Precise bioanalysis, when it matters

Choose Watson LIMS software to power the dependability you need for tomorrow's demands.

Thermo Scientific™ Watson™ LIMS Software has been widely recognized as the industry standard in bioanalytical support with over 8,000 users worldwide. It manages your bioanalytical data, creating efficiencies and promoting compliance for small- or large-molecule bioanalytical workflows for clinical and non-clinical studies. Watson LIMS software enables complete traceability and control throughout your bioanalytical study, from initiation through study closeout, while enabling compliance and adherence to industry regulations.

For over two decades, Watson LIMS software has helped bring drugs to market across the world. As the world leader in serving science, Thermo Fisher Scientific is committed to growing with the bioanalysis market and the continuous evolution of Watson LIMS software.

Power your bioanalytical workflows

Manage and build study designs

Upload sample manifests using templates with the aid of Import Study Protocol to reduce metadata transfer errors.

Maintain sample chain of custody

Record all sample shipments and monitor sample's movement, define storage locations down to plate position, and track freeze/thaw cycles and sample stability. Easily provide chain of custody records to auditors.

Achieve traceability throughout a study

Get complete study records and reports from study initiation through study closeout, including sample chain of custody, assay verification, and reconstruction events using the audit trail.

Connect lab instruments and software

Reduce the risk of manual transcription errors by automating data capture and management processes. Watson LIMS software integrates easily with instrumentation through established interfaces (e.g., SCIEX™ Analyst™ software).

Streamline method validation and sample analysis

Perform concentration evaluations to assess pharmacokinetics (PK) along with an assessment specific for anti-drug antibodies (ADA) assays. Set acceptance criteria and identify results that fall outside the expected range.

Execute efficient reporting and QA review

Generate a full study report, including method validation experiments, assay performance, and study data. Report your data in CDISC, SEND, and SDTM formats to help streamline submissions.

Get built-in security and audit trail

Benefit from maximum flexibility and configurability while preserving data integrity. System and study access are granted to authorized, role-based users, in accordance with Good Laboratory Practice (GLP).

Simplify compliance

Generate study-specific labels that meet the necessary requirements. Implement storage facilities that include visible labels and barcodes for easy identification and traceability. This helps ensure compliance with 21 CFR Part 11, FDA Bioanalytical Method Validation, and EMA guidance to facilitate audits.

Streamline data processing and reporting

Easily generate a variety of graphs, tables, and statistical calculations from study data. Sort, find, filter, and reorder grid contents for a quick way to review a specific sample's data.

Minimize quality review time

Get real-time snapshots of data quality and easily transfer study data between sponsor and CRO using pre-defined assay performance and summary tables.

Manage your bioanalytical study from initiation to study archival

Method management
Review and optimize methods through collaboration.

Study design
Model flexible study designs and apply amendments.

Method validation
Perform quantitative measurements for:

- Precision and accuracy
- Selectivity, specificity, and carryover
- Matrix effect and dilution integrity
- Stability and recovery

Sample receipt
Create new or import existing barcodes to identify samples and help ensure traceability.

Sample management
Define storage location down to plate position, track freeze/thaw cycles, and prove chain of custody.

Data acquisition
Utilize pre-defined data exchange with many data acquisition systems. Secure and scalable bi-directional instrument communication preserves data integrity.

Routine assays
Get support for LCMS and quantitative and qualitative ELISA essays, including Multiplex, ADA, and NaB assays.

Regression & data review
Analyze data using several models (linear/non-linear), annotate anomalous results, and facilitate accept/reject decisions using run acceptance tool.

Manage reassays & ISR
Identify reassays, automate reassay decisions, and report reassays and Incurred Sample Repeats.

TK/PK analysis
Manage non-compartmental analysis on individual or pooled data, bioavailability calculations, and data export in SEND PP domain format.

Immunogenicity
Calculate assay cut-points and guide users through the tiered approach to performing ADA assays.

Report & data transfer
Customize data export to client requirements and report in SEND format. Generate industry-standard reports and store using Watson LIMS software's secure Document Management System.

QA review
Review the history of attributable changes in the audit report.

Standardizing processes

Watson LIMS software is ready to help manage bioanalytical studies, from initiation through archival, working to support industry and regulatory standards. The software was designed with a deep understanding of the bioanalytical workflow and regulations. Principal Investigators, scientists, and analysts are all able to move logically through each step in their workflow, simplifying bioanalytical support for nonclinical and clinical studies.

Compliance throughout the entire workflow

- The Reassay Decision Matrix and Run Acceptance Template assists users to comply with SOPs, reducing the risk of non-compliance. Decisions are automated according to pre-configured criteria, but allow the user to override when required.
- System and study access is granted to authorized users only. Role-based access helps ensure only authorized actions can be performed by users, in accordance with GLP.
- The database stores audit trail records, which can be easily retrieved for review. These records outline all events that have been performed in the system. To facilitate an unambiguous and efficient review, a purpose-built audit records viewer is available, which enables categorizing and organizing audit events.
- Electronic signatures are designed to meet the requirements of 21 CFR Part 11 and record user identity, time/date stamp, and reason-for-save.
- Lockout/logout timers are configurable for periods of inactivity, requiring a user to reenter their username and password to regain system access.
- Watson LIMS software was designed to enable compliance with 21 CFR Part 58, FDA Bioanalytical Method Validation guidance documents, and EMA guidance documents.

Study design and sample management

Dynamic study design simplifies study setup with groups, treatments, and biological matrices, for both blinded and unblinded studies, as well as modeling the preclinical and clinical trial process. As bioanalytical studies evolve around real-world incidents, studies can easily be amended by adding or removing samples as required to reflect protocol amendments or unscheduled events. The Design Reconciliation feature also provides a way for Principal Investigators to document and correct sample manifest discrepancies all within one software system.

Compliance checks and audits are streamlined with the use of barcodes, which can be easily added from external sources or generated by the system. This allows for quick identification of samples, making the process more efficient. Location changes can be tracked using barcodes and electronic signatures. The product facilitates the creation of labels according to study requirements, and storage facilities can be displayed and barcoded to ease identification and traceability. The product also supports the use of 2D barcodes.

Analysts can quickly and easily move samples from a sample manifest into a new storage location. Principal Investigators can recreate the lifecycle of a sample in Watson LIMS software using various entities to see where the sample was stored, who handled the sample, and report freeze/thaw cycles, demonstrating a complete chain of custody from sample receipt to archival and disposal.

Pharmaceutical companies and CROs worldwide adopt Watson LIMS software as it provides a standardized way to work, helping ensure seamless data collaboration and reporting.

Delivering value

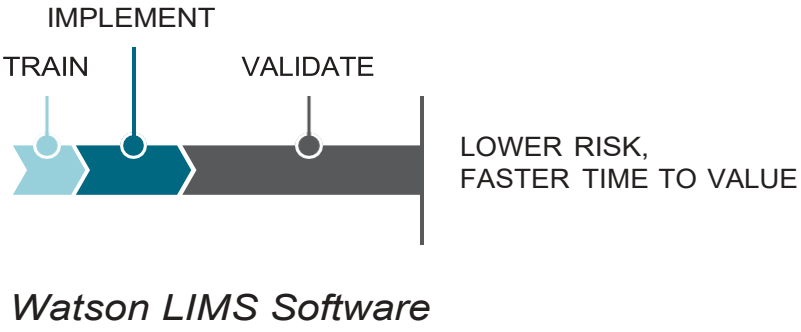
Fast implementation and expert support

Laboratories installing Watson LIMS software get more than just an industry-proven software package. Our team of experts not only understands the complex requirements of a bioanalytical lab, they also have the knowledge and experience required to help ensure every implementation is a success.

Established processes and templates mean that customers are up and running far faster than you might expect. Our team's extensive experience in risk-based validation approaches and minimal product configuration serves as a catalyst for faster time to value compared to custom-built solutions.

Realize value quickly with a purpose-built solution

- Implement and validate in half the time of a traditional analytical LIMS
- Eliminate customization and lengthy configuration
- Save time with documentation that is completed, tested, and ready to go
- Leverage a proven track record of successful implementations



Watson LIMS Software

Traditional Analytical LIMS

The dependability you need

Streamlining method validation and data analysis

Watson LIMS software supports method validation of LCMS and ELISA assays, and analysis of ADA and NaB assays, allowing scientists to perform method validation and data analysis for many different assay types within one system.

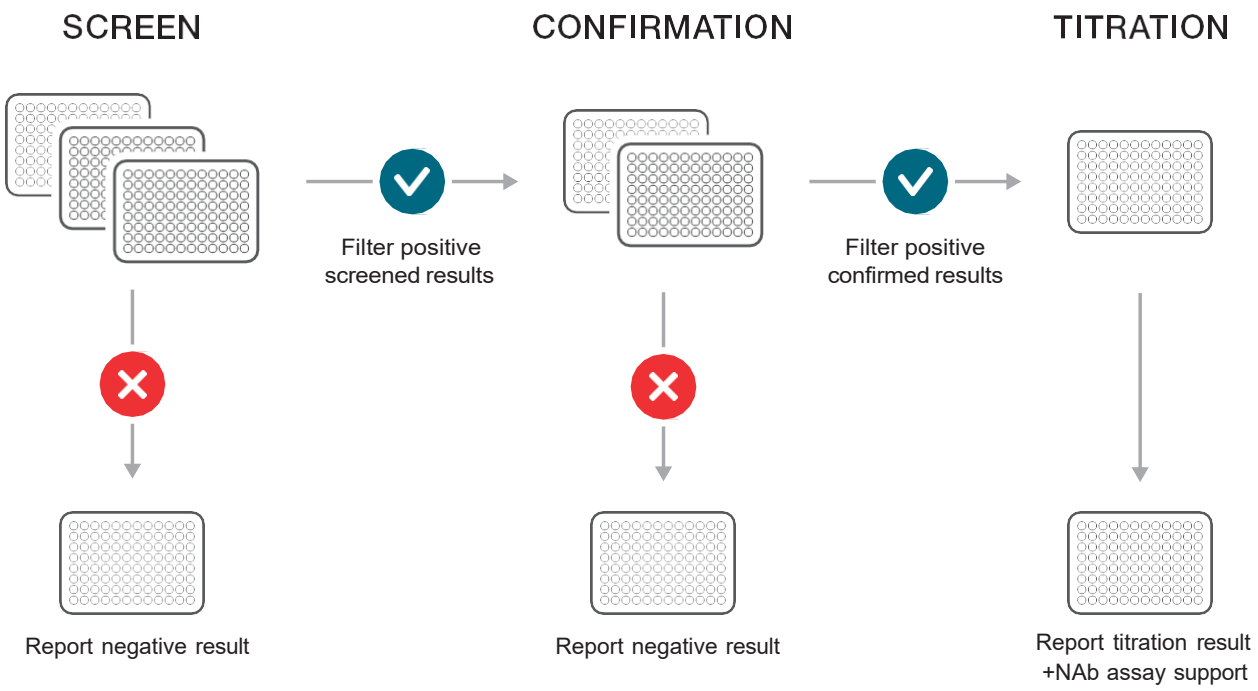
Method Validation support enables scientists to evaluate their methods for reliability and reproducibility. Predefined reports include precision and accuracy, specificity, selectivity, carryover, dilution integrity, stability (including benchtop, freeze/thaw, and long-term stability), recovery, and matrix effect.

The configurable Run Acceptance Template provides a tool to assess run performance against an SOP with defined acceptance criteria.

The integrated Pharmacokinetics Module (PK) allows the user to perform non-compartmental pharmacokinetic and toxicokinetic calculations within Watson LIMS software.

Enabling testing for immunogenicitys

Immunogenicity assays protect patients from potentially harmful anti-drug antibodies and provide insights into neutralizing antibodies that may inhibit the biologic activity of a drug. The Immune Response Module (IRM) enables a tiered approach to performing immunogenicity assessments. IRM guides its users through the tiered approach of performing screening, confirmatory, and neutralizing assays. Scientists utilize the IRM to calculate assay cut-points, create automated flags for samples outside of the cut-point, and determine if there is a reactive sample. New study-level control reports include intra/inter-run statistics, flag limits, and cut-point values reported, providing valuable data in one location.



Reassays and ISR

Reassays can be queued both from the PK and IRM modules and on review of statistical study data. Results are linked to the original for comparison, including the reason for reassay and reanalysis. The user is easily able to view the impact of the reassay result on the overall data.

The Reassay Decision Matrix enables the user to create a graphical workflow, which emulates a decision tree defined in a reassay SOP.

Built-in calculations and configurable reporting support Incurred Sample Reanalysis. The report can be quickly and easily configured from a set template.

Instrument and system interfacing

Watson LIMS software connects with other enterprise systems, instruments, equipment, and your customers, delivering increased compliance and productivity across your labs.

With an extensive library of bidirectional interfaces to commonly used bioanalytical instruments, no matter what hardware and equipment you use or might add to your lab in the future, Watson LIMS software can speak its language.

Once an analytical run has been acquired, the raw data is transferred from the data acquisition software back into the system for review and processing. Secure connections eliminate transcription errors and preserve data integrity.

Watson LIMS software has a built-in interface with numerous instrument software applications, including but not limited to:

- Thermo Scientific™ Xcalibur™ software
- Thermo Scientific™ Chromeleon™ CDS software
- Thermo Scientific™ TraceFinder™ software
- SCIEX Analyst software
- Waters™ Empower™ software

Watson LIMS software has file-based and/or IM interfacing with common instrument software, including but not limited to:

- Gyros™ Gyrolab™ workstation
- Luminex™ platform
- Molecular Devices™ SoftMax Pro™ software
- MSD™ DISCOVERY WORKBENCH™ software
- MSD™ Methodical Mind™ software
- Quanterix™ Simoa™ technology
- Secure Open Standard File Transfer (SOFT)
- Shimadzu™ LabSolutions™ software
- Waters™ MassLynx™ software

Data processing and reports

Watson LIMS software's unrivaled data processing capability easily generates a variety of graphs, tables, and statistical calculations from study data. The software allows you to easily sort, find, filter, and reorder grid contents, enabling a quick way to review a particular sample's data. Watson LIMS software also supports CDISC SEND and SDTM data standards.

Regression Analysis is centralized and automated supporting linear and non-linear models.

Considerable time is saved in collating and reporting results compared to other LIMS or laboratory data management solutions.

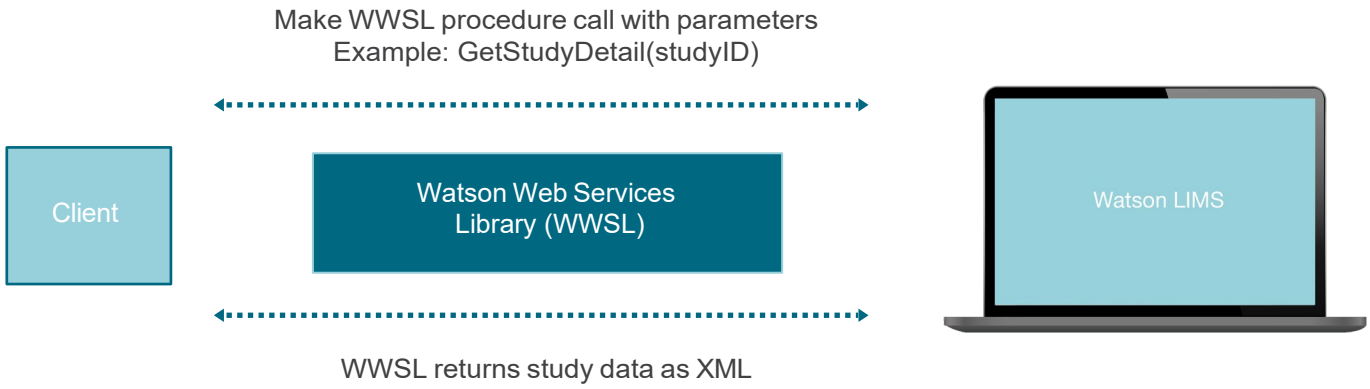
Quality review time is minimized using Watson LIMS software—the gallery of pre-defined assay performance and summary tables are a major benefit since the precision and accuracy of study data is very quickly demonstrated. Any new data added is automatically taken into account—providing a real-time snapshot of data quality. Standard data exchange enables easy transfer of study data between sponsor and CRO.

The powerful Document Management System enables you to select the documents, tables, and graphs to quickly build a full study report. All results, raw data, graphs, and reports are held in one database, which is controlled securely by user access and system roles.

Watson LIMS software is now available to be hosted through the Thermo Fisher managed cloud.

Watson Web Services Library

The Watson Web Services Library (WWSL) is a mechanism that allows external systems to seamlessly interact with Watson LIMS software using web service technology. This standard approach helps ensure secure communication through the use of the HTTPS transport protocol. With WWSL, data validation and audit trail generation are automatically handled for any data transferred into the Watson LIMS database. Supported procedures include, but are not limited to, importing study samples, creating analytes and projects, as well as updating study details, subjects, and treatments. WWSL streamlines the process of entering and retrieving information into the Watson LIMS database, providing a seamless integration solution for your lab.



Precision that evolves. Security that endures.

Version 7.7.2—enhanced through integration with Red Thread analytics

With version 7.7.2, Watson LIMS evolves—delivering stronger security, faster validation, and a foundation for the next-generation of LIMS. Watson LIMS provides enhanced functionality when used with optional Red Thread® modules by Biodata Solutions—Red Thread Fit™ for regression curve fitting, VRed Thread Verge™ for ADA cut-point analysis, and Red Thread Eval™ (coming soon) for study output validation—delivering an advanced, audit-ready analytics experience.

Key features of Watson LIMS version 7.7.2

- Security and stability: Encryption, single sign-on via ThermoFisher.com for robust, reliable performance.
- Compliance and audit trail: Enhanced traceability and regulatory alignment (GLP, 21 CFR Part 11).
- Future-ready: Foundation for modular, SaaS-based Next-Gen LIMS capabilities.
- Advanced analytics: Watson LIMS version 7.7.2 works with Red Thread modules—Fit, Verge, and Eval (coming soon)—to unlock regression accuracy, defensible ADA cut points, and automated validation.

Red Thread modules

Red Thread Fit: Automated curve fitting for accuracy and precision in PK assays

Red Thread Fit simplifies the iterative regression analysis of calibration curve data by automatically identifying the best-fit model for accuracy and precision (A&P) runs in pharmacokinetic (PK) assays. Supporting small and large molecules, Red Thread Fit applies statistical modeling to help ensure optimal regression model selection. This reduces manual effort, improves consistency, and aligns with FDA and EMA bioanalytical method validation guidance—helping teams make confident, data-driven decisions faster.

With Red Thread Fit, labs will experience:

Improved efficiency

Save hours by running your regression models on calibration curve data simultaneously rather than iteratively and embrace efficient, data-driven decision making with rigorous data analysis.

Strengthened compliance

Help ensure mandatory compliance with FDA and EMA guidelines through a fully validated system featuring audit trails, data integrity, and support for residual testing that's aligned with regulatory guidance and industry best practices.

Consistent data analysis

Help eliminate compliance risks by removing subjective decisions around residual testing and enabling consistent data analysis across every dataset, an approach that's fully aligned with regulatory guidance.

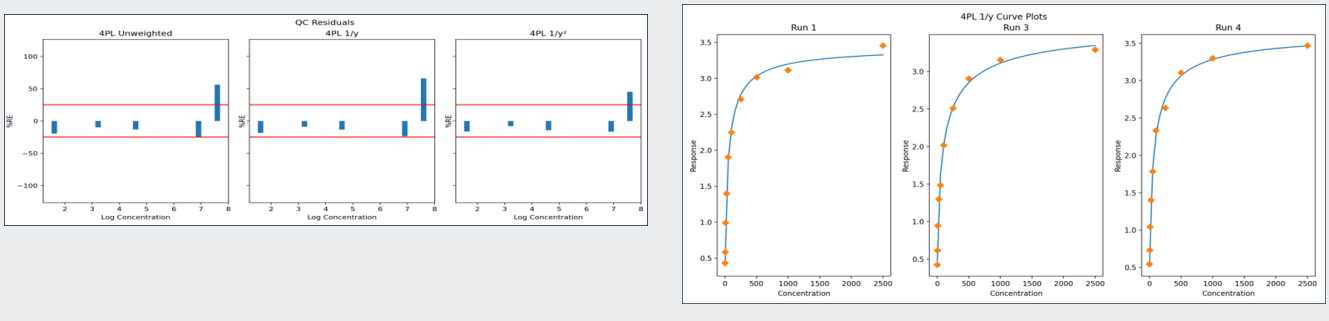


Figure description: Fully validated regression parameter optimization for your small and large molecule calibration curves with summarized data tables and graphical representations.

Red Thread Verge: Automated ADA statistical analysis for cut point, sensitivity, and LPC

Red Thread Verge accelerates anti-drug antibody (ADA) assay workflows by automating the complex statistical analysis required to determine cut point, sensitivity, and low positive control (LPC). Built on FDA and EMA immunogenicity guidance, Verge eliminates manual statistical calculations and reduces variability, delivering consistent, validated results in minutes. By standardizing ADA data interpretation, Verge enhances compliance, improves reproducibility, and supports faster decision-making in regulated bioanalytical environments.

Key features:

Increased efficiency

Do not let cut point, sensitivity, and LPC determination hold back your method validation or sample analysis. Get your results within minutes with report-ready tables and graphical visualizations and accelerate your bioanalytical drug development by weeks.

Improved compliance

Fully validated system with audit trails, data integrity, and compliance with FDA and EMA regulatory requirements and industry best practices.

Consistent and objective approach

While your bioanalysts may understand the context behind the data, biostatisticians may understand the logic behind the analytical approach, creating a disconnect between the data and its analysis. Additionally, minimal regulatory guidance may lead to subjective interpretation and inconsistent data analysis. Overcome compliance challenges through our rigorous approach based on industry best practices.

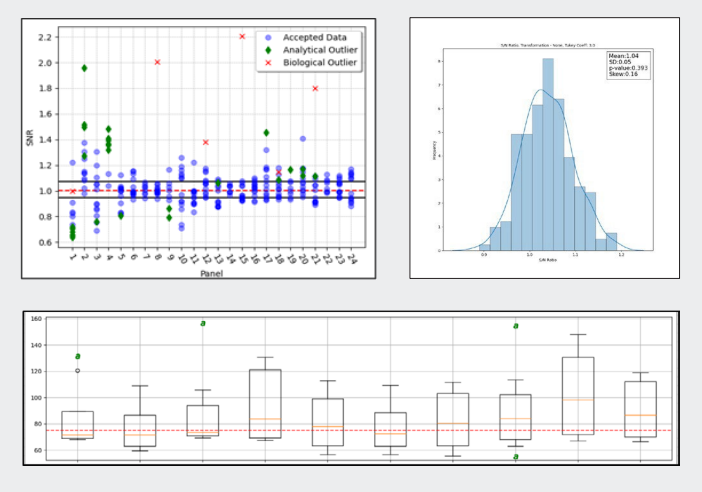


Figure description: Regulatory submission-ready data tables and visualizations for your cut point reports.

Red Thread Eval (coming soon): Automated scientific review and audit of PK data

Red Thread Eval streamlines the scientific review and auditing of pharmacokinetic data by automatically flagging results as compliant, non-compliant, or requiring further review. Built on FDA and EMA guidance and industry best practices, Eval supports objective decision-making and reduces manual review time by 85% or more. By standardizing and automating the audit processes and enhancing traceability, Eval ensures consistent and high-quality data interpretation across bioanalytical studies.

Key features:

Expert-driven efficiency and scalable savings

Maximize operational impact by leveraging the insights of seasoned subject matter experts to enhance data auditing and decision-making. Red Thread Eval's intuitive, cloud-based platform streamlines auditing and data oversight, delivering measurable time and cost savings without the need for extensive training.

Enhanced data integrity and transparent collaboration

Red Thread Eval improves scientific rigor and strengthens sponsor-CRO alignment by auditing reportable data and incorporating regulatory guidelines and industry best practices. This approach minimizes rework and miscommunication, making it possible for high-quality, interpretable data to support each phase of drug development and foster clear, consistent collaboration between sponsors and CROs.

Establish consistency and regulatory confidence across teams

Red Thread Eval promotes a standardized, objective approach to reporting that ensures consistency across your organization. Designed to align with FDA and EMA expectations and industry best practices, it supports reliable outputs that meet the demands of regulatory scrutiny.

Table 2. Batch Run Performance Summary

Batch Run ID	Analysis Date	Batch Information	Instrument ID	Batch Acceptance
1	18-Dec-2022	Sample Analysis of Group 1 Animals, Day 14	ELISA System 001	Rejected
5	25-Dec-2022	Reassay	ELISA System 001	Accepted
2	20-Dec-2022	Sample Analysis of Groups 2 and 3 Animals Day 14	ELISA System 002	Accepted
4	26-Dec-2022	ISR Evaluation	ELISA System 002	Accepted
3	24-Dec-2022	Reassay	ELISA System 001	Accepted

Analysis Result

Green
Batch Number Check Ok, No Missing batch found
All batches assayed before the earliest detected expiry date of 31-Dec-2022

Red
Batches may not have been performed within established long-term stability time, further evaluation needed
[Batch 1] marked in batch performance summary table as rejected but should be marked as accepted based off of data for calibration curve and regression model/curve parameter table and QC Samples Table

Figure description: Eliminate analytical blind spots with augmented intelligence tool that classifies your data as compliant, non-compliant, or requiring additional review in light of contextual information.

A proven partner

Experience the power of partnering with Thermo Fisher to transform your bioanalytical challenges into strengths. With over 20 years of experience serving the bioanalytical community, Thermo Fisher possesses the regulatory acumen and domain expertise necessary to drive your success. Unlike the competition, we have the ability to tap into the bioanalytical expertise of our extensive network of over 125,000 colleagues, enabling us to deliver industry-trusted and reliable solutions that bring life-saving drugs to market.

Partner with Thermo Fisher to discover the full potential of your bioanalytical workflow management capabilities.

Learn more at **thermofisher.com/watson**