

PerkinElmer leads the way in Expanded Screening with MSMS



A total solution based on
non-derivatized assay

Working with the MSMS technology leader to provide



PerkinElmer has wide experience in meeting the needs of newborn screening programs that are implementing tandem mass spectrometry. Our solution for such programs relies on instrumentation produced by Waters, the leader in tandem mass spectrometry technology. The PerkinElmer - Waters collaboration has helped us to develop products to meet the expanded newborn screening needs of today, and anticipate those of the future.

the best solution for you

Alongside its top-of-the range instrumentation PerkinElmer offers reagent kits to save your program work, time and worries relating to quality of reagents.

Further, to supplement the instrument control MassLynx/NeoLynx software package, PerkinElmer offers its unique Specimen Gate® MSMS Data Suite edition. This is fully integratable with MassLynx/NeoLynx, and provides sophisticated features for handling your neonatal screening program's MSMS data.

- PerkinElmer tandem mass spectrometry systems play a key role in the expanded screening programs of 20 US states and 25 countries.
- Between 2004 and 2007 we estimate that 11.6 million babies were screened using our MSMS assays for PKU or AA/AC.

PerkinElmer and Waters: **working together to benefit newborn screening**

- *Waters is global leader in development and manufacturing of mass spectrometry and LC systems*
- *PerkinElmer is global leader in newborn screening and a pioneer in commercial expanded screening systems*
- *Both companies have state-of-the-art quality systems to ensure the consistency of the complete solution: instruments, reagents and software*
- *The resources of both companies are harnessed to assure comprehensive training, customer support and service*



Instrumentation to meet the specific needs



2777C Sample Manager

Designed for high-throughput applications utilizing microplates

- Very compact design minimizes the use of laboratory space yet supports a capacity of up to 24 plates
- No need to wait for all plates before starting the instrument, but plates can be loaded as they become available
- Robust and innovative sample arm and injector valve design ensures highly dependable operation day in, day out



1525 μ Binary Pump

Highly reliable and specifically tuned for neonatal screening applications

- Minimized system volume provides high sample throughput with minimal reagent consumption
- Exceptional flow rate precision and accuracy with a pulse-free delivery provide the basis for obtaining maximum information from each sample



TQD MSMS Instrument

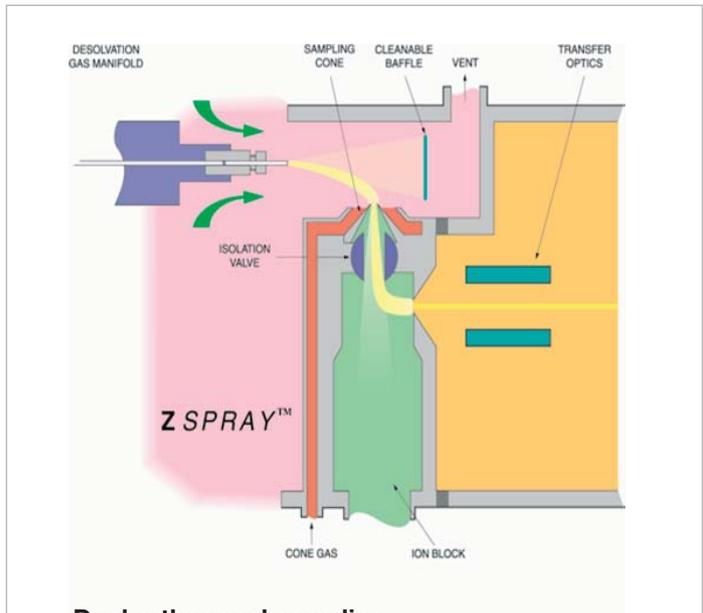
Technological advances to bring you improved sensitivity and enhanced quality

- Proven stability of the Waters Quattro™ micro, but with superior transition times due to T-Wave™ collision cell technology
- Well-tested and highly reliable Waters triple quadrupole mass spectrometer technology
- Very small footprint (35.5 cm x 84.8 cm, or 14"x 33.5") giving a space-saving total volume 25 % smaller than Waters Quattro micro

of newborn screening laboratories

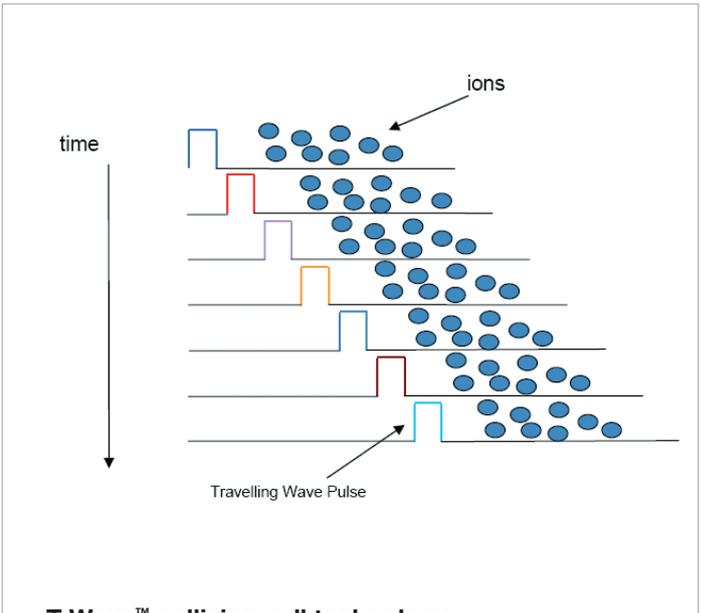
MassLynx 4.1 and NeoLynx 4.1

- The detector, binary pump and sample manager are controlled with market-leading MassLynx software. This easy-to-use mass spectrometry data program enables intelligent control over the entire MSMS system. A valued feature of MassLynx is the novel IntelliStart automated software tools for quick system start-up and system performance monitoring which helps every user to obtain the best possible data. At the core of MassLynx is the Sample List, which conveniently gathers all the sample information required for a successful MSMS analysis.
- NeoLynx software is a neonatal application enhancement to MassLynx. NeoLynx provides a highly visual tool for assessing out-of-range results for analytes of interest.
- PerkinElmer Specimen Gate MSMS Data Suite edition can be readily integrated with MassLynx and NeoLynx and provides comprehensive data handling features.



Dual orthogonal sampling

The ZSpray™ ion source represents the most rugged and sensitive API (atmospheric pressure ionization) source on the market. It features dual orthogonal sampling, a process by which the sample spray is turned through 90° twice. The first turn protects the MSMS instrument from sample matrix and thus reduces the need for instrument cleaning. The second turn maximizes the sample amount to the MSMS providing improved sensitivities. In addition to superior performance, ZSpray design allows quick and easy maintenance without the need for venting – another factor that guarantees the maximum uptime for the instrument.



T-Wave™ collision cell technology

Previously available only in very high-end triple quad mass spectrometers, T-Wave™ collision cell technology allows for increased acquisition speed and hence improved sensitivity. Faster acquisition speed also means that more analytes can be detected without extending assay time. The TQD MSMS instrument thus provides an excellent choice to support future growth in the screening program.

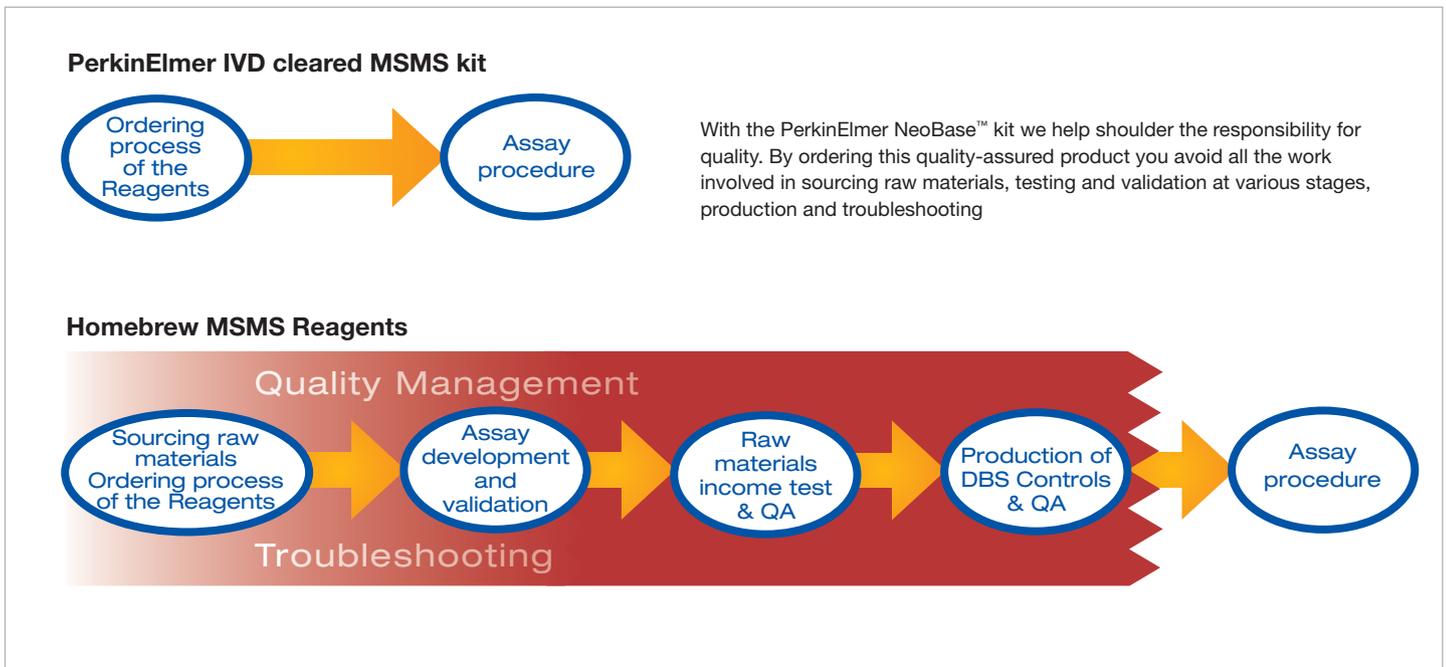
The traveling wave device described here is similar to that described by Kirchner in US Patent 5,206,506 (1993).

Quality reagents – a key success factor in you

The success of your screening program depends on your analytical performance. Performance, in turn, is directly related to the excellence of your reagents. Whether these are internal standards providing the basic intensity readings or controls to guide cut-off levels, quality is essential. With PerkinElmer reagents you can rest assured that all necessary quality assurance steps have been taken on your behalf.

- All raw materials (IS / solvents/ plates etc.) are qualified and are subject to strict quality control
- Manufacturing is controlled under strict guidelines
- High and low DBS quality controls are set at critical decision levels

Our Quality Management System is compliant with the U.S. Food and Drug Administration (FDA) Quality System Regulation (QSR) and the ISO 13485:2003 international quality management system standard, ISO 9001:2000, CMDCAS and the IVD Directive 98/79/EC.



It is possible to measure more than 40 analytes of key importance in screening for disorders of amino acid metabolism, fatty acid oxidation and/or organic aciduria

ur screening operation

The high-performance NeoBase non-derivatized assay

Currently, the most widely used tandem mass spectrometry-based method for detecting inborn errors of metabolism relies on the butylation of amino acids, acylcarnitines and free carnitine. This assay, known as the derivatized assay, allows for the measurement of 30-40 markers that are used for the screening of more than 30 genetic metabolic disorders simultaneously.

As impressive as the derivatized assay is, questions that still remain are: Can the assay be simplified? Can it accept new analytes?

The PerkinElmer 3040-0010 NeoBase™ non-derivatized MSMS assay provides a positive answer to both questions. While retaining equivalent analytical performance, it requires only 4 steps compared to 12 steps in the derivatized assay. In addition, the capability to measure proline and succinylacetone has been added.

The NeoBase kit includes 12 isotopically labeled amino acid standards and 13 isotopically labeled acylcarnitine standards. In addition, high and low DBS controls for 10 amino acids and 13 acylcarnitines are included.



Amino Acids

Internal Standards

Alanine
Arginine
Citrulline
Glycine
Leucine
Methionine
Ornithine
Phenylalanine
Proline
Tyrosine
Valine
Succinylacetone

Controls (high and low)

Alanine
Citrulline
Glycine
Leucine
Methionine
Phenylalanine
Proline
Tyrosine
Valine
Succinylacetone

Acylcarnitines

Internal Standards

Free carnitine (C0)
Acetylcarnitine (C2)
Propionylcarnitine (C3)
Butyrylcarnitine (C4)
Isovalerylcarnitine (C5)
Glutaryl carnitine (C5DC)
Hexanoylcarnitine (C6)
Octanoylcarnitine (C8)
Decanoylcarnitine (C10)
Lauroylcarnitine (C12)
Myristoylcarnitine (C14)
Palmitoylcarnitine (C16)
Octadecanoylcarnitine (C18)

Controls (high and low)

Free carnitine (C0)
Acetylcarnitine (C2)
Propionylcarnitine (C3)
Butyrylcarnitine (C4)
Isovalerylcarnitine (C5)
Glutaryl carnitine (C5DC)
Hexanoylcarnitine (C6)
Octanoylcarnitine (C8)
Decanoylcarnitine (C10)
Lauroylcarnitine (C12)
Myristoylcarnitine (C14)
Palmitoylcarnitine (C16)
Octadecanoylcarnitine (C18)



Specimen Gate® MSMS Data Suite – for efficient m



Newborn screening results in a significant amount of information that needs to be tracked. Now, the implementation of MSMS technology, with the ability to multiplex, is generating a further huge increase in the data workload. Specimen Gate MSMS Data Suite edition helps expanded newborn screening laboratories address the problem of data overload. With effective data management you stand to improve efficiency, save work and reduce costs.

Management of the screening information

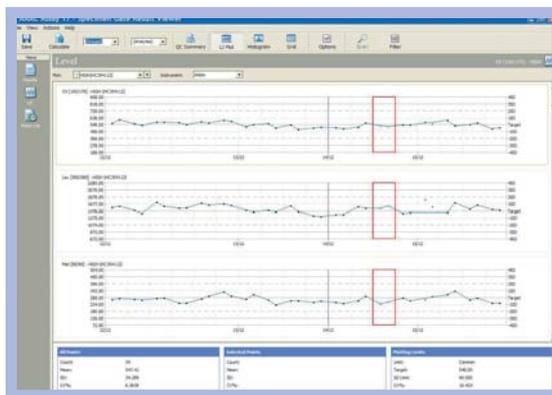
Easy to use screen displays to follow lab workflow

Designed specifically for use with MSMS instrumentation, MSMS Data Suite allows monitoring of the laboratory workflow. Users can quickly identify QC violations, elevated or decreased analytes, and evaluate cut-offs. Your lab defines the rules and the software applies these to highlight automatically the specimens of interest. There are enhanced flagging capabilities; MSMS Data Suite is designed to handle complex ratios and allow users to enter their own comments.

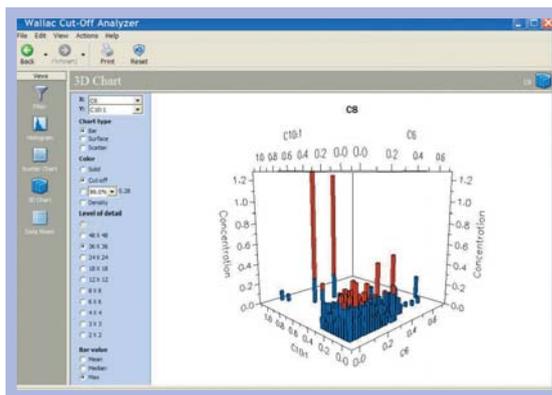
You can use the software to create QC reports in pdf format and these can be electronically signed. Workflow management and security features also mean you can allow one group of users to review plates and another group to perform the final acceptance. Access to restricted features such as result acceptance can be quickly granted or removed for any user.

- Automatically highlight QC and cutoff violations
- Cutoff analysis based on the customer's patient population
- Monitor and evaluate QC materials, trends, standards and controls
- Customer-controlled security settings
- Scalable to Specimen Gate® Laboratory, LifeCycle™, and PatientCare™
- Standard XML export provides results in a common format for additional analysis by other systems

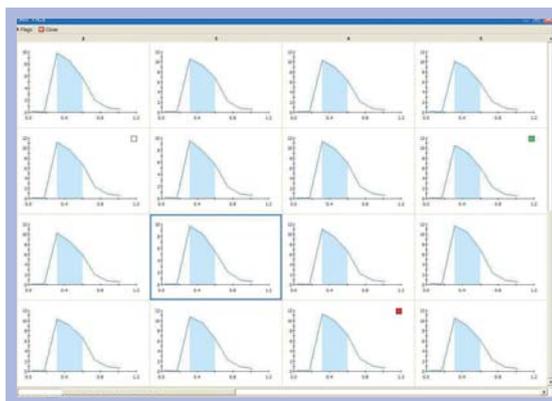
In continuous development since 1994, the Specimen Gate® software product family provides a Total Process Management Solution for your genetic screening laboratory. There are three Specimen Gate® software applications – Laboratory, LifeCycle™, and PatientCare™. Specimen Gate Laboratory is available in two editions, MSMS Data Suite edition and Enterprise edition. MSMS Data Suite is scalable, and may be extended, for example, to Laboratory or to the complete Specimen Gate solution.



Graphical tools for monitoring and evaluating QC materials, trends, and standards and controls



Electronic data storage provides a basis for QC analysis over time, analysis of cutoffs specific to the customer's patient population (shown here), and electronic records of each plate processed



Quick review of standard quality indicators such as Total Ion Chromatograms (TICs)

PerkinElmer – a better standard of customer ca



In addition to delivering excellent products, PerkinElmer provides a level of customer support that is second to none. Our centers of expertise in tandem mass spectrometry are located at Turku, Finland (Europe) and Akron, Ohio (USA). Both centers provide comprehensive customer training and are the focal points for our broad-ranging customer support and service operations.

Service and support globally

PerkinElmer’s dedicated customer support group consists of highly educated, well experienced, specialists ready to assist customers in the implementation and use of tandem mass spectrometry for amino acid and acylcarnitine screening. The group’s members participate in new product testing and evaluations and work in close co-operation with R&D and Production. A phone call or e-mail places the expertise of the customer support group at your service.

Our large installation base and years of expertise in neonatal screening have enabled us to establish a rapid-response service operation that meets, and even exceeds, the standards required by the most demanding screening laboratories.

Our service engineers are all specialists, who understand the requirements of your processes, and who will play their part to ensure that response times are short.

We offer comprehensive service and preventive maintenance agreements, available globally. Such an agreement allows you to maximize your uptime and ensure that you’ll be able to provide accurate results in a timely manner.

PerkinElmer is serving newborn screening programs in 74 countries and in every state of the USA



 Countries, states or provinces with newborn screening programs employing PerkinElmer products and methods

 Countries, states or provinces where PerkinElmer is cooperating with expanded screening programs

For more information about PerkinElmer products, please visit our website:

www.perkinelmer.com/gds

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For a complete listing of our global offices, visit www.perkinelmer.com/asooffices

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