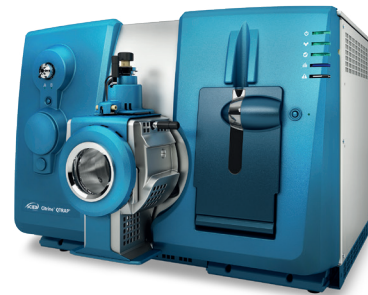


## Why Mass Spectrometry in Your Clinical Lab?

Introducing the commercial benefits of MS



In vitro diagnostic (IVD) tests are routinely carried out in clinical biochemistry labs to investigate wide-ranging diseases and conditions, and monitor ongoing treatments. This article describes the different techniques available and highlights the advantages.

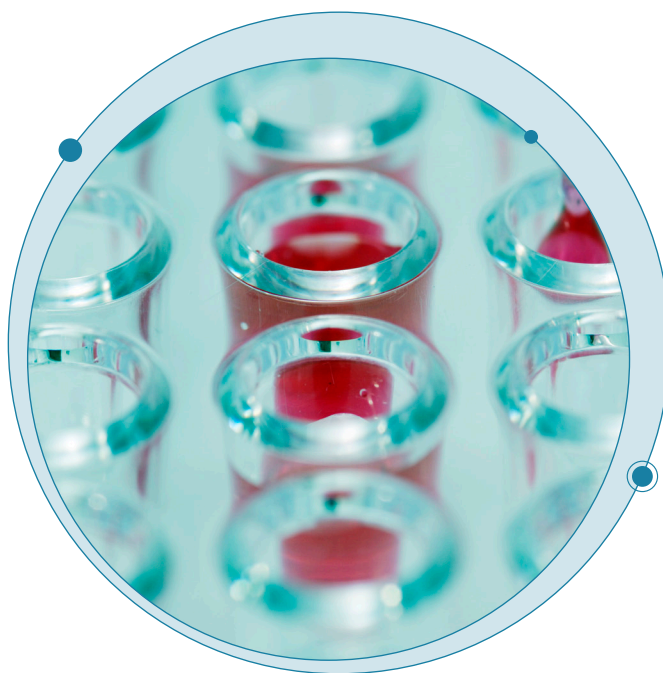
For many years, clinical scientists and clinicians have used immunoassays such as ELISAs (enzyme-linked immunosorbent assays) for analytical testing.

### Concerns with Immunoassay Performance

In the past few years there has been growing concern about the accuracy of immunoassays including those for diagnostics. Immunoassays can be susceptible to interferences, usually manifesting as a lack of specificity, particularly for analytes with similar chemical structures. This is due to cross reactivity of the antibody with a similar species, which can cause inaccurate analysis, especially for low abundant analytes. This and related issues can lead to both false negative and false positive results, which can affect patient care as well as increasing costs and labor burdens for health authorities. Immunoassays can also show significant bias in results, between labs using the same assays as well as between assays sourced from different manufacturers.

The nature of the immunoassay technique also gives rise to another inherent issue with this approach. Antibodies are not available for every possible analyte that is measured or will be measured in the diagnostic lab and developing a new immunoassay can take months.

So if a novel biomarker needs to be investigated, the immunoassay model is slow to react to such changing analytical needs.



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## Adoption of Alternatives

These concerns have driven the development of alternative testing methods based on mass spectrometry, which offers higher accuracy over immunoassays. Liquid chromatography with tandem mass spectrometry (LC-MS/MS) is particularly powerful for high-performance separation, identification and quantification of the small molecules, proteins and peptides commonly analyzed in a clinical diagnostic laboratory.

These benefits for diagnostics are clear, but clinical laboratories have been slow to adopt LC-MS/MS. Part of the reluctance to switch technologies may be attributed to a traditional perception that only mass spectrometry experts could operate the instruments and analyze results.

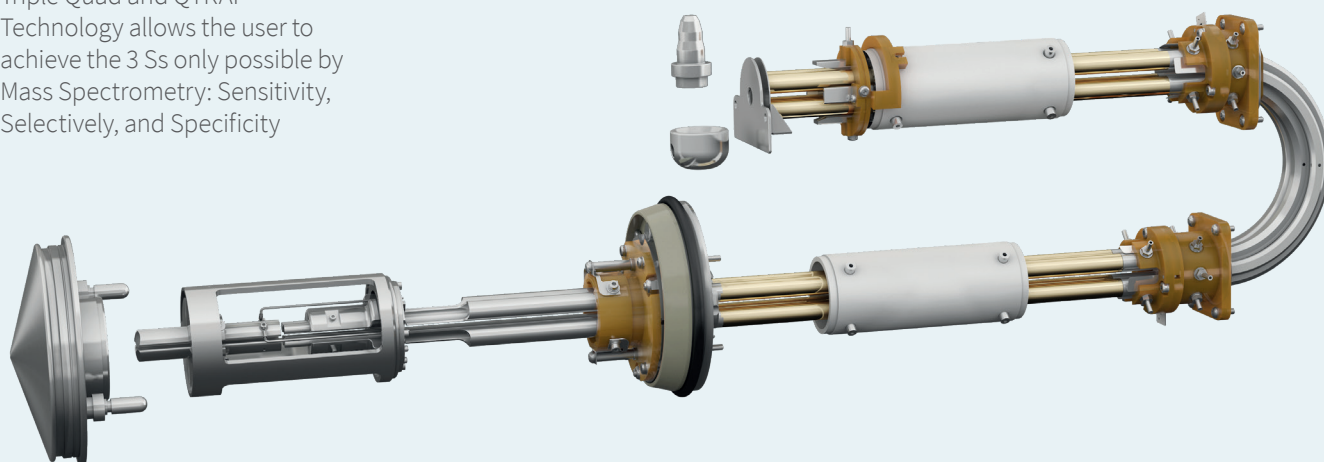
Accordingly, instrument providers have made many developments to improve the simplicity, ease-of-use and robustness of LC-MS/MS systems in recent years.

These include the registration of the MS analyzers as general medical devices in many countries around the world, ensuring confidence that MS systems and consumables are developed specifically to be safe and effective for routine clinical diagnostic laboratories, and designed to bring down costs by delivering accurate, rapid and reliable results.



## Triple Quad and QTRAP

Technology allows the user to achieve the 3 Ss only possible by Mass Spectrometry: Sensitivity, Selectivity, and Specificity



# The Benefits of Mass Spectrometry

The benefits of an LC-MS/MS approach versus a traditional immunoassay.



## The 3 S's...

### Increased Specificity

LC-MS/MS methodologies are based around the molecular structure and chemical fragmentation pathway of a molecule. Therefore, the specificity of a mass spectrometry approach compared to immunoassay is greatly enhanced.

### Increased Sensitivity

Sensitivity and specificity go hand in hand. Immunoassays can struggle with analytes in the picomolar concentration ranges, and for these “needle in a haystack” applications, their specificity can be poor. Mass Spectrometry is known and respected for its sensitivity in quantitation, and a powerful LC-MS/MS tool, such as the SCIEX Citrine MS/MS System® can detect and quantify analytes at ultra-low concentrations with the specificity mass spectrometry provides.

### Increased Selectivity

One of the common misconceptions around mass spectrometry is concerns with its susceptibility to matrix effects. Sample preparation is often needed, but the selectivity of the LC-MS/MS approach confines that to a simple and automatable process.

Powerful chromatography separates matrix from the analyte, and specific MS parameters detect and quantify the molecules of interest with confidence. What's more, advanced mass spectrometry methodologies such as those offered by the SCIEX Citrine QTRAP MS/MS System® allow ultimate selectivity from challenging matrices such as hair.

### A powerful method development tool

LC-MS/MS is an ideal platform for the concept of the Lab Developed Test (LDT). This brings the full power of mass spectrometry into the hands of the routine diagnostic lab with the ability for the user to develop and deploy their own methods quickly and easily, reacting to changes in analytical demands in a timely fashion.

### Analyte Multiplexing

Advances in LC-MS/MS technology allow for the simultaneous detection and quantification of hundreds of analytes in a single injection. Moreover, improvements in LC system technology means that switching between methods using different LC chemistries is seamless and automatic.

### Ever improving ease of use

Manufacturers have been quick to perceive that LC-MS/MS is a technique requiring a high level of expertise. Extensive development in software and user interfaces, such as the SCIEX Cliquid MD platform, has brought this powerful analytical tool to the hands of users with minimal mass spectrometry experience. With that in mind, manufacturers understand that aftercare is paramount to the success of the laboratory, and customizable dedicated clinical training programs such as SCIEX University and support packages from SCIEX Now, peace of mind and confidence are ensured.

Immunoassays are still the mainstay of the clinical diagnostics lab but as can be seen, the benefits of a mass spectrometry approach are clear. Mass Spectrometry answers a significant number of the questions over immunoassays, and its reputation as an accurate and robust routine tool, while still maintaining powerful method development capabilities, is strong and growing. The future of clinical diagnostics is in mass spectrometry.

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## Product & Data Security

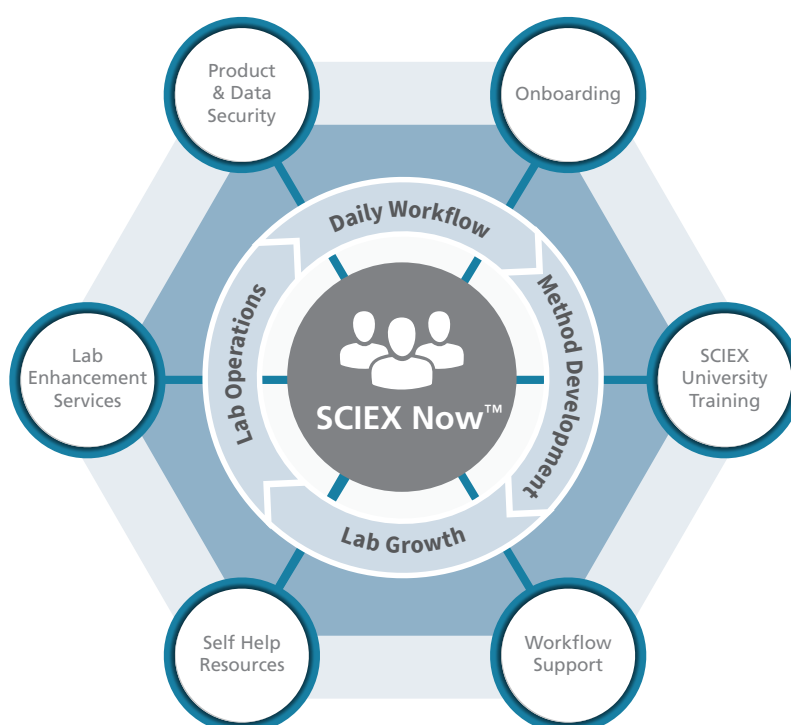
Increase your confidence with compliance services to help you safeguard your data, confirm data integrity, and ensure system modifications can be traced.

## Onboarding

We register you to SCIEX Now Online, enroll you to your SCIEX University learning path, and send you a welcome email.

## Lab Enhancement Services

SCIEX Lab Enhancement Services apply a holistic approach to your lab to increase productivity and reduce system downtime.



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Best-in-class content, personalized learning paths – delivered using the latest memory science techniques.

## Self Help Resources

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## Workflow Support

Whatever your challenge, the SCIEX Support team is here to help you achieve your scientific goals quickly and efficiently.

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