

Thermo Scientific Nautilus LIMS
Biobanking and Biospecimen Management

Leader in
Functionality,
Ease of Use
and Flexibility





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Biospecimens serve as the basis for the novel research and development needed for the discovery of tomorrow's drugs and medical treatments. The past decade has seen a surge in the number of samples generated for research and analysis—largely due to the increased focus on translational medicine and epidemiology. This has led to the development of extensive biobanks and biorepositories that feed the demand for samples and libraries to be screened by these high capacity, high throughput laboratories. With these advances, the growing need and focus on high quality sample yields and how they are accurately and efficiently managed is now a top concern for researchers who are often charged with managing enormous volumes of both samples and their relevant data.

The number and size of these biobanks and biorepositories is rapidly growing, with many national, regional and disease-specific facilities being established. The function of these biobanks is quite diverse and can range from the storage of frozen cell aliquots intended for primary pharmaceutical screening, to tissue biopsies for disease research, to patient DNA samples, to whole population studies containing multiple aliquots of fractionated blood and urine samples.

The Challenge

The challenge that biobanks face extends far beyond just the samples themselves. These facilities also need to manage the information associated with the samples, such as patient demographics, consent records, and chain of custody—all of which are required to fulfill complex sample requests from researchers, protect patient rights and ensure sample integrity. To simplify the management of the physical samples, many biobanks take advantage of the latest instrumentation and automation systems; however, while this is important, it only solves a piece of the puzzle. In order to provide a best in class service to researchers, biobanks must integrate these tools with, and take advantage of, the knowledge and data made available by a Laboratory Information Management System (LIMS).

The Critical Role of Biobanks

Some facilities, like the UK Biobank, have been extensively planned from the outset with built-in automation capabilities that facilitate the large storage capacity and desired retrieval rates, while others are based on an ad-hoc collection of samples in deep-cooled freezers that rely on manual retrieval methods. In both cases a growing and important consideration for national, regional and disease-specific biobanks is how they will ensure sample integrity, tracking and auditing.

Tracking the demographic and analytical data associated with these samples requires leading edge laboratories to store and provide the specimen information in an intuitive and time efficient manner. Biobanks can significantly accelerate development by providing users:



“With its built-in instrument integration, Nautilus LIMS has offered significant productivity gains right from the outset. It has been integrated with our existing robotics, and thus has improved the data management process considerably.

— Thor Gunnar Steinsli, LIMS Manager
HUNT Research Centre and Biobank

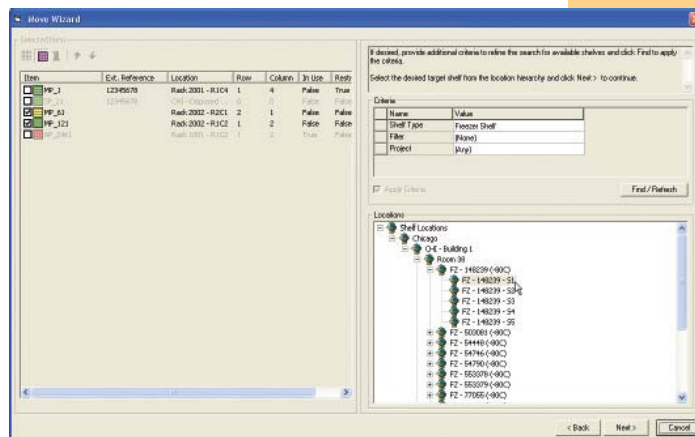
- Better logistical and operational support
- A more comprehensive understanding of the associated specimen information
- Tools that automate timely and error prone processes
- Real time information for faster, more informed decisions

Thermo Scientific solutions and services address these needs.

Count on Thermo Scientific Nautilus LIMS

To drive life science research and discovery forward, accurate, compliant and efficient management of biospecimens is critical. Thermo Scientific Nautilus LIMS is specifically designed to address the unique challenges of specimen collection, tracking, and storage for pharmaceutical discovery and clinical operations, academic and biosciences, research centers, medical institutions and contract research organizations.

Nautilus LIMS™ not only facilitates data capture and specification management, but it also facilitates chain-of-custody and handling assurance requirements. Whether storing or tracking whole blood, tissue, cellular lysates, DNA, RNA, proteins, etc., Nautilus supports organization-wide inventory control. Nautilus' web interface provides centralized global access in a secure environment. In addition, Nautilus' built-in, patented graphical workflow utility tool allows organizations to easily extend their capabilities and tailor the solution to the needs of each laboratory's unique requirements.



Sophisticated tracking of samples is required to manage biospecimens. Nautilus LIMS enables users to graphically locate samples down to their specific freezer location.

Complex Sample Management

Biobanking studies require pertinent patient information to be available for each sample being processed to ensure that researchers can search a particular disease state, race, and age range for targeted studies. Nautilus LIMS provides a central location where this information can be stored and managed without violating patient confidentiality. It also supports organization-wide inventory control so that the biobanks can easily determine if they have the samples available to fulfill an order.

Furthermore, Nautilus' configurable laboratory workflow allows individual laboratories to tailor the definitions of samples and parent/child relationships, along with the extent to which each physical item and related information is tracked by the LIMS. This can include as needed sample locations, amount tracking, associated testing, patient information, and any other complex information needed to verify and fill biobank customer requests.



“The flexibility, adaptability and stability of Nautilus LIMS combined with Thermo Fisher’s long-established experience serving the health sciences and pharmaceutical industries made Nautilus LIMS the obvious choice for the data management of this massive project.”

— LIMS manager, UK Biobank

Chain of Custody

Nautilus’ hierarchical structure also simplifies chain-of-custody for laboratories. The use of detailed hierarchical location management, aliquot/derivative and pooled sample tracking, and documented disposition of samples ensure that no matter what path a sample or aliquot takes in the laboratory, Nautilus has stored its history and can identify each user involved in the process.



Researchers need to be able to query the samples stored in the biobanks. Nautilus LIMS web interface enables them to make sample requests and track their progress.

Request Management

A biobank is not working optimally if researchers cannot easily search, organize, and request specimens from the biobank according to their research needs. Nautilus’ customer-tailored Web Access capabilities allow the biobank to do this with ease. Using the web interface, customers of biobanks will be able to track the progress of their request from creation to fulfillment without ever entering the Nautilus system directly. Once the customer request reaches the biobank, Nautilus helps users review, approve,

collect, normalize concentrations, test, and ship samples. This process can vary and be quite complex but Nautilus’ workflows allow each biobank to complete the customer request with ease. For example, the biobank technician may decide to send a different sample than what was requested (same patient but perhaps a sample at a different concentration, different volume, etc.).

Nautilus’ intuitive web interface aids integration and interaction with systems throughout the organization as well as other facilities, including regulatory agencies and labs. This enables rapid access to up-to-the-minute data and information that impacts every phase of the laboratory process.

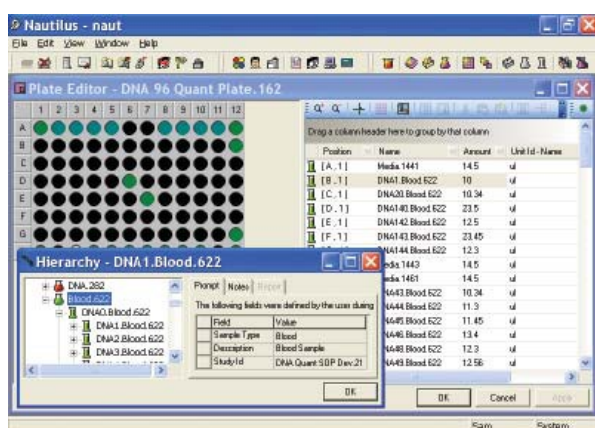
Consent Management

Consent management is an imperative for biobanks and biorepositories as it determines whether a user has the authority to check out samples and what they are permitted to do with them. Furthermore, a patient can withdraw a consent and the system must be able to trigger the destruction of all samples collected from that person, including those that are checked out and in-progress at a customer’s facility. We understand this need and have built-in sample traceability to allow for accurate decisions of which samples to dispose of or not use based on approved consent, whether those decisions are part of a manual or automated process. Nautilus has the ability to store and view the actual consent, along with any restrictions that may have been documented.



Instrument Integration and Automation

Many biobanks today use a high level of automation and take advantage of the latest advances in instrumentation to manage their biospecimens. Nautilus is designed to simplify instrument and automation system integration. Previously disparate systems can now be integrated to allow for data to be electronically passed between them, eliminating manual error-prone processes and increasing productivity and data reliability. A short learning curve, easy integration and improved automation mean that standardizing with Nautilus has a rapid return on investment and lower total cost of ownership. Laboratories have noted increases as high as 72% in user-to-IT ratio, 40% in user efficiency and >50% in work samples per month when standardizing on a single LIMS.



Patient demographics and chain of custody information must remain associated with the biospecimens. Nautilus' superior plate handling allows users to manage all aliquots and its hierarchy ensures that sample information is available from the biospecimens down to the individual aliquot.

Extensive Plate Management

Nautilus simplifies plate tracking by defining plate configurations and fill patterns, letting users build and format work-action and decision-tree processes against project requirements. Advanced plate handling within Nautilus includes graphical workflows, plate editors, and built-in integration functionality that enables increased throughput and automation. Users can automate data flow or manipulate it manually, using capabilities like drag-and-drop within a graphical plate editor. Previously disparate systems can now be integrated to allow for data to be electronically passed between them, eliminating manual error-prone processes and increasing productivity and data reliability. Furthermore, Nautilus simplifies printing and scanning of 1D and 2D barcodes.

Unifying LIMS and Analytical Instrument Data

Until now, LIMS and analytical systems have been autonomous and disparate. The Data Manager solution in Nautilus moves toward fully integrating these two platforms by providing the ability to store raw data from instrumentation and converting this data to a platform-independent format. By linking this data to LIMS entities directly, users can make informed decisions since they have access to all of their instrument data in a single interface. Users can compare analyses from disparate instruments and overlay the results. Data Manager bridges the gap, maximizing the value of existing analytical instruments and protecting investments in the future.



Data Compliance and Security

Nautilus has configurable electronic signature templates along with audit capabilities to comply with 21 CFR Part 11 so users are fully aware of what processes they must follow. Nautilus' database design fully utilizes an Oracle RDBMS to enforce data security, auditing and compliance. Since Nautilus stores business rules in the database, security is always active, even when a third party application (e.g., Excel, or other reporting packages) accesses the data. This unique architecture enables integration with the entire laboratory in a flexible, secure manner that ensures the authenticity, integrity and traceability of the laboratory's data. Moreover, Nautilus is part of an integrated solution that enables organizations to track the genomic and phenotypic data associated with these biospecimens and comply with HIPAA and other privacy laws.

Partnering with Thermo Fisher Scientific

We offer a comprehensive end-to-end solution for all of your biobanking needs. In addition to Nautilus LIMS, Thermo Scientific BioBank is an automated sample management module designed to safely store biological samples at -80°C for a wide range of research applications such as cell based assays, bacterial clones, protein, DNA and RNA libraries. The BioBank holds thousands of samples in a range of configurations, including standard and deep well microtiter plates and cryotube racks. A special feature of the BioBank is its CO₂ backup that

protects samples up to 12 hours during power outages.

New products in the line of Thermo Scientific 2D barcoded screwcap tubes include ABgene®, Matrix® and NUNC® tubes in volumes from 500l to 12ml and supplied in automation-friendly, microplate footprint racks of 24, 48 or 96 tubes according to tube size. The critical nature of



biobank samples make permanently attached 2D barcodes for secure sample tracking and chain of custody a superior choice over traditional labels, which can fall off. Organizations who take advantage of the rapidly growing set of Thermo Scientific tools and technologies aimed at biobanks and biorepositories will greatly reap the benefits of enhanced sample integrity, tracking and audit trail.

To learn more about Nautilus LIMS and our full line of Informatics offerings, please visit www.thermo.com/informatics or contact us at +1 215 964 6020. The company's Stem Cell Excellence program can be found at www.stemcellexcellence.com.

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