waters_connect for IVD Software and the QUAN Review Application

A better workflow for faster results. Streamline with precision; elevate lab efficiency with waters_connect for IVD Software.

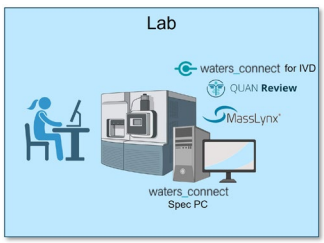
THE WATERS_CONNECT FOR IVD SOFTWARE AND THE QUAN REVIEW APPLICATION ARE DESIGNED TO SIMPLIFY POST-ACQUISITION PROCESSING, DATA REVIEW AND DATA MANAGEMENT IN THE CLINICAL LABORATORY.

The requirement for data generated in the clinical laboratory as well as the rigorous method performance characteristics defined by the FDA and CLSI guidelines[1] is burdensome to all laboratory staff including directors, supervisors, technicians, and quality personnel. In the field of quantitative LC-MS/MS, the need for efficient, accurate and user-friendly data review software is paramount.

1. CLSI C62-Ed2:2022.

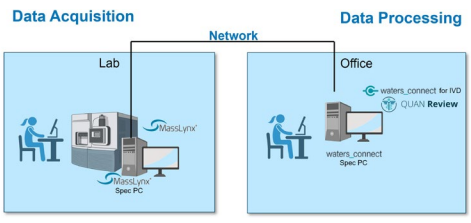
The software introduces a series of innovative features including; Dashboard for exception focused review (XFR), Peak Integration for a "PanoGramic" view of multiple peaks at a glance and Filtering for specific exceptions to identify potential issues sooner. This significantly reduces the burdensome aspects of batch quality control by improvements in workflow, a modernized interface, and the ability to flag exceptions based on rule sets.

DEPLOYMENT OPTIONS



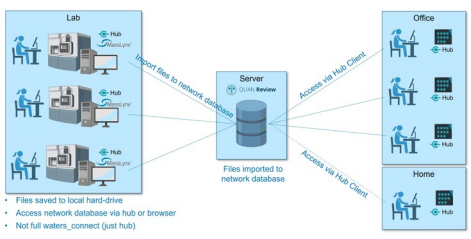
Single Workstation

- Combined MassLynx™ and waters_connect™ for IVD workstation



Dual Workstation

- Separate MassLynx workstation up to 3 systems and a single waters_connect for IVD workstation



Network

- MassLynx workstation with waters_connect for IVD HUB client
- Server with waters_connect for IVD
- Web browser access using waters_connect for IVD HUB client

HOW IT WORKS

Administration

- Access management (users, roles, policies and security)
- Software and Database management (licensing and audit logs)

The Explorer Application

- Import sample lists and raw data
- Manage data and methods

The QUAN Review Application

- Create methods, calibrator & QC levels, and rule sets
- Review by exception workflow
- Report (pdf) and export results (csv by analyte, csv by injection, or XML)

WORKFLOW STEPS

STEP 1

- Import MassLynx Tandem Quad MRM data in Explorer (Figure 1).

STEP 2

- Import the complete batch including MassLynx Sample List (SPL) and RAW data files using Explorer (Figure 1).

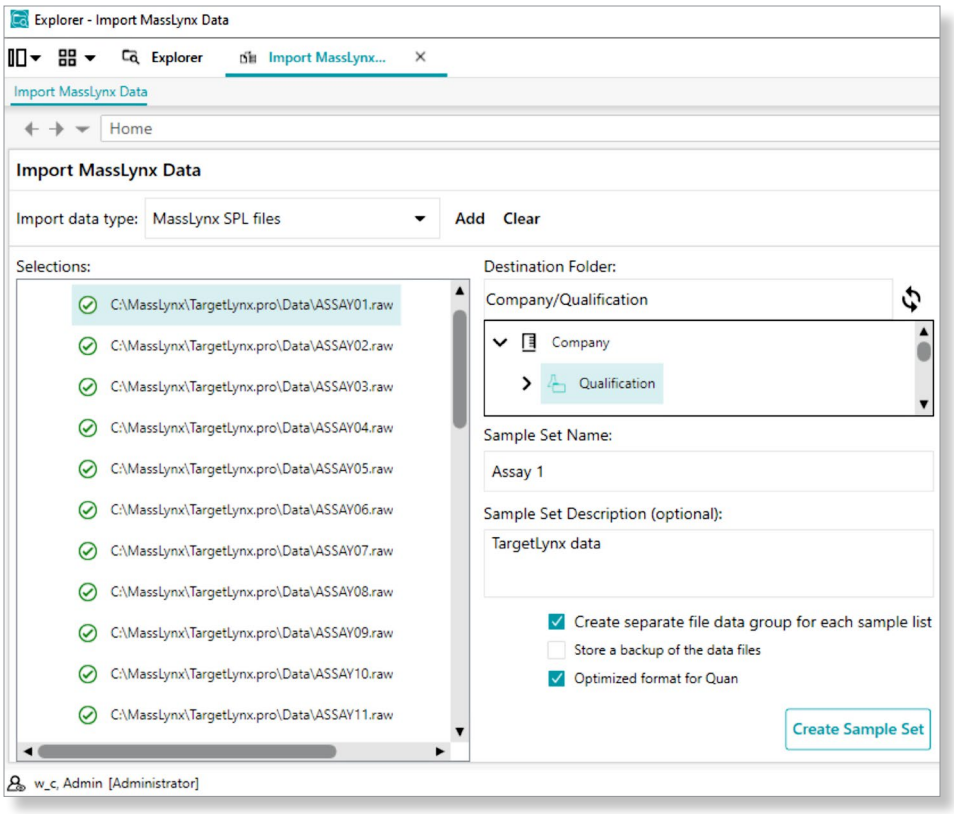


Figure 1. Selection of MassLynx Sample List (SPL) in Explorer for data (RAW) import.

STEP 3

- Create a QUAN Review processing method (imported from TargetLynx™) and a rule set to set method performance characteristics. This is a one-time operation prior to performance validation according to local guidelines and standard operation procedures (Figure 2).

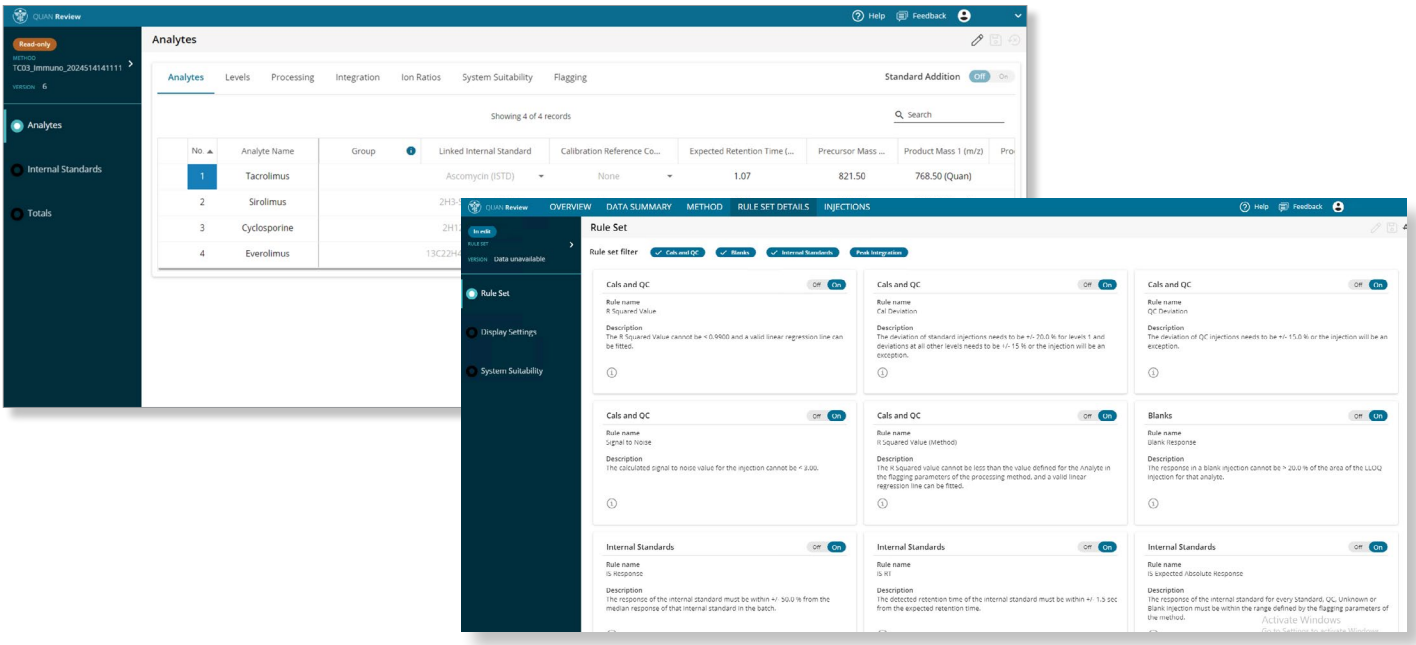


Figure 2. Analytes defined in the QUAN Review processing method and default rule set (inset). ***Note: The rule set may be customized dependant on method performance characteristics.***

STEP 4

- Create a results set by processing the imported data using a QUAN Review method and rule set.
- The Dashboard summarizes the batch status and highlights data exceptions utilizing the applied rule set (Figure 3).

Figure 3. An example of the Overview page showing exceptions in the Cals & QCs (n=2), Blanks (n=2), Internal Standards (n=3), and Peak integrations (n=7).

WORKFLOW ENHANCEMENTS

Overview and dashboard

On a single page, the user is able to review all the batch-specific performance data including system suitability, calibrators and QCs, blanks, internal standards, peak integration and unknown samples (Figure 3). A task-oriented workflow decouples complicated data review into simplified steps which allows the user to quickly navigate through data and accelerates the review process.

Exception Focused Review

The method performance parameters defined in the rule set, based on standard operating procedures and validation limits, allows the user to quickly identify and address errors in the data. Flags and alerts are displayed on the Dashboard and in more detail on the Overview page of the data review workflow. By clicking on the alert (exception) hyperlinks from either the Dashboard or the Overview, the user can easily investigate questionable data. For example, clicking on the Cals & QCs page from the Dashboard allows the user to quickly identify that the R^2 linearity check for Tacrolimus is failing (Figure 4) and that one Sirolimus Level 8 QC replicate is failing (inset). The Exception Focused Review functionality can reduce data review time by up to 50% as compared to TargetLynx.

Figure 4. Cals & QC summary showing two exception filters. (1) R Square (Method) for Tacrolimus and (2)QC deviation for Sirolimus (inset).

PanoGramic display

The user can view multiple chromatograms to quickly identify data quality issues (*e.g.* peak shape, retention time and interferences) which is essential when reviewing large or complex data sets. The peak integration display for Tacrolimus shows the one is found in an unknown sample is in an unknown sample (Figure 5). Analyte or internal standard chromatograms can be quickly selected and displayed through Exception and Sample type filters (Figure 6).

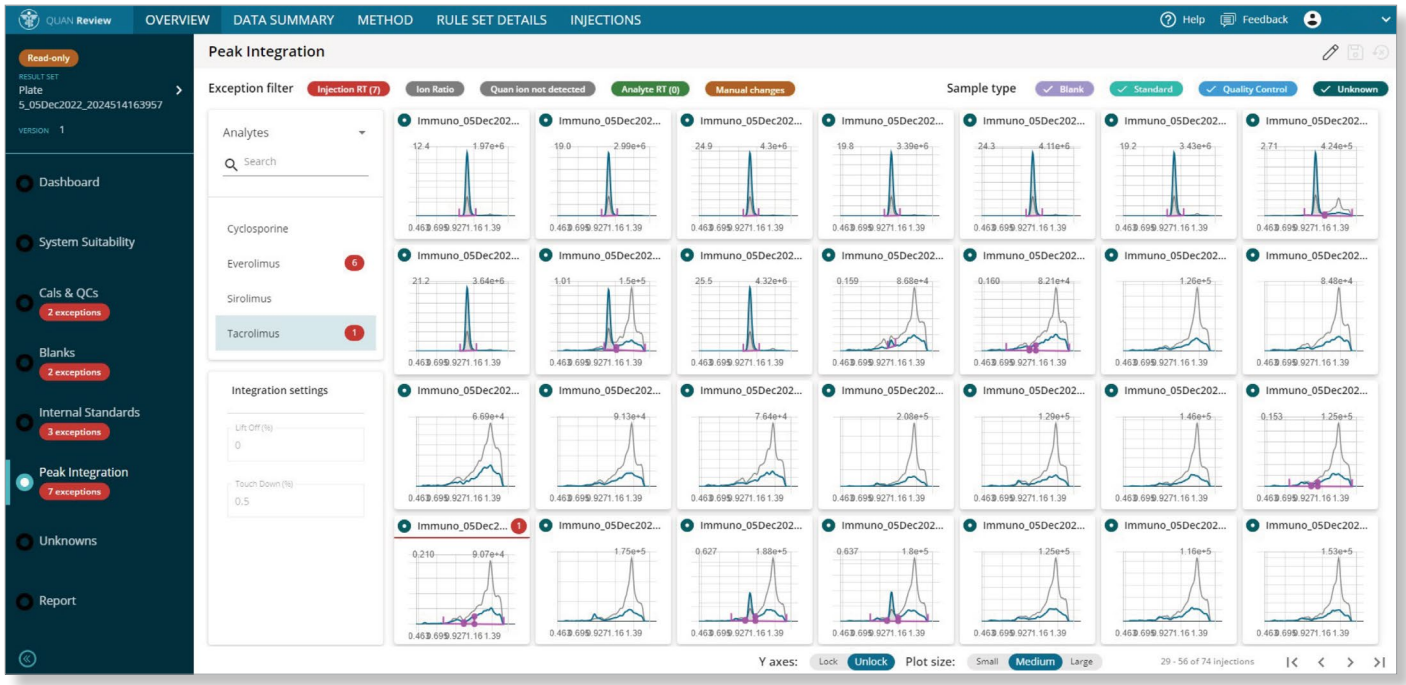


Figure 5. Peak integration for Tacrolimus which identifies the unknown sample with one exception for injection RT.

Figure 6. The Peak Integration for Sirolimus standards with Y-axes locked on the highest standard and the Plot size set to Large.

Connectivity

The software streamlines connections to lab information management systems (LIMS), reducing or eliminating manual input.

Data output

The user can export the reviewed and processed data for further analysis or reporting. The XML exported report can be consumed by the latest MassLynx LIMS Interface in the form of HL7 messages to a LIMS.

Key Benefits

- Reduce data review by up to 50%*
- Dashboard summarizes key parameters on one screen
- Exception focused review to quickly resolve errors
- PanoGramic display of multiple chromatograms to quickly identify problems/ambiguous data

** As compared to TargetLynx Software.*

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