**Thermo Scientific Clinical LIMS: Delivering Lab-Centric Solutions for Patient-Centric Results**

“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.”

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### The Challenges

- 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.
- Researchers and clinicians need lab processes that are responsive to physician and patient needs, while meeting the technical complexities of a medical research lab.
- 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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### Advancing Medicine Requires Next Generation Informatics Solutions

The improvements related to understanding the unique genetic makeup of both patients and disease have allowed physicians to utilize specialized diagnostic tests to diagnose and treat their patients. Due to the patient specific nature of the testing, labs must have in place all of the tools and compliant methodologies that are required to support CLIA and HIPAA regulations. Furthermore, labs also need to manage complex sample oriented workflows (including sophisticated instruments and automation) and support business processes. The new challenge for clinical testing labs responding to the increase in genetics testing is converging the functionality of informatics systems that manage patient information and those that manage lab and sample data.

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### The Solution

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

Thermo Scientific Clinical LIMS is developed on the proven, world class Thermo Scientific Informatics platform which offers unmatched flexibility and ease-of-use, increased automation and throughput of sample analysis for clinical laboratories that require sophisticated sample management, research tools and business enterprise integration. Built to support the laboratory’s end-to-end clinical business process, Thermo Scientific Clinical LIMS enables bi-directional communication between physicians and the lab via a dedicated Lab Web Portal.

The Clinical LIMS also enables customer service follow-up and CRM interface, patient management, final report generation and automated delivery, benefits investigation, interface with a billing provider, and the ability to interface with multiple clinical vocabularies. The Clinical 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.
Figure 2. The Lab Web Portal cuts overall turnaround time (TAT) by employing electronic TRF submission and patient reporting, automated shipment tracking, and regular notifications to sender and receiver.

Key Features and Benefits

- **The Physicians’ Interface** provides a secure web-based interface for submission of test requests to the lab, tracking sample progress, and access to published patient reports. The Lab Web Portal features an integrated dashboard with tailored KPI alerts, on-demand querying, and pre-packaged reports. The Lab Web Portal employs automated shipment tracking with regular updates to sender and receiver, allowing for improved capacity planning at the lab.

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

- **Billing & CRM** is enabled via integration with existing business systems that manage accounting and customer information. Customer service can set up rules to automatically flag samples with known discrepancies or make manual observations. Sample follow-up is facilitated internally and/or via CRM interface. An integrated dashboard is used to organize the workload and send alerts.Automated clinical data delivery through HL7 communication provides accurate information to the billing partner to allow increased reimbursement in a timely fashion.

- **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. Thermo Scientific Clinical LIMS supports usage of standard clinical terminologies and interfaces with clinical vocabularies (ICD, CPT, LOINC, SNOMED, etc.).

- **Complete Data Security and Audit Trail** capabilities address the needs of both the laboratory data and PHI. All patient information is stored in compliance with HIPAA privacy regula-
tions including software accessibility, PHI separation and data integrity, personnel HIPAA training, and the storage, retrieval and secure electronic transmission of lab test results. The auditing capabilities monitor all views and changes to any record in the system. The Clinical LIMS supports compliance with CLIA and 21 CFR Part 11. 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. All data is stored in a database and access is managed through privileges based on role, operator and group, ensuring data security and traceability.

• The Configurable Hierarchy manages data collected during the sample testing process and accommodates varying laboratory needs. Configurable hierarchy is integrated with chain-of-custody, location management, aliquot/derivative and pooled sample tracking. The disposition of a sample or aliquot is documented, ensuring that the Clinical LIMS stores its workflow history throughout the testing process.

• Workflow Management is designed to emulate laboratory processes via an intuitive graphical interface. The patented Workflow Manager expedites the mapping of static and dynamic processes without the need for custom programming, allowing users to organize data and manage tasks effectively.

• Biospecimen and Plate Management includes graphical workflows and plate editors, as well as built-in integration functionality that facilitates increased throughput and automation. The plate editor allows manual editing with user friendly functionality such as drag-and-drop. High throughput processes and plate based assays can be emulated using graphical workflows which include features such as replication, compositing, pooling, and cherry-picking.

• Instrument Integration & Automation includes robotics, next-generation sequencing, analyzers, etc., and facilitates standardization of processes and simplifies operations across the clinical network. This results in fewer transcription errors, improved data quality and cost savings.
• Enterprise Business Integration facilitates enterprise level information exchange by integrating the Clinical LIMS 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.

Delivering Lab-Centric Solutions for Patient-Centric Results
The emerging fields of translational and personalized 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 Scientific Clinical LIMS 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.

By unifying the distinct laboratory and patient management functionality needed by researchers and technicians involved in clinical testing and molecular diagnostics, Thermo Scientific Clinical LIMS delivers what no other stand-alone LIMS or LIS can: lab-centric solutions for patient-centric results.

For More Information
about Thermo Scientific solutions for clinical diagnostics, visit www.thermoscientific.com/clinicallims
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