

Waters™

Waters Clinical Diagnostics Solutions

Trust. Flexibility. Efficiency.
Built into Every Solution.

MassTRAK™ Solutions



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Trust. Flexibility. Efficiency. Built into Every Solution.

At Waters, we recognize the critical role hospital laboratories play in delivering timely, accurate diagnostics that drive patient care. Our solutions are built to support your lab's evolving needs—whether you're expanding test menus, improving turnaround times, or meeting rigorous regulatory standards.

Rooted in three foundational pillars, our approach is designed specifically for clinical lab environments like yours:

Flexibility to integrate seamlessly into your existing systems and workflows

Efficiency to help your team deliver high-quality results—faster and with fewer hands-on steps

Trust in proven technologies backed by decades of scientific innovation and global support

From LC-MS/MS systems to automated sample prep and data management tools, Waters offers comprehensive solutions that enable your lab to operate with confidence—today and in the future.

SAMPLE HANDLING ▪ AUTOMATION ▪ MASSTRAK IVD SOLUTIONS
INFORMATICS ▪ SERVICE AND SUPPORT ▪ FINANCING

MassTrak IVD Systems

DISCOVER OUR SOLUTIONS FOR BETTER CARE

Ensuring that the results you provide are accurate and timely is critical in providing the best patient care, but faster results should not sacrifice quality.

There's no need to compromise compliance, flexibility, or performance. Waters MassTrak IVD Systems allow you to customize your instrumentation to your analytical needs providing accurate results, while maintaining regulatory compliance.

Our MassTrak IVD Systems are built on our many years of experience in clinical diagnostics, so you can increase your testing capabilities to provide better care.

With our clinical diagnostics solutions, you can:

- **Meet your unique application needs** with a range of instrumentation
- **Adapt to your laboratory requirements** with customized workflows
- **Achieve end-to-end compatibility** with multiple automation solutions for streamlined workflow
- **Ensure regulatory compliance to Quality System Regulation, ISO 13485:2016, and local regulations***

*MassTrak IVD Solutions are not available for sale in all countries. Please contact your local sales representative for additional information.

COMPLIANCE

FLEXIBILITY

PERFORMANCE

Explore Our Solutions



Ideal for routine quantification

ACQUITY™ UPLC™ I-CLASS PLUS WITH XEVO™ TQD IVD SYSTEM

Meet routine quantitative LC-MS/MS application requirements for confident quantification and patient sample confirmation in the clinical environment.



Ideal for routine and low concentration analyte quantification

ACQUITY UPLC I-CLASS PLUS WITH XEVO TQ-S MICRO IVD SYSTEM

Ensure accurate routine low concentration analyte quantification with this robust and sensitive IVD instrument. Achieve consistently low levels of quantification with a dynamic range for multiple analyses.



Ideal for complex trace analyte quantification

ACQUITY UPLC I-CLASS PLUS WITH XEVO TQ ABSOLUTE XR IVD SYSTEM*

Accurately quantify trace analytes with absolute power and extreme robustness to perform esoteric testing in-house with a compact and sustainable instrument reducing send out cost and turnaround times.

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MassTrak IVD Systems Capabilities

EQUIP YOUR CLINICAL LABORATORY WITH THE RIGHT ANALYSIS

With a wide range of MassTrak IVD Systems you can be assured to have the right instrument for your analytical challenges in the clinical laboratory. In the pursuit for accuracy and precision to transform data into better care, Waters MassTrak IVD Systems deliver high quality and robust results for your laboratory. LC-MS/MS is swiftly becoming the technique of choice where your analysis requires more sensitivity, increased specificity, and greater flexibility.

	 ACQUITY UPLC I-CLASS PLUS/ XEVO TQD IVD SYSTEM	 ACQUITY UPLC I-CLASS PLUS/XEVO TQ-S MICRO IVD SYSTEM	 ACQUITY UPLC I-CLASS PLUS WITH XEVO TQ ABSOLUTE XR IVD SYSTEM*
Thymidylate synthase inhibitors	✓	✓	✓
Alkylating agents	✓	✓	✓
Azole antifungals	✓	✓	✓
Inosine-5'-monophosphate	✓	✓	✓
Urine biogenic amines	✓	✓	✓
High level androgens	✓	✓	✓
Immunosuppressive agents	✓	✓	✓
Vitamin analysis	✓	✓	✓
Toxicological compounds	✓	✓	✓
Antibiotics analysis	✓	✓	✓
High level progestogens	✓	✓	✓
Low level progestogens		✓	✓
Low level androgens		✓	✓
Mineralocorticoids		✓	✓
Plasma biogenic amines		✓	✓
Free androgens			✓
Free thyroid hormones (T3/T4)			✓
Thyroglobulin			✓
Tricyclic antidepressants		✓	✓
Anti-psychotics		✓	✓
Estrogens			✓
Monoclonal therapeutic drugs			✓
SARS-CoV-2 LC-MS			✓

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Flexible Options



MEET YOUR UNIQUE WORKFLOW REQUIREMENTS

Configuring an LC-MS/MS instrument to fit your workflow and analytical needs can be challenging while maintaining regulatory compliance.

Personalize your **MassTrak IVD System** to meet your lab's analytical requirements with the broad range of customizable options. With the ACQUITY UPLC I-Class PLUS System, you'll shorten analysis times, reduce solvent usage, maximize resolution, and speed up access to the data you need for critical decisions.

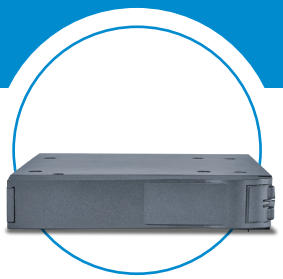
Find out how you can further optimize your lab performance and workflow efficiency with the flexible options below.

MEET YOUR LAB REQUIREMENTS WITH THESE FLEXIBLE OPTIONS



COLUMN MANAGER

When performing multiple analyses on one single instrument, one column may not be enough. With the column manager, you can connect multiple columns that will automatically switch depending on what analysis is being performed – improving your productivity and saving you time.



COLUMN HEATER

Our single column heater is ideal for dedicating your system to a single type of analysis and achieving your workflow requirements.



SAMPLE ORGANIZER

If you're analyzing a large number of samples, the sample organizer is a perfect option. With a capacity of 12 plates or 1,152 samples, the sample organizer will help keep your analysis running even when you're away by automatically introducing the plates into the instrument for analysis.



SAMPLE MANAGER FTN OR FL

Achieve sample injection versatility for your applications. Maximize the injection volume range from 0.1 to 1000 µL with a needle-in-flow path injector and achieve the lowest inject-to-inject cycle times with a loop-based injector. Ensure compatibility with Waters sensitive mass spectrometers with programmable method settings and ultra-low carryover.

MassTrak IVD Reagent Solutions

IMPROVE PATIENT RESULTS WITH CERTIFIED REAGENTS

Clinical diagnostic laboratories that would like to improve patient results with LC-MS/MS analysis in their lab often struggle to find regulatory approved and fit-for-purpose reagents for their assays.

Our ever-expanding line of MassTrak IVD Reagent Solutions* for quantitative analysis is the answer.

With MassTrak IVD Reagent Solutions,* your lab will get:

- **Regulatory approved solutions** for laboratory compliance
- **Calibrators and controls** with metrological traceability ensuring assay performance
- **Ease-of-use** that is adaptable to any laboratory workflow

**MassTrak IVD Reagent Kit Solutions are not available for sale in all countries. Please contact your local sales representative for additional information.*

MASSTRAK STEROID SERUM SETS (IVD)



MASSTRAK IMMUNOSUPPRESANT SETS (IVD)



Discover More

Explore Our Solutions



MASSTRAK IMMUNOSUPPRESSANTS KIT (IVD)

FDA 510(k)-cleared LC-MS/MS assay for the precise, accurate and specific quantification of tacrolimus to support transplant patient care.



MASSTRAK VITAMIN D KIT (IVD)

Waters MassTrak Vitamin D Kit is CE marked to the IVDR (EU) 2017/746 for the quantitative assessment of 25(OH)D2, 25(OH)D3, and total 25(OH)D in human plasma and serum.



MASSTRAK STEROID SERUM CALIBRATOR, QUALITY CONTROL, INTERNAL STANDARD AND OPTIMIZATION SETS (IVD)

MassTrak Steroid Serum Sets (IVD) offer three clinically relevant panels of labelled and un-labelled endogenous steroid compounds, lyophilized in human serum for routine clinical analysis.



MASSTRAK IMMUNOSUPPRESSANT CALIBRATOR, QUALITY CONTROL AND INTERNAL STANDARD SETS (IVD)

With MassTrak Immunosuppressant Standard Sets, you can ensure optimal method performance to account for sample matrix effects for the analysis of cyclosporine, sirolimus, tacrolimus, and everolimus in human whole blood samples.

Sample Handling

START WITH THE CLEANEST SAMPLE

When it comes to preparing and analyzing your sample, whether in urine, serum, plasma, or whole blood, Waters provides a variety of products to ensure you have the cleanest sample with the best resolution, allowing you to obtain an accurate and robust results.

Prepare

Quickly remove phospholipids and proteins out of your biological samples with Ostro™ Pass-through Sample Preparation Plates. Providing a simple pass-through protocol that requires minimal or no method development, this family of sample preparation products allows for quick implementation to optimize your laboratory's workflow.

When it comes to a wide range of analysis, the Oasis™ Sample Extraction family is available in seven sorbents to give flexibility and selectivity for effective solid-phase extraction across acidic, basic, and neutral molecule types. With µElution Extraction Devices, no evaporation and reconstitution are necessary due to elution volumes as low as 25 µL, which is ideal for SPE clean-up and analyte enrichment of small sample volumes.

Analyze

Waters ACQUITY™ UPLC™ Columns (IVD), with their patented sub-2-µm hybrid particle chemistry, enables you to harness the power of separation efficiency and robustness, maximizing your sample throughput, resolution, and sensitivity.

Note: Oasis and Ostro sample preparation products are for research use. Clinical use requires laboratory validation.

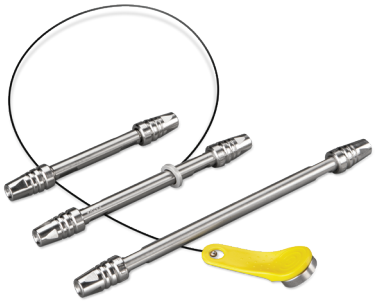
OASIS™
SAMPLE EXTRACTION PRODUCTS



OSTRO™
PASS-THROUGH
SAMPLE PREPARATION PRODUCT



Acquity
UPLC™





Automation Solutions

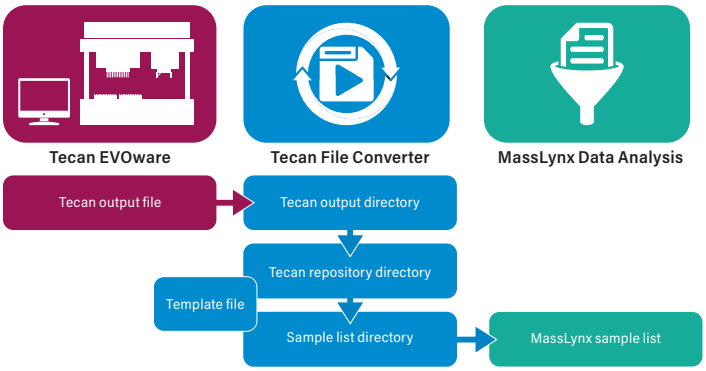
MEET YOUR AUTOMATION AND THROUGHPUT REQUIREMENTS

Achieve the flexibility, ease of use, customization, and scalability you need from automation while best leveraging your budget.

Our range of automation solutions seamlessly integrates with automated liquid handlers, software, and application scripts.

Regardless of your lab throughput, you can maximize reproducibility and meet your workflow requirements – whether that's with the Andrew+™ Robot or ensuring reproducibility of your SPE protocols with the Extraction+™ SPE Connected Device.

With our prepared automation scripts for automated liquid handlers, your lab can reduce the time and need for script development to start analyzing samples much faster.



Schematic of Tecan File Converter v2.0 automating the exchange of information between EVOware and MassLynx.™

MEET YOUR LAB REQUIREMENTS WITH THESE FLEXIBLE OPTIONS



LOW VOLUME

- Throughput: ~1–96 samples/day
- Single Clinical application using SPE
- Control Imprecision and variability
- Minimize transcription errors
- Reduce manual steps
- Types of sample preparation supported: SPE, PPT, LLE with Pipette+ Robot
- Sample tracking and traceability



MEDIUM/HIGH VOLUME

- Throughput: ~96–192 samples/day
- Multiple clinical applications
- Minimize the number of manual steps
- Control technician to technician pipetting Imprecision
- Free up technician time for other tasks
- Minimize transcription errors
- Types of sample preparation supported: SPE, PPT, LLE
- Sample tracking and traceability



HIGH VOLUME*

- Throughput: ~>192 samples/day
- Multiple clinical applications
- Maximize technician hands off time
- Control technician to technician imprecision
- Sample tracking from primary tube to result
- Minimize transcription errors
- Types of sample preparation supported: SPE, PPT, LLE
- Complete sample tracking

**Applicable to Tecan Liquid Handling Systems only - not sold by Waters*

Informatics Solutions

ACQUIRE, ANALYZE, AND MANAGE CLINICAL DATA

MassLynx (IVD) Mass Spectrometry Software with TargetLynx™ (IVD) Application Manager increases the speed at which you can convert your sample data into valuable knowledge and provides you the fundamental platform to acquire, analyze, and manage information in a clinical environment.

Automate and connect

Automate the exchange of information between MassLynx and a third-party LIMS or middleware provider with **MassLynx LIMS Interface.** Improve the data workflow and eliminate transcription errors.

Integrate

The Analytical Instrument Hub (ISS-AIH) software provides seamless software integration capable of communicating and connecting with any laboratory analyzer with the ability of being interfaced in either uni- or bi-directional messaging streamlining your laboratory data.

Monitor

Waters IntelliStart™ Software provides a simple and automated system check procedure to ensure that your Waters LC-MS/MS system is operating properly so you don't risk losing precious samples and time.

Control

Now you can manage system access of specific users and assign access rights to different system functions, giving you more control and increasing the ease-of-use for the everyday user with MassLynx Basic Security.

Process and Report

TargetLynx (IVD) Software provides comprehensive data processing with uncomplicated results review in complex samples despite extreme matrix variability.



Waters Solutions Data Workflow

Service and Support

THE SERVICE COVERAGE YOUR REGULATED LAB NEEDS

FlexCHOICE™: mySystem Coverage Solutions for Clinical Laboratories

Instrument performance, uptime, and cost control are critical for clinical laboratories. To ensure that time-sensitive sample analysis and high throughput are always available, you rely on regular instrument maintenance and rapid intervention when there are any problems.

Waters FlexCHOICE: mySystemCoverage is designed to provide maximum uptime with regular performance maintenance visits and guaranteed on-site response if remote technical support doesn't resolve a system issue.

Service and support

- Priority on-site support
- Remote technical support with 2-hour call back
- Access to Waters certified field personnel
- Labor and travel for repair included
- 48-hour on-site response time*

Performance maintenance

- Annual Performance Maintenance
- Genuine Waters Quality Parts™ included
- Firmware updates

**Availability may vary by region and system configuration.*

Financing

CUSTOMIZED FINANCING SOLUTIONS FOR YOUR LABORATORY

Waters empowers scientists all over the world with the most advanced analytical technology available. What you may not realize is that – through Waters Capital—pushing the boundaries of science is more accessible than ever before. Waters Capital offers a variety of flexible capital, financing, and licensing options customized for what your laboratory needs today and tomorrow – making science more accessible.

Waters Capital provides:

- Access to innovation
- Financial flexibility
- Expert responsiveness

Waters Capital provides financing solutions to help our customers access the technology they need to focus on what matters most – science and discovery. We offer a range of flexible financing and asset management solutions to maximize budgets and protect against obsolescence. Whether faced with capital budget constraints, aging technology, or simply the need for more equipment, Waters Capital can help.

Training

Waters Academy – Clinical is our dedicated online platform offering a wide range of educational resources designed to support laboratory professionals working in clinical diagnostics. Whether you're looking to deepen your understanding of LC-MS/MS or optimize your workflows, we offer flexible training formats to meet your needs:

Online Learning

- Access expert-led courses and resources anytime, anywhere
- Self-paced platform
- Build and maintain core competencies across a variety of clinical applications

Instructor-Led Training

- Hands-on, in-depth training sessions held at Waters facilities
- Sessions focus on specific topics and technologies
- Guided by experienced instructors in a collaborative, immersive environment

Onsite Training

- Customized training at your facility
- Tailored to your lab's workflows, systems, and priorities

waters.com/clinical

For *in vitro* diagnostic use. Not available in all countries.

For your local sales office, please visit waters.com/contact

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Waters™

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