

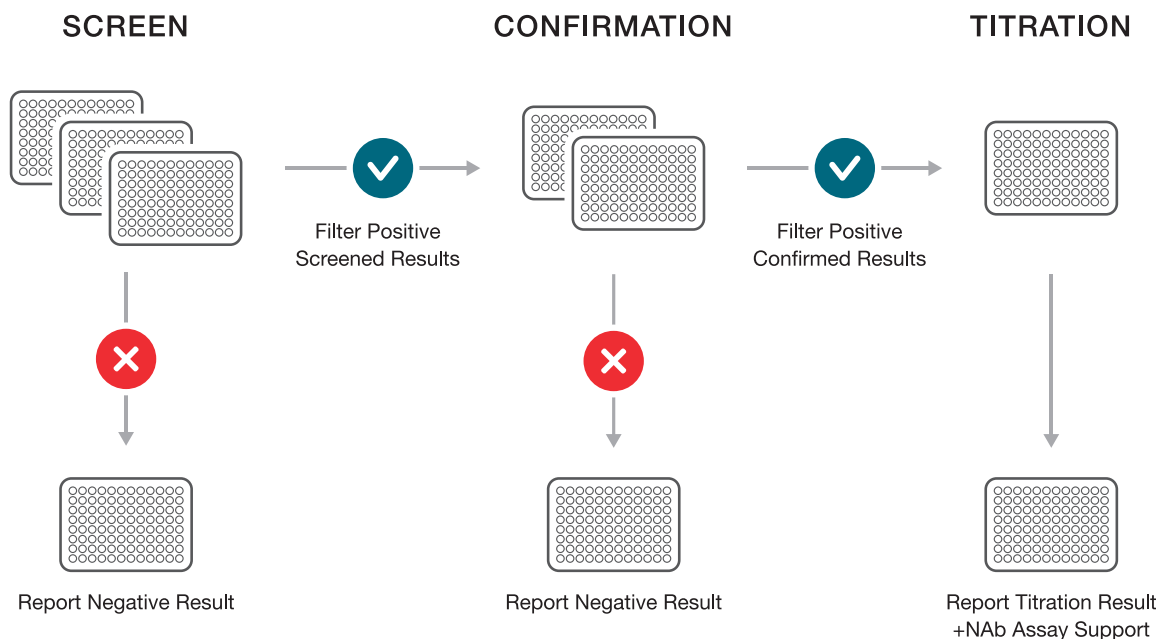
# Watson LIMS software for large molecule bioanalysis

## Power your bioanalytical workflows

Thermo Scientific™ Watson LIMS™ software provides bioanalytical laboratories a platform to manage their studies from initial design through closeout and archival. It enables laboratories to streamline method development, validation, and execution simplifying sample analysis and reducing project timelines. In addition to optimizing the bioanalytical workflow, Watson LIMS software also ensures complete traceability and sample chain of custody. Whether the laboratory is focused on only biologics or has a mixed portfolio of small and large molecules, Watson LIMS software provides a complete solution for bioanalytical laboratories.

## Leveraging Watson LIMS software to perform immunogenicity testing

Watson LIMS software's **Immune Response Module (IRM)** supports immunogenicity (ADA) assays and guides users through the tiered approach for performing screening, confirmatory, and neutralizing assays. Controls can be set for screen, confirmation, and titer assays in accordance with the laboratory's standard operating procedures (SOPs). Scientists can define and calculate assay cutpoints within the system and set flags for any sample that has a result below the cutpoint. Watson LIMS software also manages pharmacokinetic (PK) analysis enabling PK and ADA data to be reviewed together.





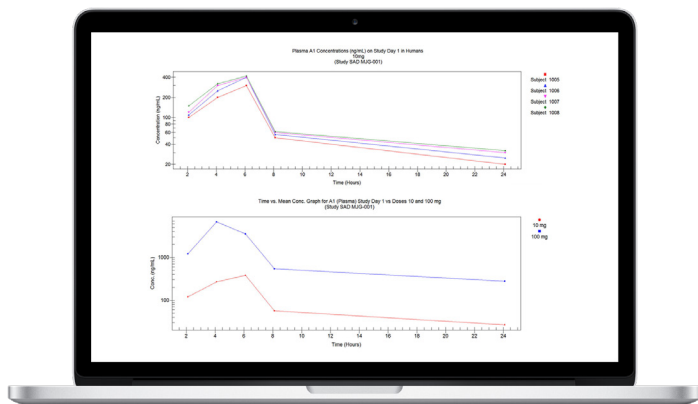
### Watson LIMS software for large molecule PK analysis

The **Pharmacokinetics Module** for Watson LIMS software allows principal investigators to model their study design and executes their specific PK assays as specified in their protocol and SOPs for each molecule. Samples that are out of specification can be flagged in the **Run Acceptance Template**. These out of range samples then can be automatically queued for reanalysis according to the protocol defined in the **Reassay Decision Matrix**.

Watson LIMS software integrates with plate readers and other instrumentation via Thermo Scientific™ Integration Manager™ software, moving data directly from the instrument software into Watson LIMS software ensuring data integrity. The system performs non-compartmental PK and toxicokinetic (TK) calculations eliminating the need to perform calculations in a spreadsheet or another platform. All data review can be done within Watson LIMS software and principal investigators can use the PK study report to easily review results from each sample. By conducting ADA and PK assays in Watson LIMS software, principal investigators can see if there are any indications that an ADA response may be muting the PK or a possible discrepancy in a patient's result.

### Enabling audit readiness and compliance in your study

Designed in alignment with industry best practices and regulatory guidance documents, Watson LIMS software enables audit preparedness. Upon inspection, principal investigators can quickly provide inspectors with all of the information they need from raw data files to study archival records with the appropriate electronic signatures and audit trail. By having all of the necessary data in one system, it streamlines the audit process and eliminates the need to find this information in other systems or laboratory notebooks. Watson LIMS software is an industry-trusted solution simplifying study execution and driving compliance in the laboratory.



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