



BETTER RESULTS CAN
CHANGE THE WORLD



Waters

THE SCIENCE OF WHAT'S POSSIBLE.®



INNOVATION THAT CHANGES THE ROUTINE

Clinical laboratories around the world are focused on reporting quality and truth in results. Accurate results are necessary for clinical research and discovery, as well as routine diagnostic testing. Waters provides a diverse portfolio of LC-MS/MS systems – some designed for the research laboratory, as well as a versatile array of medical devices for *in vitro* diagnostic use. Waters' focus has delivered the first FDA-cleared LC-MS/MS assay that integrates separations science, mass spectrometry, consumables, data management software, service and support. So, whether you are in search of a novel biomarker, identifying the latest designer drug or looking to take a routine lab test to a new level of performance, Waters can help you make a difference.



CLINICAL DIAGNOSTICS

Working with Clinical Laboratories around the world, Waters has pioneered an integrated medical device portfolio, as well as, the first FDA-cleared LC-MS/MS assay for *in vitro* diagnostic use that includes separations science, mass spectrometry, consumables, data management software, services and support. Waters medical devices are designed to meet your laboratory's needs and range from UPLC® to LC-MS/MS to fully integrated LC-MS/MS analyzers with automated sample preparation. This versatile system portfolio provides options as you develop methods and implement LC-MS/MS for routine use in the clinical laboratory.



VIRTUALLY IMMEASURABLE DIFFERENCES
CAN MAKE **LITERALLY** IMMEASURABLE DIFFERENCES

MEDICAL DEVICES

Waters manufactures an extensive portfolio of LC and MS Medical Devices for *in vitro* diagnostic use that offer clinical laboratories an alternative to systems manufactured for clinical research use only. Waters designs, manufactures and services its medical devices in accordance with an established quality system.

UltraPerformance Liquid Chromatography

ACQUITY UPLC®

Improves chromatographic performance, increases laboratory productivity, facilitates faster assay development and decreases operational costs through energy and solvent reductions.



ACQUITY UPLC I-CLASS

Achieve efficient separations with greater selectivity and enhanced sensitivity due to increased resolution.



UPLC-MS/MS

ACQUITY® TQD

Developed for integrated UPLC®/MS/MS quantitative applications with excellent analytical detection limits, resolution, and sample throughput for routine quantitative applications.



Automated Sample Preparation

MASSTRAK ONLINE SPE ANALYZER

Designed as a fully integrated LC-MS/MS system that automates every step in SPE sample preparation without the need for manual intervention.



“WATERS ISN'T JUST MY INSTRUMENT PROVIDER,
THEY'RE MY SCIENTIFIC PARTNER!”

John Engen, Ph.D. Associate Professor,
Chemistry and Chemical Biology, Northeastern University

Mass Spectrometry

■ XEVO® TQ MS

Solution for advanced quantitative UPLC-MS/MS applications, providing high sensitivity, selectivity and robustness combined with the capability to visualize qualitative information in every sample.



■ XEVO TQ-S

Designed for the most demanding quantitative UPLC-MS/MS applications. The ultimate in tandem quadrupole performance allows you to achieve the highest sensitivity in complex matrices and studies that may have been previously out of reach.



■ XEVO TQD

Developed for routine quantitative UPLC-MS/MS applications, providing accessibility to the sensitivity, selectivity and robustness needed to ensure maximum productivity with minimum effort.



THERAPEUTIC DRUG MONITORING

Therapeutic Drug Monitoring (TDM) is a branch of clinical chemistry that specializes in the repeated measurement of drug levels in whole blood, serum or plasma for drugs with a narrow therapeutic window. Considered the gold standard, LC-MS/MS offers increased sensitivity and superior specificity compared to Immunoassays and is becoming widely adopted for routine use in clinical laboratories around the world.

Waters has pioneered a TDM solution for LC-MS/MS. The MasTrak Immunosuppressants Kit is the first commercially available kit designed specifically for use with LC-MS/MS and cleared by the FDA for the quantification of tacrolimus in kidney and liver transplant patient whole blood samples as an aid in the management of tacrolimus therapy.



MassTrak Immunosuppressants Solution for Monitoring Tacrolimus

- The MassTrak Immunosuppressants Solution enables the accurate, precise and specific quantification of Tacrolimus on a Waters ACQUITY UPLC coupled to an ACQUITY TQD (LC-MS/MS system).
- 510 (k) cleared and CE marked for the quantification of the immunosuppressive drug Tacrolimus (FK506; Prograf®) in liver and kidney transplant patient whole blood samples as an aid in the management of Tacrolimus therapy.
- The MassTrak Immunosuppressants Solution is specific for the parent drug Tacrolimus and can overcome the inherent weaknesses of immunoassays due to mass selection. Immunoassays can be nonspecific, cross reaction with drug metabolites may lead to the overestimation of the parent drug.
- The MassTrak LC-MS/MS method for immunosuppressant drug monitoring offers increased sensitivity, consistently measuring tacrolimus at low ng/mL levels (0.5 ng/mL).
- Cost effective compared to immunoassay. Lower consumable and operating costs than immunoassay methods.

MassTrak Immunosuppressants Product Specifications

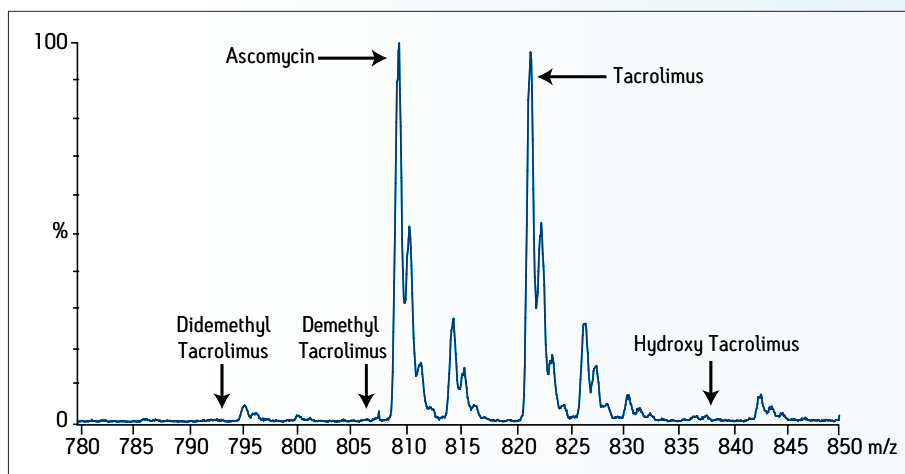
Assay Name	MassTrak Immunosuppressants Kit
Method	UPLC/MS/MS
Run Rate	~ 30 samples/hr
Reportable Range	0.5-30 ng/mL
Calibrators	*6 points: 0, 3, 6, 12, 20, 30 ng/mL (nominal values)
Controls	*3 levels: 2, 8, 22 ng/mL (nominal values)
Internal Standards	Ascomycin
Sample Type and Volume	Whole blood (preserved in EDTA), 50 µL
Sample Preparation	Manual pretreatment
Column Chemistry	MassTrak TDM C ₁₈ , 2.1 mm x 10 mm

**Actual concentrations are lot specific.*



Unparalleled Specificity

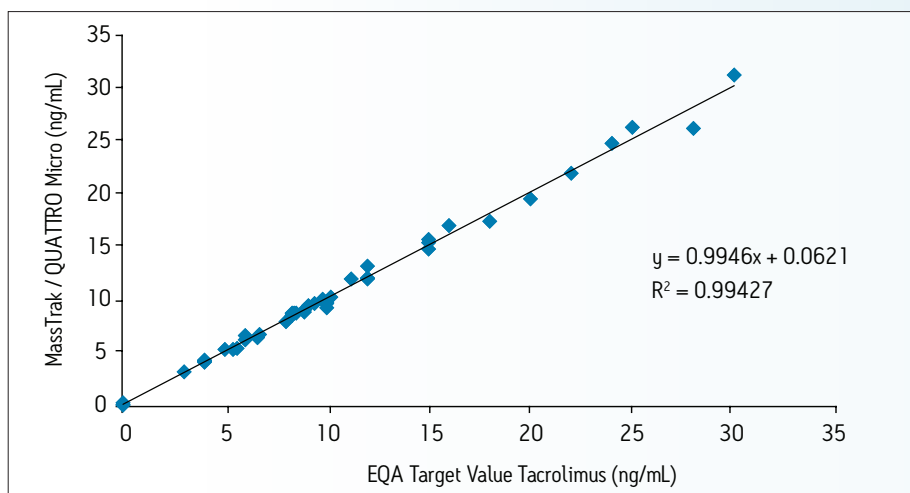
LC-MS/MS assays are specific for the parent compound. The MassTrak Immunosuppressants assay provides Tacrolimus concentrations independent of the level of known metabolites in patient samples.



Mass spectrum for Tacrolimus highlighting specificity for the parent compound without cross reactivity from drug metabolites.

Excellent Correlation

Harmonization of intra and inter-laboratory results benefits the quality of care for the ultimate end users, transplant recipients.



Correlation study comparing the MassTrak Immunosuppressants Kit test results to the international immunosuppressive drug measurement proficiency testing scheme (Analytical Services International Ltd.) target values for Tacrolimus.

Reliable Precision

Keeping within the therapeutic range is crucial to successful patient outcomes. Precise measurement of Tacrolimus ensures confidence in quality results. The MassTrak Immunosuppressants Kit exhibits a total imprecision of $\leq 10\%$ total CV, resulting in quality results and agreement across samples.


Sample	Mean (ng/mL)	N	Within Run		Between Run		Total	
			SD	%CV	SD	%CV	SD	%CV
Low	2.04	80	0.11	5.6	0.04	2.1	0.16	7.6
Medium	10.91	80	0.35	3.2	0.04	0.4	0.4	3.7
High	29.90	80	0.72	2.4	0.51	1.7	1.12	3.7

Three different pools of patient whole blood (low, medium, and high) were analyzed in duplicate, and two assays were performed each day for 20 days.

NEWBORN SCREENING

Waters and Perkin Elmer: Working Together to Benefit Newborn Screening

Waters and Perkin Elmer have collaborated to provide the NeoBase™ kit in combination with the ACQUITY TQD intended for the measurement and evaluation of amino acids, succinylacetone, free carnitine, and acylcarnitine concentrations from newborn heel prick blood samples dried on filter paper. Quantitative analysis of these analytes and their relationship with each other is intended to provide analyte concentration profiles that may aid in screening newborns for metabolic disorders. Developed, validated and manufactured by Perkin Elmer, the kit contains everything needed to perform these analyses with confidence.



MILLIONS OF BABIES HAVE
BEEN SCREENED USING
WATERS TANDEM MASS
SPECTROMETERS AROUND
THE GLOBE.

CLINICAL RESEARCH

The development of potentially life-saving diagnostics and medicines starts with clinical research. Clinical research scientists utilize cutting edge methods and technologies to elucidate mechanisms of disease and develop treatments intended to positively impact healthcare outcomes. Due to advanced levels of sensitivity and selectivity combined with the ability to quantitatively measure multiple analytes in a single analytical run, more and more scientists are adopting LC-MS/MS as their research tool of choice.

Waters Clinical Research Portfolio combines separation sciences, mass spectrometry, consumables, laboratory informatics software, and service for quantifying known and unknown analytes in a variety of matrices. Waters works with academic, government and commercial research organizations to support research initiatives ranging from pain management drug research to the quantification of fat-soluble vitamins and steroid hormones, to proteomics, metabolomics, and lipidomics. Revolutionary healthcare discoveries are made at the intersection of knowledge and technology. Don't trust your valuable research with outdated or unproven technologies. Waters can help your laboratory achieve experiments that may have been previously out of reach and discover the science of what's possible.



BECAUSE **GOOD ENOUGH**,
SIMPLY ISN'T **GOOD ENOUGH**

FORENSIC TOXICOLOGY

Forensic Toxicology analysis encompasses a diverse subset of applications each requiring unique, sample types, preparation techniques, and methodologies for a wide variety of compounds. To address such test complexities, Waters provides cutting-edge, integrated systems solutions combining UPLC and mass spectrometry to optimize laboratory throughput while delivering the highest degree of accuracy and sensitivity.

From broad based screening methods using the latest Time-of-Flight instruments to focused quantitative methods utilizing LC-MS/MS techniques, Waters provides system solutions with compound libraries and informatics to help your laboratory achieve results that deliver the truth.



UNMATCHED **ACCURACY** AND
SENSITIVITY AT YOUR BENCHTOP

DO NOT CROSS

SHERIFF'S LINE DO NOT CROSS

SHERIFF'S LINE DO NOT CROSS

MassTrak Solutions for Screening

Waters has developed three separate and complementary approaches to accurately identify unknown compounds, leveraging LC-MS/MS and LC/TOF technologies for forensic toxicology screening:

Systematic Toxicological Analysis (STA): A general LC-MS/MS screening method to identify unknown compounds of interest when used with ChromaLynx™, a unique automated data processing software tool that ensures you routinely perform faster analysis and data interpretation.

Multiple Reaction Monitoring (MRM): A targeted LC-MS/MS screening method that employs pre-defined individual traces, corresponding to specific toxicological compounds of interest, to increase sensitivity and specificity when used in conjunction with ChromaLynx software.

Accurate Mass Screening (TOF): Use of Waters patented MS^E technology, allows users to acquire an unrestricted exact mass data set including fragment ion information with excellent sensitivity in a single run. This enables retrospective analyses without sample re-injection and prediction of elemental composition which can be extremely beneficial when dealing with new designer drugs and analogs.

Advantages of MassTrak Solutions:

- Ease of use and efficiency: All screening solutions employ the same LC method to reduce complexity and increase throughput.
- Verified process to help ensure accurate, reproducible results.
- Comprehensive, relevant compound libraries developed in conjunction with practicing Forensic Toxicologists. Waters' library database includes retention time, precursor and product ion information to provide the highest degree of confidence in results.
- Simplicity of implementation: All method and library information required to perform the analysis is provided with the support of Waters industry leading service professionals to make implementation smooth and seamless.

MassTrak Solutions for Quantification

Waters maintains a library of the latest in quantitative methods for forensic toxicology, to save you the time and effort of developing complex methods from basic principles. We are committed to utilizing our newest instruments to provide the latest cutting edge applications across a diverse set of sample matrixes and compound classes including:

Compound Classes

- Opiates
- Amphetamines
- Synthetic and/or "Designer Drugs"
- Cannabinoids
- Benzodiazepines
- Cocaine and metabolites
- Ethanol biomarkers
- Anti-psychotics/anti-depressants
- Hallucinogens

Matrices

- Urine
- Blood/plasma
- Oral fluid
- Hair
- Post-mortem blood
- Sweat
- Meconium
- Bone



Waters is committed to the development and manufacture of products that solve today's most challenging separations problems. To learn more about Waters consumable products for clinical diagnostics, research or forensic toxicology visit www.waters.com/clinicalconsumables

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