCIEX community by submitting questions and comments
- Receive notifications from SCIEX with content based on your preferences

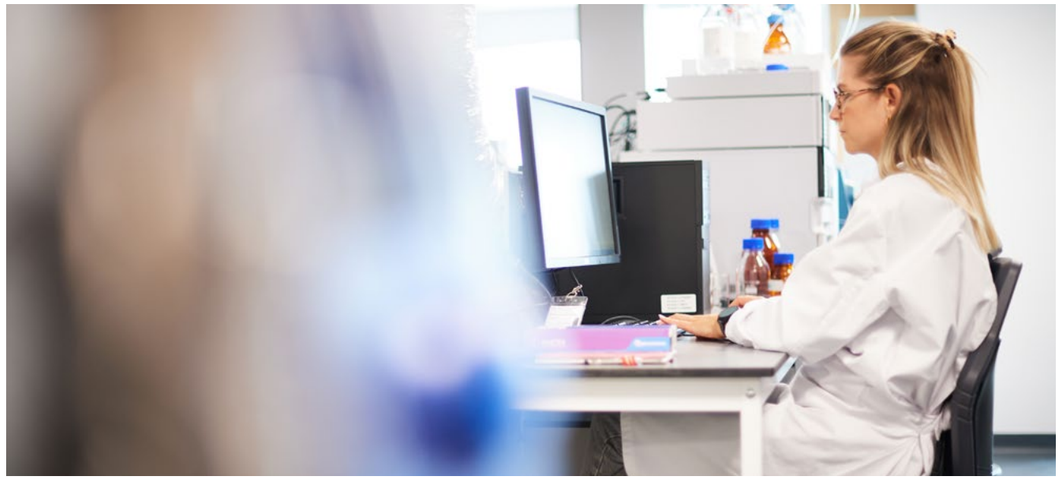
Contact us

SCIEX Now learning hub

- SCIEX Now learning hub success programs provide LC-MS and CE training customized to meet your exact needs
- With a selection of training methods and certifications available, you can build a mass spectrometry program that is most suited to your lab and users
- Starting with a clear understanding of your desired learning outcomes, we aim to help you improve lab productivity and consistency by designing and delivering a program that is focused on knowledge advancement and retention

Learn more

Clinical knowledge center



Empowering clinical mass spectrometry users with the resources they need to succeed. The clinical knowledge center is a resource and education platform for clinical mass spectrometry users. It is designed to provide the technical knowledge required to successfully implement mass spectrometry in a clinical laboratory setting.

The clinical knowledge center includes:

- Training videos for new and expert mass spectrometry users: browse an extensive library of educational videos on topics ranging from understanding the basic elements of mass spectrometry experiments (such as sample preparation, running your mass spectrometer and interpreting your data) to overcoming challenging applications using LC-MS/MS solutions from SCIEX
- Extensive technical content covering specific LC-MS/MS skills: discover technical solution that support the development of clinical testing procedures, technical performance standards, quality control and regulatory compliance
- Access to Learning Hub personalized success programs: help maintain engagement and promote information retention with training modules that are customized to meet your laboratory and staff needs
- Laboratory optimization services: let us assess your laboratory environment to help you quickly increase throughput, reduce costs, improve quality and optimize laboratory operations
- SCIEX areas of expertise: leverage our expertise in areas such as software and IT services, regulatory compliance, laboratory relocation, consulting and customized laboratory training

Learn more

LC-MS/MS planning and implementation guide

Expand your clinical laboratory capabilities by incorporating LC-MS/MS

The LC-MS/MS planning implementation guide was developed to help new mass spectrometry users prepare and plan for the purchase, implementation and operation of an LC-MS/MS system in their clinical laboratory. Our guide is a valuable resource that walks you through everything you need to know about getting started with mass spectrometry.

The guide includes useful information answering the following questions:

- What is mass spectrometry?
- Which mass spectrometer is the right fit for my analytical needs?
- What do I need to consider when adding mass spectrometry to my clinical laboratory?
- How do I prepare my organization for a successful implementation?
- How can SCIEX help ensure a smooth adoption and transition?

Learn more

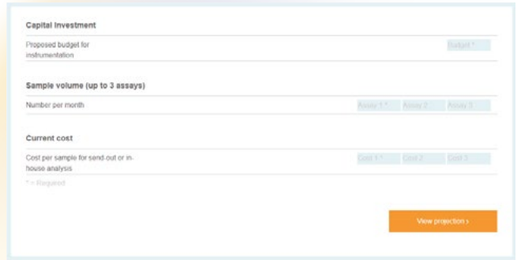
The ROI calculator tool

Find out how profitable your lab could be with LC-MS/MS technology

The ROI calculator is a tool that helps you determine the profitability associated with capital expenditures for your organization. SCIEX offers this tool to help you explore the financial value a mass spectrometer can bring to your clinical laboratory.

See how profitable your lab could be in 3 easy steps:

1. Enter your budget
2. Enter the sample volume
3. Enter the sample cost



Learn more

The power of precision

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International Sales
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sciex.com/offices

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