



ABBOTT INFORMATICS

STARLIMS

**BIOREPOSITORY INDUSTRY
LIMS SPECIFICATION
DOCUMENT**

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INTRODUCTION

The purpose of this document is to list the main functionality and features available in STARLIMS solutions for the Biorepository Industry.



SAMPLE MANAGEMENT

BIOREPOSITORY AND TRANSACTIONS

FEATURE / FUNCTIONALITY	DESCRIPTION
Sample Reception	Users can easily record the receipt of a batch of samples from an external party into the biobank and validate what physically arrived. Users can also record the sender's information, assign a project to the specimens, and immediately define their long-term or short-term storage destination within a single action.
Custodian Tracking	Users can designate other staff members as owners or custodians to a set of samples or sample containers. This allows for a clear indication of whom within the staff is currently responsible for the specimens.
Aliquot / Split	Users can create derivatives or aliquots of specimens to facilitate their processing needs. Aliquots can then be used for additional testing, archival, and external distributions. Gives the user flexibility to further define output sample types, for example, the user can create DNA aliquots from whole blood samples or slides of tissue from a single tissue block.
Test Ordering	Allows the user to assign any type of test to a specimen in the biobank. With this, a user can potentially search for a sample in the biobank and perform a chemistry test against the specimen or qualitative test such as analyzing the concentration of DNA from a specimen.
Pooling	Users can consolidate a batch of samples together into a single sample to help facilitate efficient testing or assist with insufficient quantities of specimens.
Project Association	Samples can be associated to established projects for invoicing and cost analysis. This also allows a user to designate specific storage locations to projects and thereby only allowing specific sample types to be stored as per the project's configuration.
Comment Annotation	Tack on supplemental information and notes on any sample in the biobank.

SAMPLE MANAGEMENT

FEATURE / FUNCTIONALITY	DESCRIPTION
SPREC	Define how a specimen should be handled or processed and realize how it's actually handled using Standard Pre-analytical Code or SPREC.
Thaw Counting	Allows the user to track the number of times a specimen is taken out of a freezer and thawed. With this, the user can determine the qualitative integrity of the sample and take appropriate action.
Chain of Custody with Electronic Signatures	All actions performed against a specimen are timestamped and user tracked from reception to final disposal. Said actions can be configured to require the user to sign an electronic signature and authenticate with the system for any action that is to be performed on the specimen, thereby further preventing unauthorized actions.
Visual Inspection	When the user physically examines a specimen and the container it resides in, the system allows the user to document and record notes regarding the condition of the specimen.
Disposal	When discarding samples from the biobank, the user can mark as disposed in STARLIMS. STARLIMS will never delete the data for full traceability purposes.
Sample Quantity Adjustment	Sample quantity and volume can be adjusted through a number of actions such as aliquoting, splitting, and pooling. Additionally, the user can correct the sample quantity at any time.
Move Samples	Track a sample's movement between locations from a technician's bench to a rack in the freezer.
Sort Samples within Container	Easily and quickly scan specimens into storage boxes using default fill patterns.
Attachments	Append supplemental information to samples in the biobank.
Genealogy	Easily view samples' parent-child relationships in a hierarchical fashion. Decipher where a sample came from, whether it's from determining a slide came from a block of tissue or if DNA came from a specific whole blood sample.

FEATURE / FUNCTIONALITY	DESCRIPTION
Specimen Metadata Options	Biorepository metadata templates allows users to add specimen attributes or fields beyond what the system comes with, thereby offering scalability and flexibility to capturing data. Once the new attributes are added to the specimen and data is captured upon them, researchers can immediately use that attribute in queries.
Functional Scalability	The biobank can add to the list of default actions that can be performed on a specimen by utilizing the STARLIMS Designer to create their own forms. Once created the forms can easily be added from the UI and take full advantage of the controls and permissions functionalities.

CONTAINER MANAGEMENT

STORAGE CONTAINER MANAGEMENT

FEATURE / FUNCTIONALITY	DESCRIPTION
Storage Container Layout and Capacity Definition	The system allows defining storage containers with different sizes, layouts, shapes and capacity to be used for specimen storage.
Handling Storage Containers	The storage containers can be handled as inventory items - they could be labeled, stored, moved to a different storage location, disposed, shipped, assigned to a project or stored in other storage containers.

CONTAINER MANAGEMENT

FEATURE / FUNCTIONALITY	DESCRIPTION
Handling Specimens in Storage Containers	The system allows the users to perform transactions on the containers and their contents. The users can, for example, ship an entire container instead of shipping individual samples. All actions performed on a container or their contents are captured in Chain of Custody.
Storage Container Usage	The storage containers can be used in Biorepository transactions for storing specimens and specifying the storage positions. The users can search for available containers by different search criteria or create new containers Add Hoc if needed.

LOCATION MANAGEMENT

STORAGE LOCATION MANAGEMENT

FEATURE / FUNCTIONALITY	DESCRIPTION
Location and Sublocation Types	Users can define a template representing a hierarchical structure of how they wish to represent their locations. This hierarchy can range from site, building, room, freezer, shelf, and rack. The template can then be reused to quickly add multiple freezers of the same structure.
Move Locations	Quickly move a sub location such as a shelf from one freezer to another.
Storage Conditions	Record storage condition attributes such as temperature for a given location.
Specimen View	Drill down and select a location to quickly catch a glimpse of the inventory of specimens at that location.

SHIPPING AND RECEIVING

WORK ORDERS / PACKING / SHIPPING

FEATURE / FUNCTIONALITY	DESCRIPTION
Outgoing Shipments	Users can track outgoing shipments of samples with attributes such as destination address, contact representative, and tracking information. Users can also assign multiple boxes and/or packages to be part of the shipment using barcode scanning.
Shipment Receipts	Track and QC reception of samples from intra-lab shipments. This lets the user physically receive specimens against a manifest and record discrepancies, if any, in the shipment.
Packing	Prior to shipping, users can track the packing process, print packing lists, and manage consumable inventory as they're packing.
Pack List	Users can pre-scan the samples into a list and expedite the packing process prior to shipment.
Work Orders	Capture internal or external requests for sample processing workflows such as packing and shipping or a special service such as a DNA extraction.

WORKFLOW MANAGEMENT

SERVICE MANAGER

FEATURE / FUNCTIONALITY	DESCRIPTION
Support for Configurable Workflows	STARLIMS allows a user to create a business workflow template, that is represented by a series of steps and actions, in order to track the stages of sample processing. Workflows such as aliquot-pack-ship and DNA extraction can be accomplished using the workflow manger.

WORKFLOW MANAGEMENT

FEATURE / FUNCTIONALITY	DESCRIPTION
Workflow Versioning	Versioning workflows allows for complete record keeping of how a workflow template was previously configured. Additionally, it allows the user to have an active workflow template while configuring the next template iteration.
Support for Assembly of Workflow Steps and Actions	The assembly of steps allows for a cohesive and linear progression through a defined workflow. Using the STARLIMS Designer, the Biobank can create and design compatible forms to be used as steps in such a workflow. After which, the steps can be reordered or reused in different workflows. This gives the flexibility of creating something tailored to the Biobank without compromising any core functionalities of the system.
Test Ordering and Assignment	The workflow management tool allows a user to configure tests that could be assigned to a specimen at any step within the workflow. For example, while performing a DNA extraction against whole blood, a qualitative concentration test can be assigned to the DNA sample.

SEARCHING THE BIOBANK

QBE (QUERY BY EXAMPLE)

FEATURE / FUNCTIONALITY	DESCRIPTION
Standard Search by Specimen Attributes	The standard search by specimen attributes allows to perform quick searches by pre-defined standard specimen attributes like Specimen Identifier, External Identifier, Sample Type, Status, Location, Storage Container, Expiration Date, etc. The Standard search comprises frequently used search criteria.
Configurable Standard Search Screen	The Standard Search screen is configurable which allows to define customer specific standard search criteria.

FEATURE / FUNCTIONALITY	DESCRIPTION
Advanced Search by Specimen Attributes	The Advanced search allows the users to select additional specific search criteria from a pre-defined template, e.g. subject attributes, trial related information, location attributes, etc.
Configurable Advanced Search Template	The Advanced Search template is configurable via a QBE template, allowing to customize advanced searches without additional coding.
Advanced Search by Metadata Specimen Attributes	The advanced search by metadata specimen attributes allows searches by user defined metadata templates associated with the specimen.
Standard Search by Patient	The standard search screen provides an option to search by sample patient information.
Standard Search by Project	The standard search screen provides an option to search the specimens by the projects they are associated with.
Search by User Defined Carts	The Cart functionality allows the user to scan items that are physically placed on a cart. This allows the user to traverse the building facility and pull the cart manifest from a different work station without having to re-scan the items for immediate processing.
Query by Example (QBE)	The QBE is a powerful tool which provides the capability to create complex queries without the need to write SQL statements. QBE Manager is used to create QBE templates that can be used for ad hoc queries or that can be used in a combination with a Crystal report.
Report Query	The Report Query tool allows a QBE template to be used as a data filtering mechanism to run a Crystal report.
System QBE	The System QBE tool allows any QBE template to be used for ad hoc querying of the system. The data that is returned from the query can be grouped and sorted using standard STARLIMS grid capabilities. In addition, the data returned from the query can be exported to Excel.

ROLES AND PERMISSIONS

INVENTORY SETTINGS

FEATURE / FUNCTIONALITY	DESCRIPTION
Configurable Actions	<p>Actions that can be performed on samples in the Biobank such as aliquoting, storing, and consuming can be controlled by a number of parameters such as:</p> <ul style="list-style-type: none">• User's role• Sample type or container type• Status of specimen
Configurable E-Signatures	<p>All actions performed against a specimen are timestamped and user tracked from reception to final disposal. Actions can be configured to require the user to sign an electronic signature and authenticate with the system for any action that is to be performed on the specimen, thereby further preventing unauthorized actions.</p> <p>The format of the electronic signatures can be further configured to:</p> <ul style="list-style-type: none">• Include / exclude witness• Include / exclude additional comments and justifications
Configurable Statuses	<p>Users can add their own statuses to the default library of statuses that comes with STARLIMS, thereby allowing the biobank to track statuses more granularly as well as re-using familiar terms or vocabularies your lab is used to.</p>

DEVELOPMENT

CLINICAL TRIALS

FEATURE / FUNCTIONALITY	DESCRIPTION
Subject Tracking	Participating subjects can be tracked and anonymized for a given trial.
Accessioning	Customer-configurable, template-driven accessioning screens that allows for a simplified receipt of collection kits. STARLIMS intelligently fills out pertinent information based upon the study definition to expedite the process of logging in. Additionally, users are able to digitally attach any incoming requisition that accompanies a specimen.
Study-Specific Reference Ranges	Users are able to further define tests by creating study-specific reference ranges. This means, for example, if a study will consist of subjects from a specific geographic location, the user can reflect the ranges of said location for a specific study without augmenting the default ranges defined in the test library.
Time points and Master Schedules	Administrators can define visit elements, tolerance limits, visit sequence, and tests to be performed on a given visit.
Kit Building	The STARLIMS Inventory Manager is coupled with Trial Manager to allow users to define kit components, track manufacturing, inventory levels, kit building and distribution.
Facilities / Contacts	Administrators can further define collection sites and facilities as well as primary contacts such as principal investigators, study coordinators, or other research personnel.

PROJECT MANAGER

FEATURE / FUNCTIONALITY	DESCRIPTION
Defining Projects	The system provides the ability to define projects for a specific client, define the project terms, contacts of personnel involved, define specimen types allowed for the project, project storage locations, and user accessibility to project items.
Handling Specimens by Project	The Project Management tools provide the option to define the type of specimens allowed for a project, and to specify SPREC codes and additional metadata that will be captured for the project specimens. This information is being captured when specimens are created/received in Biorepository and allows users with access to the project to review and query the data. The users with Read/Write access to the project can perform Biorepository transactions on the project specimens.
Handling Project Storage Locations	The Project Management allows specifying the locations where the project specimens will be stored. This helps the users finding the right storage locations for the received items, organizing the storage by projects and facilitates finding the project specimens.
User Access to Projects and Project Items	The Project Management tools allow providing specific users with access to certain projects. The users who do not have access to a project cannot query and review project specimens. The users with Read Only access to the project can view the project information and items but cannot modify any project data. The users with Read Write privileges can access and modify project data and items.

LIBRARY MANAGEMENT

MATERIALS MANAGER / TEST MANAGER

FEATURE / FUNCTIONALITY

DESCRIPTION

Material Library Definition

Any tangible item that will be used in the Biobank can be defined in this application. The vast library ranges from sample containers, to types of samples, to reagents. This also allows the user to further define:

- Aliases
- Container structure
- Shipping boxes
- Ingredients (relevant to kit building)
- SPREC
- Safety attributes

Test Library Definition

Users can define a library of tests ranging from different disciplines such as chemistry, microbiology, qualitative, etc. With this, the biobank can further configure:

- Relevant equipment
- Methods
- Calculations
- Criteria-based reference ranges and panic limits
- Applicable sample collection tubes
- Auto-approval flags

CROSS FUNCTIONAL

FEATURE / FUNCTIONALITY	DESCRIPTION
Advanced Analytics	Accelerate your lab by transforming your data into actionable insights. From powerful visualizations that more clearly illustrate key activities to predictive analysis capabilities that help you anticipate critical events, Advanced Analytics gives you the insight you need to manage your lab.
Scientific Data Management System (SDMS)	Scientific Data Management System for centralized management of documents, lifecycle management and automatic document routing and indexing; parsing and recognition technology that transforms a variety of documents or files into searchable structured information.
Mobile Device Support	Access your lab remotely and stay connected. Abbott Informatics mobile support offering gives you the ability to access some of the data of your lab on the go. The mobile solution is optimized for a wide range of screens and devices.
Web-based solution for global deployment and collaboration	<p>Web-based solution, leveraging the .NET framework and other advanced Internet technologies such as HTML5. This means a single installation on a server where any update or configuration that is made to the system is immediately apparent to any client machine without the need of client installation.</p> <p>Multilingual solutions available for global deployment.</p> <p>The Web-based interface also makes it possible to track your specimens anywhere within the enterprise— even providing outreach capabilities to third parties and customers by leveraging HTML5.</p>

FEATURE / FUNCTIONALITY	DESCRIPTION
Interfacing Tools	By leveraging the many options and tools for interfacing, STARLIMS can automate the importing of data from a wide variety of systems using different protocols. These system-to-system communications can be established via web services (SOAP / WCF / RESTFUL), file-based (text, CSV, HL7, ASCII, etc.), and direct database communications.
Fusion	Fusion provides flexible interface connectivity to instruments as well as non-instrument interfaces such as 3rd party ordering systems.
Crystal Reports Integration	Users can view, print, and save reports from within the STARLIMS application. Report content can range from test result reports, pull lists, packing lists, statistical throughputs, low inventory, barcode labels and many more. With a Crystal Reports designer license, the biobank can create their own reports and import them directly into STARLIMS for immediate usage.

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