



LABORATORY KNOWLEDGE. DELIVERED.™

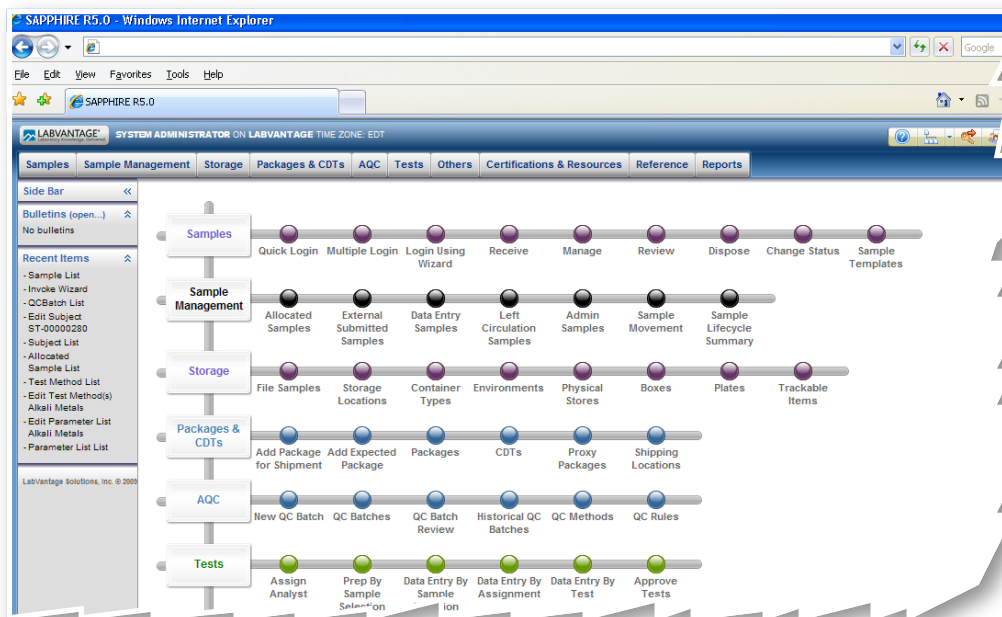
LABVANTAGE® BIOBANKING SOLUTION

LABVANTAGE BioBanking Solution

One of the key issues facing biotechnology and pharmaceutical companies today is the complexity of managing the increasing number of bio-specimens (tissue, blood, DNA, RNA, etc.) generated during the clinical trials process. With heightened regulatory and privacy compliance necessitated by Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs), 21 CFR Part 11, Health Insurance Portability and Accountability Act (HIPAA) and Internal Review Board (IRB) requirements, a solution that accurately tracks patient consent, HIPAA waivers, laboratory conditions, and electronic signatures is critical. Furthermore, as organizations recognize the additional value of utilizing samples during the discovery process for pharmacogenomics and pharmacoproteomics, solutions need to be able to easily store, locate, and access vital biospecimens along with critical genomic, proteomic, and phenotypic information without difficult system integration.

Recognizing the diverse challenges of running a successful and efficient biorepository, LABVANTAGE has created the LABVANTAGE Biobanking Solution. Developed in conjunction with the original developer of the Spectrum™ specimen management system, the biobanking module addresses the need for data capture, location management, handling assurance, and operational efficiency required to manage a biorepository at any organization.

LABVANTAGE enables centralized biological specimen tracking from “cradle to grave” to comply with GLPs & GCPs, satisfy patient consent requirements, enhance scientific accuracy, and improve development efficiency. Whether storing or tracking whole-blood, tissue, cellular lysates, DNA, RNA, proteins, etc, LABVANTAGE supports organization-wide inventory control. LABVANTAGE offers intricate chain-of-custody functionality, including detailed location & shipment management, aliquot/derivative & pooled sample tracking, and electronic signature captured transfer & disposition. Moreover, as an integrated solution, LABVANTAGE enables organizations to track the genomic and phenotypic data associated with these biospecimens under compliance with HIPAA and other privacy laws.

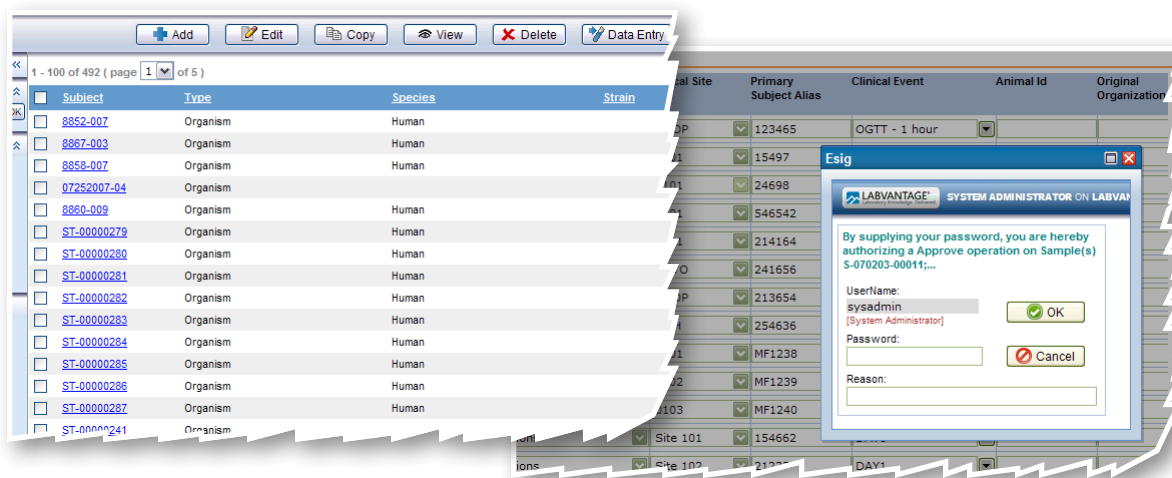


LABVANTAGE® BioBanking Solution

LABVANTAGE BioBanking Solution (CONT'D)

MANAGING COMPLEX BIOGRAPHICAL INFORMATION

LABVANTAGE's robust data entry workflow collects and verifies "biographical" information about each received sample. Examples include: subject, diagnosis, tissue type, collection or experimental timepoint, collection site, material preparation, collection method, supplier assigned identifiers and container type. Samples can be routed for additional verification by a second operator. Data entry approval is indicated with an electronic signature.

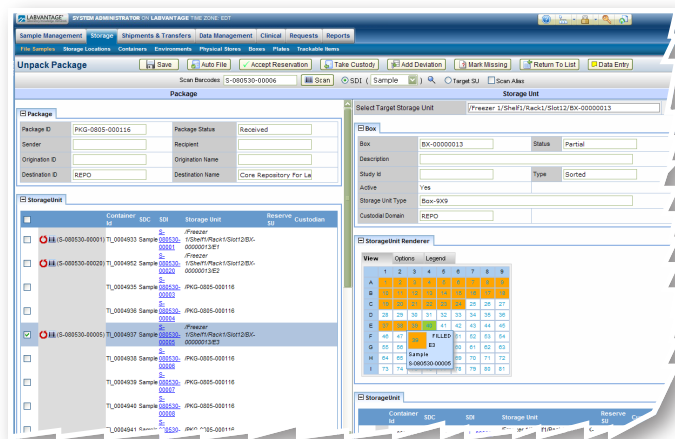


TRACKING CHAIN OF CUSTODY

LABVANTAGE provides several features for ensuring chain of custody when materials are transferred or used. Transfers between groups are recorded with tracking numbers and electronic signatures. The solution also supports check-out of samples from storage locations to specific individual custodians. Batches of samples may be grouped into containers, and tracked as a single custodial unit such as a rack, slide flat, or box.

UTILIZING VARIOUS STORAGE CONTAINERS

Each laboratory's storage space is divided into "Physical Stores" with a user-defined number of shelves, racks and boxes. Boxes may be further divided into X and Y locations. LABVANTAGE also manages temporary and transit storage locations. The solution can report a complete history of transfers, custodians, and location changes. It tracks the segregation of GLP and non-GLP storage and samples, allowing companies to confidently combine their clinical and non-clinical infrastructure.



MANAGING COMPLETE GENEALOGY

Aliquots, derivatives and pooled samples are fully tracked within LABVANTAGE, which records complete sample genealogy for each sample. As a browser-based solution, individuals internal and external to the

LABVANTAGE BioBanking Solution (CONT'D)

LABVANTAGE® BioBanking Solution

repository, can perform this function. If desired, through a special interface, external applications may also register aliquots directly. Aliquots inherit their parent’s consent restrictions automatically, allowing a company to maintain commitments to restrict its use of a material in the laboratory.

RECORDING FINAL DISPOSITION

If the sample is destroyed, consumed, missing, archived or transferred outside of the biorepository, this status is registered within LABVANTAGE with an electronic signature. In cases where multiple aliquots are created and consumed, the user can record the disposition by noting the SOP controlling the particular process.

COMPLYING WITH REGULATORY AND LEGAL REQUIREMENTS

Samples collected in patient registries and biomarker studies can be governed by narrow consent and contractual restrictions on their use, even for discovery based pharmacogenomics. The solution provides a “consent manifest” to each user of a material, indicating the permissible activities on each sample. The solution maintains detailed location management, data control, and an electronic signature on handoff to create a nonrepudiable audit trail.

Consent	Response	Sign-off
<input type="checkbox"/> I consent to allow my samples to be used in genomics research.	Yes	Oct 3, 2011
<input type="checkbox"/> I permit the use of my sample for oncology related studies.	Yes	Oct 3, 2011
<input type="checkbox"/> I permit my sample and all derivatives of my sample to be banked.	Yes	Oct 3, 2011
<input type="checkbox"/> I permit the sharing of my samples with other investigators.	Yes	Oct 3, 2011
<input type="checkbox"/> I permit the collection of my clinical data.	Yes	Oct 3, 2011

INTEGRATION WITH LIMS, CDMS, & EDC

As a module of LABVANTAGE platform technology, the LABVANTAGE BioBanking Solution is seamlessly integrated with other laboratory information management functionality for life sciences research and development. Moreover, with its open architecture, LABVANTAGE can quickly integrate with existing enterprise data capture systems and clinical trial or data management systems. Accordingly, with LABVANTAGE, organizations can utilize the same solution to manage genomic, proteomic, biomarker, and other discovery-based experiments, link to previously defined clinical protocols, pathology, and other clinical information without duplicating manual entry, and track genomic, proteomic, and phenotypic information associated with any sample across the R&D pipeline and into the supply chain.

ENSURING APPROPRIATE RESTRICTIONS

Sample restrictions are recorded for every sample within LABVANTAGE. Each study can define one or more “restriction classes,” each representing a particular type of consent or legal obligation relevant to that study. A “restriction manifest” provides a reminder of the usage constraints on each sample. A restriction indicator is also printed on the material’s label.

Study Id	Clinical Protocol Id	Storage Status	Conditional Approval	GLP	Subject Id*	Restriction Class	Clinical Site
MAYO	P12345-123	Received	<input type="checkbox"/>	<input type="checkbox"/>	01082008-45	Institutional Use Only	0101
MAYO	P12345-123	Received	<input type="checkbox"/>	<input type="checkbox"/>	01082008-49	None	0102
MAYO	P12345-123	Received	<input type="checkbox"/>	<input type="checkbox"/>	03122008-51	None	6820
MAYO	P12345-123	Received	<input type="checkbox"/>	<input type="checkbox"/>	07252007-05	Institutional Use Only	6820
MAYO	P12345-123	Received	<input type="checkbox"/>	<input type="checkbox"/>	03122008-55	None	0102
LABV01		Received	<input type="checkbox"/>	<input type="checkbox"/>	07252007-30	Clinical Data Collection	MAYO
LABV01		Received	<input type="checkbox"/>	<input type="checkbox"/>	07252007-11	Allow Genomics Research	CHOP
LABV01		Received	<input type="checkbox"/>	<input type="checkbox"/>	07252007-13	Clinical Data Collection	MGH
LABV01		Received	<input type="checkbox"/>	<input type="checkbox"/>	08162007-22	Allow Genomics Research	CHOP
LABV01		Received	<input type="checkbox"/>	<input type="checkbox"/>	07252007-37	Sample Banking	MAYO
MFLD		Received	<input type="checkbox"/>	<input type="checkbox"/>	ST-00000359	No Restrictions	0101
MFLD		Received	<input type="checkbox"/>	<input type="checkbox"/>	ST-00000318	Institutional Use Only	0102
MFLD		Received	<input type="checkbox"/>	<input type="checkbox"/>	ST-00000360	No Restrictions	0103

LABVANTAGE BioBANKING SOLUTION (CONT'D)

SUPPORTING GLP OPERATIONS

As a 21 CFR Part 11 enabled system, LABVANTAGE was designed specifically to support GLP and GCP sample banking and distribution. It carefully maintains the segregation between GLP and non-GLP materials, laboratories and storage locations. The solution was designed to meet FDA requirements for sample identification and integrity.

TRACKING WITH BAR CODES AND RFID

LABVANTAGE supports barcode or RFID symbology, which reduces the need for keyboard entry. Further, it supports customization of label formats for different purposes. The solution also support legacy SPECTRUM™ bar code labels and 1D symbologies.

The screenshot displays the LABVANTAGE BioBanking Solution interface. On the left, a table lists sample records with columns for Description, Status, Study Code, and Tracking. The table shows several records with IDs 010 through 033, all with a status of 'Created'. Above the table are various action buttons like 'Edit', 'Manage Contents', 'Pack Boxes', 'Receive', 'Remove From Hold', 'Cancel', and 'Print Labels'. On the right, a sample label is shown with the LABVANTAGE logo, a large barcode, and the text '*Sample Id*'. Below the main barcode is a smaller barcode labeled 'Root Parent Sample:' and a box containing 'GLP: GLP_FLAG' and 'Restrictions: R_FLAG'.

Description	Status	Study Code	Tracking
010	Created		
011	Created		
012	Created		
013	Created		
014	Created		
033	Created		

PROVIDING ACCESS TO MULTIPLE LABORATORIES AND REMOTE EMPLOYEES OR CUSTOMERS

Today's sophisticated organizations need to be able to efficiently share information across multiple laboratories and with employees and customers outside of the physical laboratory. LABVANTAGE facilitates this capability through its browser-based architecture.

- LABVANTAGE is loaded on a central application server (not individual PCs), and is accessed by users via the Internet or company Intranet, offering a lower cost of deployment compared to traditional client/server applications.
- Internet/Intranet access to LABVANTAGE is secure and protected by passwords and role-based rights.
- Organization decision-makers outside the lab or biorepository can access dashboards and reports, increasing visibility throughout the enterprise, and expediting decision-making processes.
- Customers can input orders/samples, and directly access information, improving customer service and satisfaction.
- LABVANTAGE is easy to learn and use because its interface has the familiar look of many websites. This intuitive usability promotes system acceptance both within and outside the organization.

IMPROVING OPERATIONAL EFFICIENCY

LABVANTAGE improves operational efficiency by allowing samples to be more closely tracked around the lab and within storage. Furthermore, batch accessioning and data entry features can increase the responsiveness of the biorepository.

LABVANTAGE BioBANKING SOLUTION (CONT'D)

COST EFFECTIVELY ADDING FUNCTIONALITY

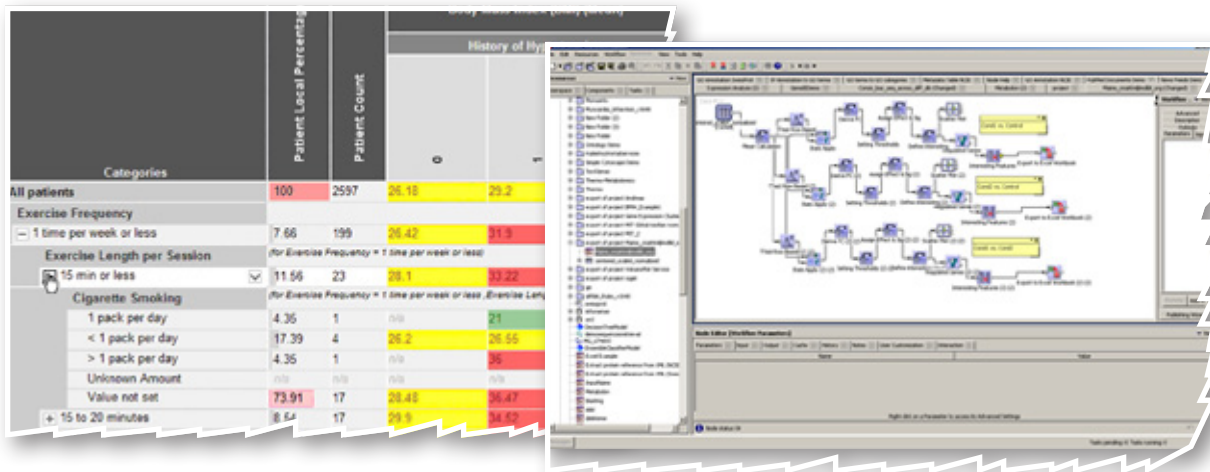
Evergreen™ Professional enables the creation and/or modification of new LABVANTAGE web pages, facilitating the rapid construction of a laboratory's or biorepository's unique configuration requirements. Whether it is for initial implementation or ongoing modifications due to changing business environments, Evergreen™ equips organizations with a configurable and maintainable solution. Moreover, for those organizations unsure of whether to "Build" or "Buy," LABVANTAGE coupled with Evergreen™ Professional is the ideal solution, offering in-house development teams a solid development platform, or outsourced professional services organizations an easy-to-use configuration tool. In both cases, configuration is accomplished at a much lower cost, and in a much shorter time frame, than would be experienced with custom coding. Moreover, because LABVANTAGE is configured, rather than customized, solutions are able to leverage future upgrades of LABVANTAGE

ACHIEVING HIGH SYSTEM PERFORMANCE AND RELIABILITY

Because organizations demand processing vast amounts of data in the least amount of time, laboratories need a solution that can perform at a fast, efficient, reliable level. LABVANTAGE enables laboratories to utilize a cluster environment to enhance its performance, scalability, and reliability. A cluster is a group of application servers that work together as a single logical server to manage client object requests among themselves. Clustering facilitates load balancing, a process that routes client requests to servers within the cluster. If one or more servers fail, the application server routes client requests to other servers within the cluster so there is no break in service. Moreover, overall performance is scaled up with additional nodes in the cluster.

COUPLING BIOSPECIMEN MANAGEMENT WITH INTEGRATIVE ANALYTICS

The LABVANTAGE BioBanking Solution with Integrative Analytics couples the best of laboratory information and biorepository management with the best of data integration and interactive analytics. This enables organizations to not only more effectively operate their laboratories, execute their protocols, and manage their samples, but also enter, mine, and analyze the data stored throughout their heterogeneous scientific and operational systems. The LABVANTAGE Biobanking Solution with Integrative Analytics provides researchers with real-time access through LABVANTAGE to a broader set of scientific data such as genomic, phenotypic, proteomic, and correlative clinical data stored in other systems throughout their organization. The solution arms scientific researchers with the information and analysis tools needed to conduct translational research under compliance with HIPAA and other privacy laws.



BIOBANKING SOLUTION SAMPLE FLOW

The LABVANTAGE BioBanking Solution was designed to flexibly support the operations and data storage required for sample collection, repository management and location tracking. It can accommodate this process in the context of a clinical trial, a biobanking operation, genomics and proteomics discovery and other discovery or development activities. Users may collect samples from a variety of sources including clinical sites, collaborators and external 3rd party sources. When these materials arrive, the operators can accession, store and provide the samples to scientists to perform sample processing and scientific assays. Samples may also be distributed to outside organizations. Throughout all of these processes, patient confidentiality and consent agreements can be verified and honored at every step. Furthermore, samples that produce data for an FDA submission must be identified and stored using GLPs. LABVANTAGE is a complete tracking solution, maintaining complaint chain of custody records and accountability at each step of the process.

A New Study Begins

- Study management module allows users to develop and track various studies or collections of samples
- Various study-specific information may be defined, including timepoints & sites
- System can handle external links to CDMS or DMPK protocol management systems
- Each study may define one or more consent agreements in advance
- Bar code kits may be generated in advance and sent to the collection sites.



Collecting Specimens

- Specimens are collected by clinical sites, collaborating laboratories or internal facilities
- Samples can be labeled with LABVANTAGE bar codes or any other labeling scheme
- Information about samples can be pre-registered for the samples before they arrive
- “Sample Collection Form” connects information about the subject with samples collected



Sample Delivery

- Samples can be shipped to the banking facility via courier or overnight delivery (if they are not located on-site)
- LABVANTAGE allows remote sites to set up transfer of materials and enter packing information
- LABVANTAGE records the status and disposition of each received package as it is processed into the biorepository



Accessioning

- Biorepository accessions samples into LABVANTAGE, assigning locations for the material in storage
- LABVANTAGE provides batch entry features and automatically connects samples to a package
- Received samples are placed in a queue for data entry, and the solution may be configured to require quarantine of the material prior to data entry.



LABVANTAGE® BioBanking Solution

BIOBANKING SOLUTION SAMPLE FLOW (CONT'D)

- LABVANTAGE supports scanning both “native” and “external” identifiers to reduce the need to relabel materials after receipt

Data Entry & Verification

- LABVANTAGE receives or processes information about samples, subjects, studies and sites.
- Information may be electronically loaded, or entered manually from paper capture
- LABVANTAGE supports record “locking”, requiring a data manager to approve the sample and certify the data stored in the system.



Sample Distribution

- LABVANTAGE supports direct check out from freezers or local repository storage
- If samples must be distributed, they can be packed together into a labeled bag, box or shipping container
- Delivery of the package is tracked in LABVANTAGE
- Receiving party executes an electronic signature to acknowledge receipt



Samples Tracking in the Organization

- LABVANTAGE's browser-based technology enables scientists, lab managers, and C-level executives to view the location of and information about a sample from their desktops.
- Samples stored in controlled freezers or other locations
- Location of each sample maintained within LABVANTAGE at all times with full “chain of custody”



Aliquots & Derivatives

- Aliquots and derivatives can be recorded in LABVANTAGE and bar-coded or RFID'd
- LABVANTAGE maintains sample “genealogy”
- LABVANTAGE tracks new sample type & related information



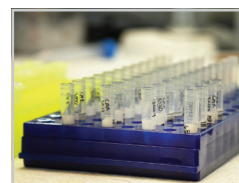
Sample Processing

- Results, assays and instrument data can be accumulated in the LABVANTAGE LIMS
- System also supports direct integration with external LIMS systems to record new identifiers for aliquots and derivatives



Sample Transfer

- Samples may be transfers offsite using a robust shipping and receiving mechanism

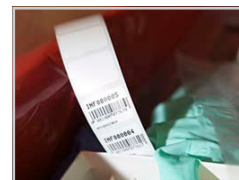


BIOBANKING SOLUTION SAMPLE FLOW (CONT'D)

- Receiving party executes an electronic signature to acknowledge receipt of the materials
- Receiving party can review a manifest describing the contents of the shipment and its consent restrictions
- Electronic signatures recorded in LABVANTAGE on each handoff

Sample Return and Disposition

- Samples may return to the same or different repositories for storage, archiving or transfer to 3rd parties.
- LABVANTAGE records final disposition of each material to complete the “chain of custody”
- Dispositions include: Destroyed, Consumed, Decommissioned and Missing



LABVANTAGE OVERVIEW

LABVANTAGE Solutions, Inc. is an innovative global provider of enterprise solutions tailored for leading laboratories. We serve numerous laboratories focused on:

- Research & Discovery
- Development (including Life Sciences Pre-clinical & Clinical Development)
- Formulation & Process Research
- Raw Material Testing
- Quality Management

Our global customer base encompasses companies across multiple industries including:

- Pharmaceutical & Biosciences
- Health & Personal Care
- Food & Beverage
- Process Chemicals
- Petrochemicals
- Parts, Hardware & Equipment
- Law Enforcement & National Security
- Contract Services

LABVANTAGE is a thin-client Laboratory Information Management Solution (LIMS) tailored to manage an organization's critical laboratory information across its worldwide R&D pipeline and manufacturing supply chain in order to optimize productivity and more effectively share knowledge.

Headquartered in Somerset, New Jersey, United States, LABVANTAGE also has offices in High Wycombe, United Kingdom and Kolkata, India, and utilizes a strategic network of global business partners to provide regional sales and customer support.

LABVANTAGE is a privately held affiliate of The Chatterjee Management Group Company, a \$1.5 billion private investment group that invests globally in infrastructure, communications and information technology companies.

LABVANTAGE Brochure

www.labvantage.com

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