NEWBORN SCREENING

1st and 2nd Tier screening Workflow Solutions using Mass Spectrometry

Waters™

Completing Your MS Workflow

Newborn screening programs enable early identification, referral, and treatment of babies born with rare disorders.

The needs of laboratories carrying out such work differ in scale and scope, and thus the range of analytical systems and data management solutions need to be able to accommodate such variety.

Waters™ Corporation's long history and experience in supporting this critical area of screening continues to evolve through listening to and understanding the needs of our users today and the future.

ENJOY FLEXIBILITY IN ALL TIERS OF SCREENING WORKFLOW OR FURTHER TESTING.

Waters is here to work with you to offer choice and enable you to make the decisions on what works for your laboratory.

Our mission is to optimally enable newborn screening laboratories through the provision of proven solutions including mass spectrometry, data management software, training, and support.

OMNI-Lab NBS Informatics

Every lab is unique, and OMNI-Lab's scalable, browser-navigated approach, and flexible rules can be adapted to suit each newborn screening lab's needs.

OMNI-Lab is a complete single database laboratory information management system that meets all the requirements of the newborn screening laboratory.

All features and functions are focused towards the patient/baby ID to enable easy result collation and management. From patient and card registration through results authorization to report delivery and follow-up, OMNI-Lab NBS provides all the features necessary to successfully manage the newborn screening laboratory.

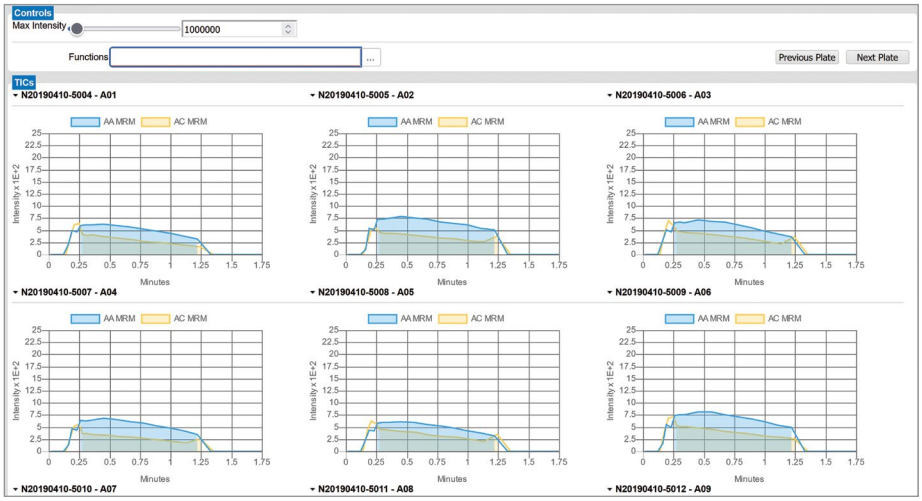
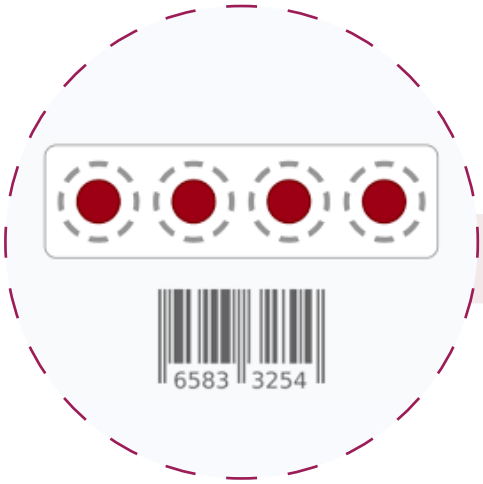


Figure 1. OMNI-Lab NBS includes all functionality for management of tests, results, reporting, and follow-up of outcomes data.

1ST TIER NBS WORKFLOW

The beginning of any workflow starts with the patient's dried blood spot sample. OMNI-Lab and Waters Instrument Hub (WIH) can connect your automated puncher to your analyzer, simplifying data transfer.



ACQUITY™ UPLC™ I-Class PLUS and Xevo™ TQD Systems

DATA TRANSFER

WIH Data Management

1st Tier NBS screening workflow requires confidence in your analytical platform with the added flexibility of either plate automation or chromatography or both.

RenataDX™ System

RESULTS PROVISION

Direct or by remote 24/7

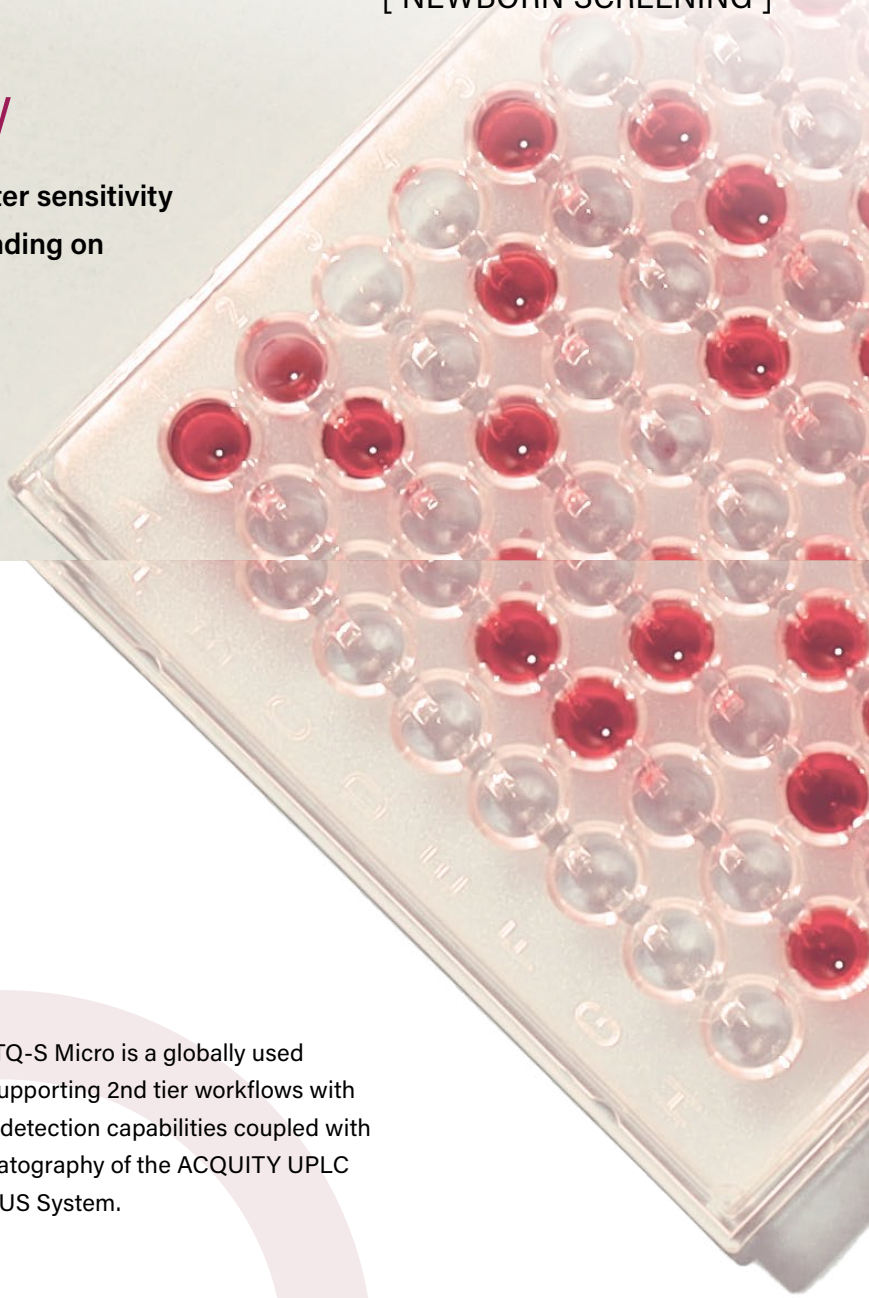
DATA CONSOLIDATION

OMNI-Lab Data Management

We provide effective data management from simple platform connectivity with Waters Instrument Hub (WIH) to a fully flexible LIMS designed to meet your specific newborn screening needs with OMNI-Lab.

2ND TIER NBS WORKFLOW

For harder to detect molecules, requiring greater sensitivity in identification, Waters provides choice depending on your requirements.



ACQUITY UPLC I-Class PLUS and Xevo TQ-S micro Systems

The Xevo TQ-S Micro is a globally used platform supporting 2nd tier workflows with enhanced detection capabilities coupled with the chromatography of the ACQUITY UPLC I-Class PLUS System.

ACQUITY UPLC I-Class PLUS and Xevo TQ Absolute Systems

The newly launched Xevo TQ Absolute System offers even greater sensitivity for those instances where truly advanced detection is required.

SOLUTION ELEMENTS IN SUMMARY

Waters understands the variations in workflow requirements and can provide standalone, automated, and connected platforms to meet multiple user needs.

MassTrak™ ACQUITY UPLC I-CLASS PLUS/ XEVO TQD IVD SYSTEM

- Throughput of up to 26 samples/hr = 8 plates in 6.5 hrs
- HL7 compliant MassLynx™ LIMS Interface
- Optional Column Manager allows switching to chromatographic analysis
- Optional Sample Organizer increases capacity to 11 plates for very high-volume laboratories
- Compatibility with Laboratory Developed Tests (LDTs) and third-party reagent kits of your choice

RenataDX SYSTEM

- Fully integrated flow-injection tandem mass spectrometry (FIA-MS/MS) IVD System
- High-throughput analysis of analytes from dried blood spots
- Compatibility with LDTs and third-party reagent kits
- Throughput of up to 26 samples/hr = 8 plates in 6.5 hrs
- 11 x 96 well plates or 4 x deep well plate capacity

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

- Z-Spray geometry, efficiently removes neutral molecules
- Reproducible low levels of quantification for difficult analysis
- Minimal instrument downtime with simple tool-free maintenance and cleaning procedures
- Established globally in 2nd tier workflows

MassTrak XEVO TQ-ABSOLUTE IVD SYSTEM

- Intuitive informatics software solutions
  - Control user access
  - Monitor system
  - Process and review results
- Tool-free maintenance protocols
- Up to 5x better sensitivity for challenging negative ionizing compounds vs. TQ-S Micro
- Sustainable design with 45% smaller in size and uses 50% less nitrogen gas and electricity than comparable mass spectrometry systems

QUICK AND EASY DATA MANAGEMENT WITH WIH

- Securely review data any time, anywhere
  - Communicate with third-party instrumentation
  - Import and Review QC and Results
  - Export data to OMNI-Lab or third-party LIMS
- Fast, easy deployment
- Small footprint, browser-based application can be installed in parallel with existing infrastructure for pilots, trials, and second-tier assays

OMNI-LAB NBS PUTS YOU IN CONTROL

- Full Featured NBS Program Management
  - User-defined rules, cutoffs, reports, and workflow
  - Laboratory systems, result reporting, and follow-up data
  - Electronic Test Orders and Results (ETOR)
  - Works with any platform, technology, or chemistry
- Ability to collate data from laboratory, external, and POC (Point of Care) testing
- Browser-based software with 24 x 7 x 365 technical support
- Built-in library of interfaces to Waters and third-party NBS instrumentation
- Built-in support for electronic interfaces including HL7 and FHIR
- Securely review data any time, anywhere

APPLICATIONS, ANALYZERS, DATA CONNECTIVITY

Enabling carefully and **co-operatively guided NBS workflow solutions** to meet your 1st and 2nd Tier mass spectrometry screening needs.

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

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