Thermo Fisher Nautilus LIMS Software

Delivering data management and workflow solutions for genomics, clinical diagnostics and biorepository laboratories

Key Words: LIMS, LIS, genomics, proteomics, molecular diagnostics, NGS, biorepository, physicians' interface, patient management, HL7, data security & compliance, configurable hierarchy, workflow management, biospecimen & plate handling, instrument integration & automation, enterprise business integration, CLIA & HIPAA compliance, electronic TRF, PHI

The challenges

- Genomics and Proteomics labs require a LIMS that can handle high-throughput data volumes, manage advanced plate handling and pooling, and integrate with instruments and liquid handling robots using out-of-box graphical configuration tools to empower scientists to map their lab protocols in an intuitive and flexible way.

- Clinical diagnostics labs require distinct Laboratory Information System (LIS) and Laboratory Information Management System (LIMS) functionality in one cohesive system to meet the technical, integration and business needs of the emerging fields of translational and personalized medicine.

- Biorepository labs need to manage specimen processing, testing, storage and chain-of-custody including for aliquots derived from incoming specimens, as well as track specimen volumes/amounts, patient consents, request management and shipments, to maintain the quality and integrity of the specimens.

- Clinical labs need informatics solutions that can easily integrate with internal applications and laboratory instrumentation, as well as external partners and collaborators.

- Diagnostics labs need to deliver faster turnaround of results to physicians to enable more informed and personalized patient health care, while maintaining compliance with CLIA and HIPAA regulations.

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The solution

To meet these challenges Thermo Fisher™ Nautilus™ LIMS software delivers comprehensive laboratory and patient management functionality needed by researchers and technicians involved with genomics, molecular diagnostics, proteomics, clinical testing and biorepositories. The first comprehensive solution to combine the sample-centric functionality of a LIMS with the patient-centric functionality inherent in a traditional LIS, Nautilus LIMS software bridges the gap between the two and delivers a complete and streamlined solution.

Nautilus LIMS software is developed on a proven informatics platform which offers unmatched flexibility and ease-of-use, increased automation and throughput of sample analysis for clinical diagnostics and genomics laboratories that require sophisticated study, sample and plate management research tools and business enterprise integration. Built to support the laboratory's end-to-end business process, Nautilus LIMS software enables bi-directional communication between the lab and external systems.

Nautilus LIMS software also enables customer service follow-up and CRM interface, patient management, final report generation and automated delivery, interface with a billing provider, and the ability to interface with multiple clinical vocabularies. The LIMS is designed to be fully compliant with key industry regulations; those related to protecting patient privacy (HIPAA) and those related to clinical testing (CLIA). Our solution also supports the most widely used ANSI-accredited standard for interoperability of health information technology (HL7) and enables laboratories to operate in compliance with GLP and 21 CFR Part 11.

Key features and benefits

- **The clinical portal** provides a secure web-based interface for the submission of biospecimens and test requests to the lab. The Portal includes features such as provider, practice and patient searches and data entry, dynamically linked fields and TRF submission printing. The drag-and-drop Form Designer lets users easily configure TRF submission forms as needed, such as for molecular diagnostics clinical assays as well as for study-related assays.

- **Patient management functionality** facilitates comprehensive patient clinical record tracking including demographics and medical history, insurance and consent information, providers and practices, clinical notes, testing results history and reports. All Protected Health Information (PHI) is stored and managed in compliance with the privacy and security rules of the Health Insurance Portability and Accountability Act (HIPAA).

- **Dashboards** can be created which offer tailored key indicators of real-time laboratory performance and facilitate the organization of the workload. Use the built in Explorer Tool to manage the lab's work, using features such as intuitive folders, full text search, multi-level grouping and sorting, dynamic ad hoc queries, exporting to files and printing.

Figure 1. The Clinical Portal's Test Request Forms (TRF) mimic paper forms and offer built in features like provider, practice and patient searches and data entry, dynamically linked fields and TRF printing with barcodes.

Figure 2. Users can configure their own electronic forms without any programming experience using the drag-and-drop Layout Designer.

- **Workflow management** is designed to emulate laboratory processes via an intuitive graphical interface. The patented Workflow engine configuration tool expedites the mapping of lab protocols and assays without the need for any custom programming. This allows users to organize data and manage tasks efficiently, configure new lab protocols and assays, and take ownership of their LIMS.

- **Advanced plate handling** supports plates of any size, fill patterns and dimensions using out-of-box graphical configuration tools. Plate maps can be defined to contain sample replicates and QC controls (NTC, Positive and Negative DNA Extraction Controls, Calibration Standards, etc.). Plate workflows and plate actions include features such as the ability to create child replicate plates, split plates, pooled plates, compressed plates (e.g., 96 well plates → 384 well plates) as well as cherry picking. The plate actions can be performed both interactively by the user as well as electronically via files from liquid handling or tube sorting robots. The parent-child hierarchies of both the plates as well as the aliquots are tracked automatically by the LIMS.

- **The plate editor** provides a graphical interface to view and edit plates. Features include adding and removing aliquots to/from plate wells, probing plate wells with stock reagents, and verifying the contents of the plate manually via barcode scanning and electronically via a flat bed scanner file upload (such as for Thermo Scientific™ Matrix™ 2D barcoded tubes). The Plate Editor also provides multi-level grouping, full text search, ad hoc queries, exporting and printing.
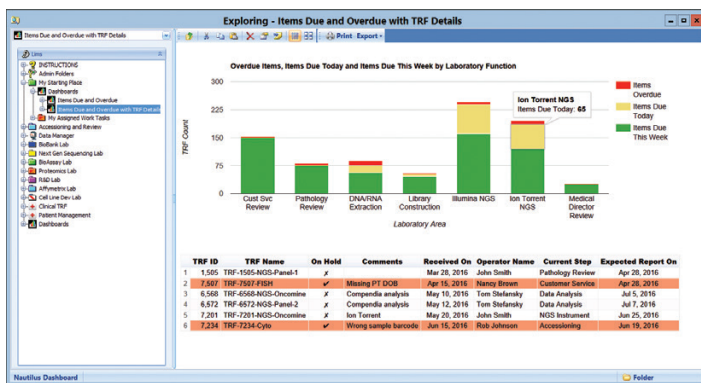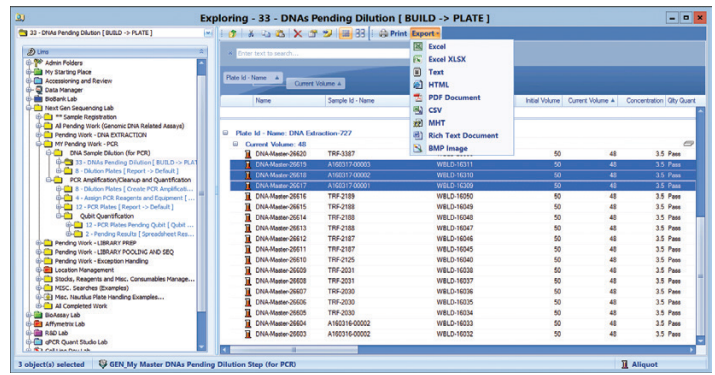

Figure 4. Built in Explorer to view and manage data with full text search, multi-level grouping, ad hoc queries, exporting and printing.

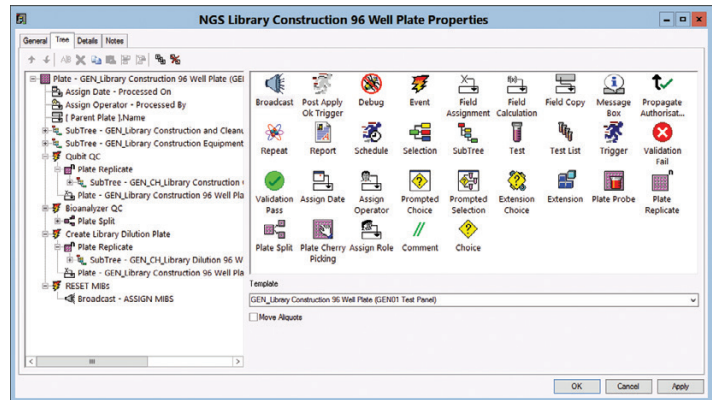Figure 5. Patented Workflow Configuration is designed to emulate laboratory processes via an intuitive graphical interface.

Figure 3. Intuitive dashboards can be created to help users manage their data with ease.
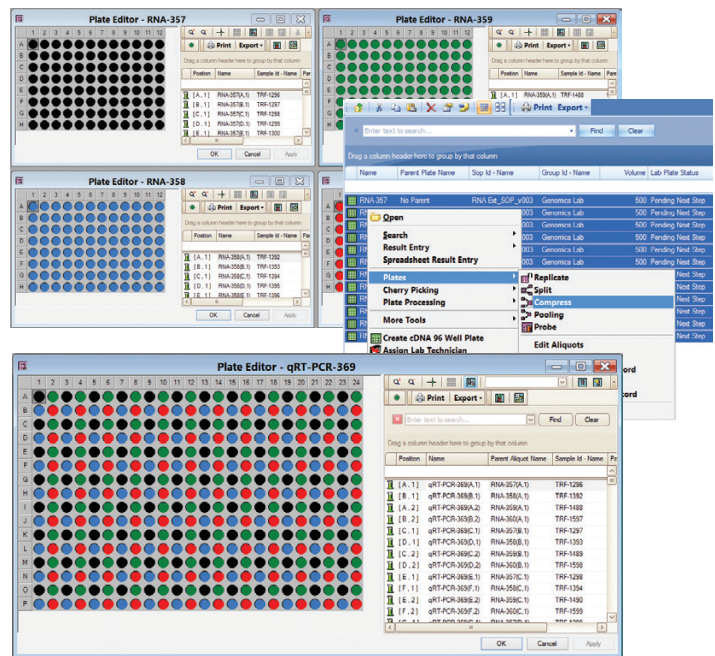

Figure 6. Advanced out-of-box plate handling lets scientists configure their plate maps and protocols with ease.

- **Instrument integration** and the uploading of data from files may be carried out using an out-of-box graphical configuration tool. This flexible tool may be used for many purposes such as to login studies, plates, samples and aliquots; to record analytical tests and results; and to manipulate plates and aliquots via robots. This results in increased productivity, fewer transcription errors, improved data quality and cost savings.

- **Aliquot pooling** such as for Next Generation Sequencing may be performed easily both interactively by the user and electronically via instrument integration. The pooled aliquots may be assigned to plate wells automatically when needed. The full hierarchy of all associated parent and child aliquots is fully tracked using a proper relational database model.
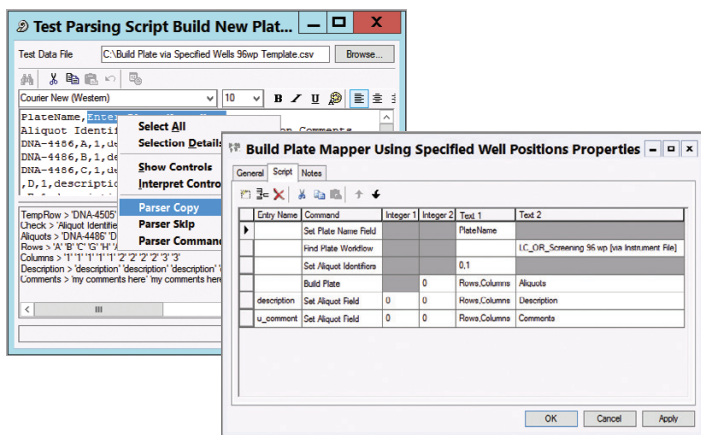
- **Equipment, reagents and lab consumables** may be managed including equipment service and calibration records and lab consumable inventory tracking and data such as lot numbers, expiration dates and any required QC testing. Both equipment and reagents may be associated with plates, aliquots and worksheets to provide full traceability and quality assurance compliance.

- **Biorepository** related features are provided such as patient consent, storage tracking, request management, shipment tracking, approvals and electronic signatures as well as specimen volume/amount tracking and freeze-thaw counting.

Figure 7. Instrument integration and uploading data from files is performed using graphical configuration tools.
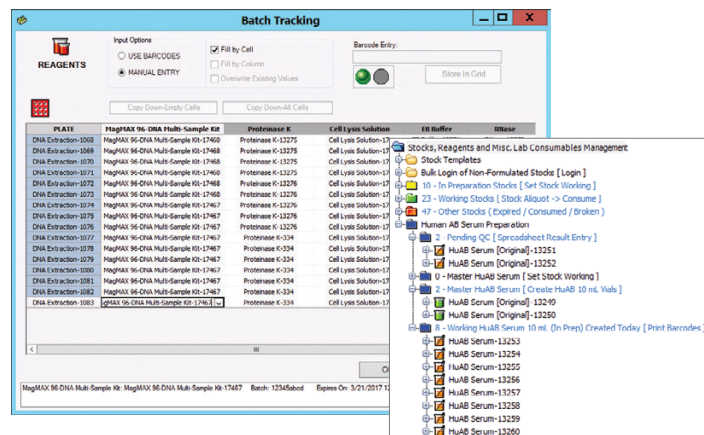

Figure 9. Track equipment, reagents & lab consumables. Associate them with plates, aliquots and worksheets to provide full traceability and achieve QA compliance.
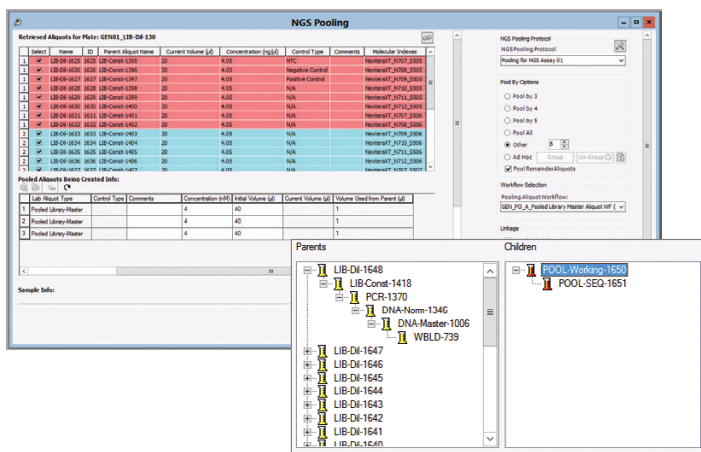

Figure 8. Create pooled aliquots interactively using the flexible pooling wizard or automatically via instrument integration.
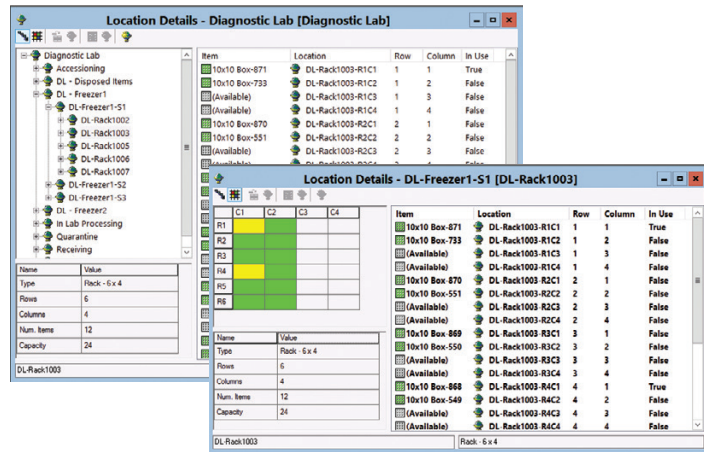

Figure 10. Specimens can be tracked at any location whether on the lab bench, in a freezer or LN2 tank or at an offsite storage location. Samples, plates and containers can easily be moved from one location to another, checked in & checked out and disposed.

- **Specimen storage locations and chain-of-custody** may be tracked as needed whether on the lab bench, in a freezer or LN2 tank or at an offsite storage location. Locations are managed using a configurable hierarchy, which can be from the site down to the individual rack slot position of the plate or storage box on a shelf within a freezer. Specimens such as blood, DNA, FFPE tissues, slides and cell cultures are all tracked easily using Nautilus LIMS.

- **Files, documents and images** such as SOPs, DNA full length sequences, pathology images, final reports and scanned consent forms may be stored in the LIMS and associated with one or more data records, both interactively by the user or electronically.

- **Reports** can be configured and generated, such as master mix lab bench reports, plate maps, collection kit and submission forms, 1D and 2D barcode labels, and final reports.

One of the major goals of the translational research movement has been to bridge the gap from bench to bedside and any initiative to blend the LIS with the LIMS can be understood as an extension of this quest. The lesson from all of this is obvious. We now need to make an effort to understand the relative strengths of LIS and LIMS and proceed to develop new systems that capture the best features of each of them.

—Bruce A. Friedman, M.D., Active Emeritus Professor of Informatics Department of Pathology, University of Michigan School of Medicine
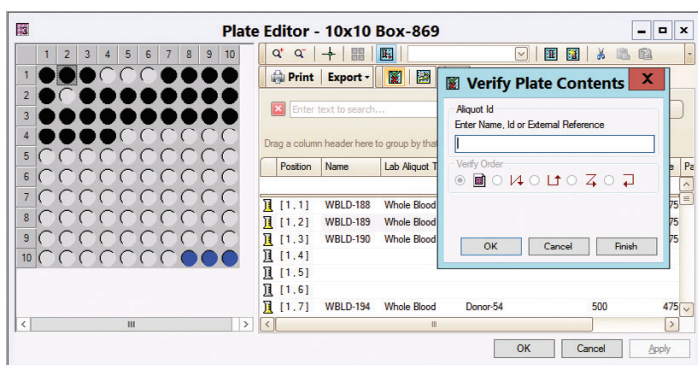

Figure 11. The Plate Editor includes many features such as drag & drop, adding & removing new and existing aliquots to/from plate wells, and verifying the contents of the plate manually via barcode scanning or electronically via a file upload.
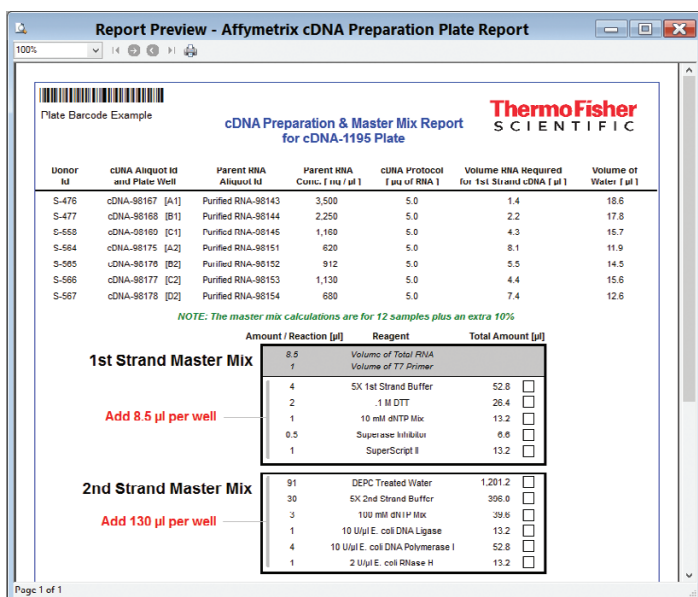

Figure 12. Reports may be configured and generated, such as sample preparation reports with associated sample dilution volumes and master mix calculations.
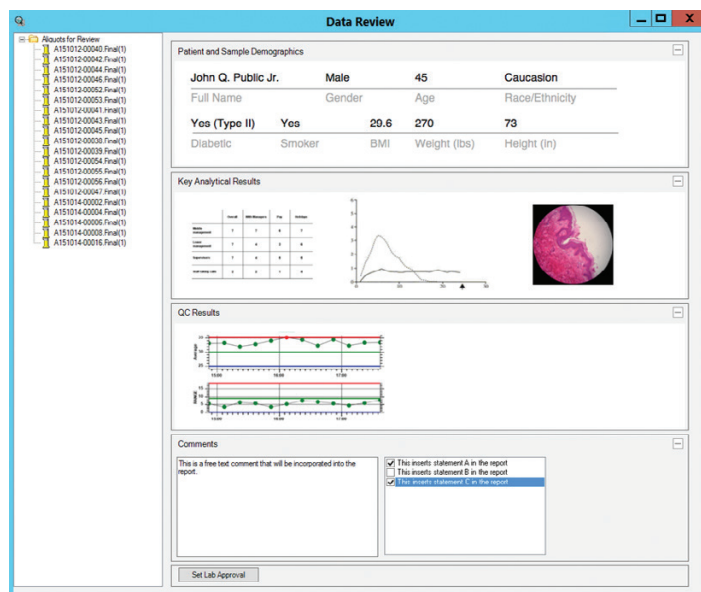

Figure 13. Lab Managers and Medical Directors can review & approve analytical results using the Data Review tool, which allows all relevant information to be displayed and approved from within a single window, and which provides a method for reviewers to associate comments with the items as needed.

- **For patient reports,** the complete reporting life cycle can be managed, including the authorization and release of reports by the Medical Director. All patient reports are stored in a read-only format (PDF) and corrections or amendments to reports are handled in accordance with CLIA sec. 493.1291.

- **Clinical vocabularies and Health Level 7 (HL7)** messaging supports CLIA mandated exchange of laboratory information between clinical laboratories and external partners. This interface facilitates sample accessioning, patient results reporting and secure patient billing. Nautilus LIMS software supports usage of standard clinical terminologies and interfaces with clinical vocabularies (ICD, CPT, LOINC, SNOMED, etc).

- **Complete data security, audit trail and electronic signature** capabilities address the regulatory requirements for both the laboratory data and PHI. The auditing capabilities monitor all views and changes to any record in the system. The LIMS supports compliance with CLIA and 21 CFR Part 11. All data is stored in the database and access is managed through privileges based on role, operator and group, ensuring data security and traceability.

- **Enterprise business integration** facilitates enterprise level information exchange by integrating Nautilus LIMS software with other systems like EMR, CRM, ERP, billing via HL7 messaging, web services and application interfaces. Process metrics such as turnaround time, failure rates and statistical quality control enable efficient, streamlined operations by uncovering bottlenecks and improving processes. The integration of these systems allows for optimized data correlation and collaboration, end-to-end data tracking, secure data exchange, and maximizes the organization's investment in its information technology.
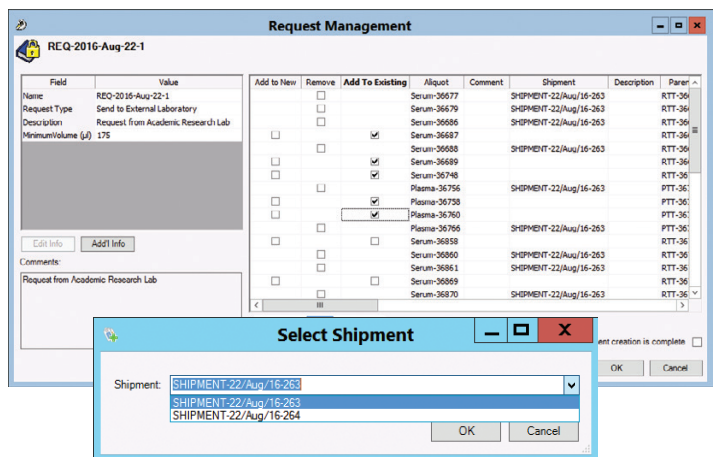
Figure 15. Once the Request for the biorepository specimens has been approved, specimens may be added or removed to new or existing Shipments, and the Shipments are directly linked to the corresponding Request. Once the Shipments have been created, additional business logic and data may be tracked for each Shipment, such as the date shipped, the shipping delivery method and the waybill number.
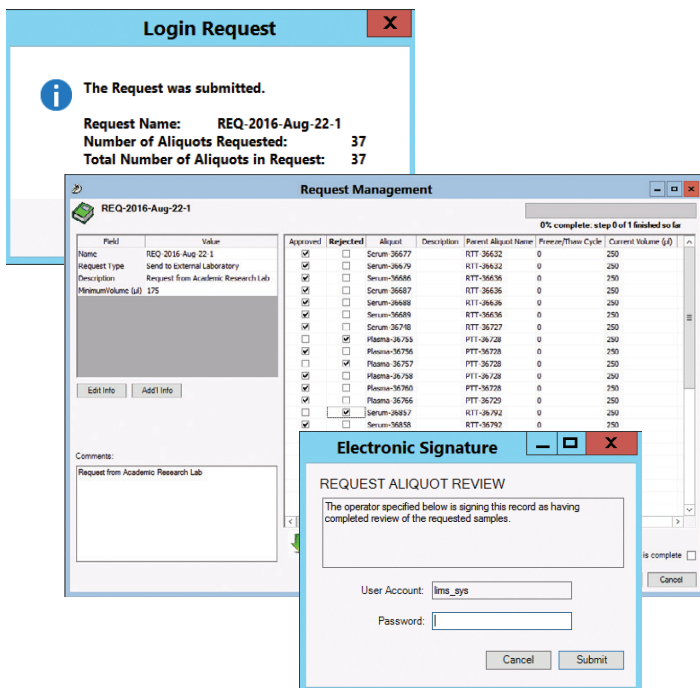

Figure 14. Users can search for and select specimens from the Biorepository and assign them to a Request. Business rules can be incorporated which will automatically prevent certain specimens from being added to a Request. Specimens assigned to a Request are approved or rejected by a manager, with electronic signatures which are optional.
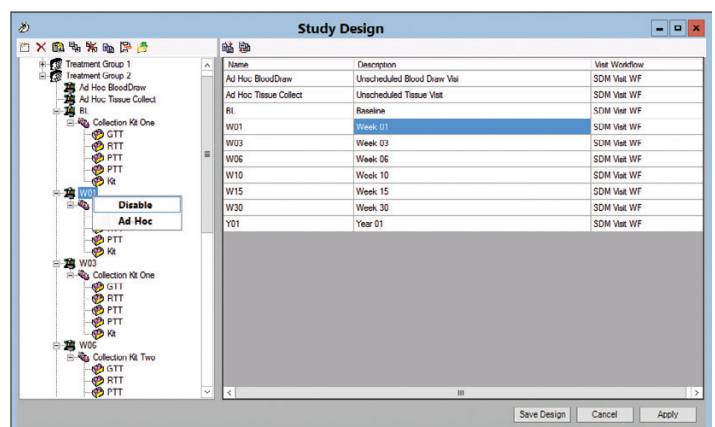

Figure 16. Research studies can be designed and executed using the Study Design tool. As part of clinical studies, sample specimens may need to be collected from the study participants at designated time intervals, in some cases over the course of many years. The study design tool provides an intuitive method for setting up these studies, and as the study evolves over time, the study parameters can be modified if required.

Laboratory Data Management Solutions

The emerging fields of translational, personalized and precision medicine have been the catalyst for a more symbiotic relationship between patient-centric processes and the sample-centric lab environment. The ultimate goal of this new symbiosis is a streamlined end-to-end information flow following the patient from the point of care, to molecular testing and results analysis, to diagnosis and treatment.

Thermo Fisher Nautilus LIMS software satisfies this critical need by delivering a comprehensive sample and patient management solution which enables physicians and healthcare staff to have pertinent data readily available to optimize patient care. This unique solution standardizes ordering and reporting practices and improves patient laboratory and healthcare documentation, allowing laboratories to manage healthcare information more efficiently and improve compliance with laws governing medical records management. Thermo Fisher Nautilus LIMS software unifies the distinct laboratory and patient management functionality needed by researchers and technicians involved in clinical testing and molecular diagnostics.

For Genomics labs and Biorepositories, Thermo Fisher Nautilus LIMS software provides all the tools required to manage high throughput volumes of data, advanced plate handling and specimen storage management, to empower scientists to configure new protocols and assays and effectively manage their data.
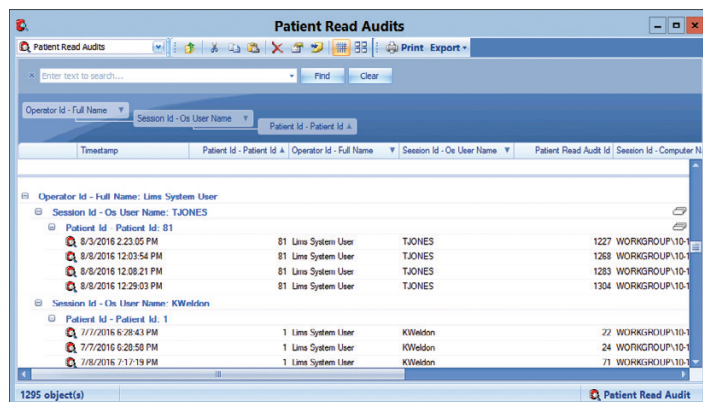

Figure 17. Read only audits may be enabled for Protected Health Information (PHI) data, to comply with the Health Insurance Portability and Accountability Act (HIPAA).
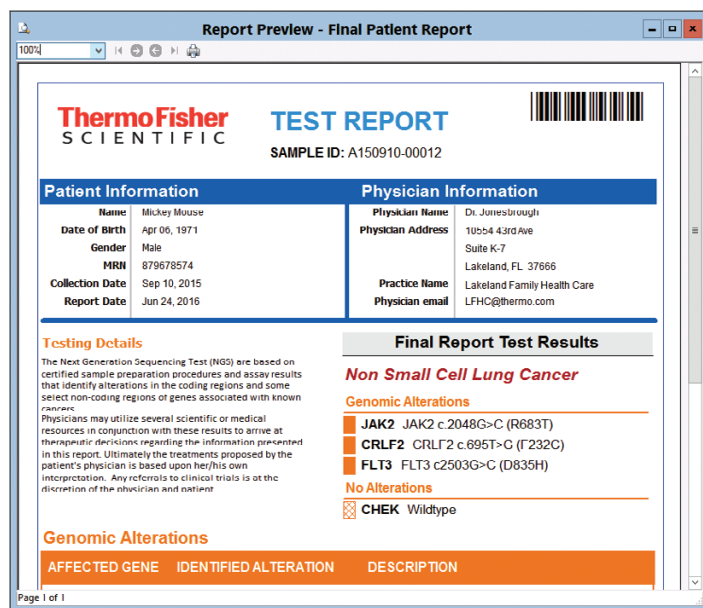

Figure 18. Clinical diagnostics reports can be generated and stored in the LIMS database with an associated reporting life cycle, including the handling of amended and corrected reports.

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