



P-Wave Inc.

Breaking Communication Barriers

**Laboratory Automation Presentation
16th Annual Quality Assurance Conference**

**Electronic Document Management/
Document Control – Integration with LIMS
Institute of Ecosystem Studies (IES) Case Study**





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Presentation Definitions

- LIMS (Laboratory Information Management System) - is computer software that is used in the laboratory for the management of samples, laboratory users, instruments, standards and other laboratory functions such as invoicing, plate management, and work flow automation.
- LDMS (Laboratory Document Management System) – is a computer software that is can be an enhancement to a LIMS or standalone and provides an easier way to manage all of your laboratory documents and data. An LDMS may provides complete traceability, audit tracking and electronic signatures and creates a searchable format for document and data retrieval.





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Presentation Definitions

- EDC (Electronic Document Management) - is a computer system (or set of computer programs) used to track and store electronic documents and/or images of paper documents.
- Data Integration - is the process of combining data residing at different sources and providing the user with a unified view of these data.
- API (Application Programming Interface) – programming protocol that allows different programs or systems to pass data from one application to another.
- XML (Extensible Markup Language) is a flexible way to create common information formats and share both the format and the data on the World Wide Web, intranets, and elsewhere. Can make data “normalized” allowing it to be accessed for an undetermined length of time

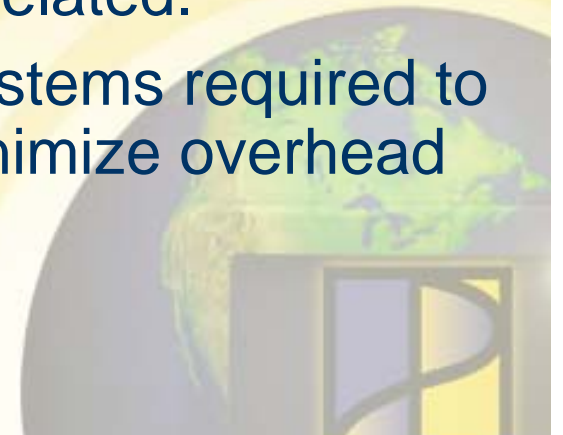


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Trends Driving Need for Integrated LIMS and LDMS

- Increasing volume of data and documents.
- Increasing regulatory pressure and higher expectations from regulators for data validation and sophisticated analysis.
- NELAC – Setting higher standards for quality systems and records management.
- Disparate unconnected systems creating islands of data that cannot be retrieved, shared or correlated.
- Adoption of electronic/computerized systems required to improve compliance, efficiency and minimize overhead operating costs.





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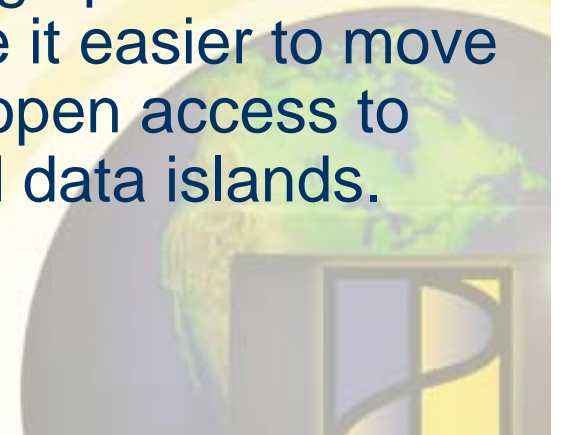
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Trends Enabling the

Implementation of Electronic

Systems like LDMS

- Low cost for electronic storage (disk space) makes it possible to archive and store large amount of data generated from lab operations.
- Web-based server technology have made group/team collaboration possible and improved access to information across the organization regardless of geography.
- Efforts to standardize computer language protocols (XML, WebDav, and HTTP) have made it easier to move data across systems and create more open access to information. Fewer closed systems and data islands.





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Laboratory Automation

Systems for Integration Case

Study

- LIMS – Accelerated Technology Laboratory's Sample Master® - is a complete and total data management solution for various types of laboratories. Sample Master® is modular by design allowing customers to purchase only modules that are required and allowing for expansion as the laboratory grows.
- LDMS – P-Wave's LabCORE™ provides document/data management and workflow in a web based, enterprise class application that is FDA 21 CFR Part 11 compliant. LabCORE offers a comprehensive, interoperable framework that is affordable for organizations of all sizes and focuses on compliance issues as well as data and document management throughout the enterprise.



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The Institute of Ecosystem

Studies (IES) – Case Study

- IES (www.ecostudies.org) is a world-renowned, private, not-for-profit, non advocacy, ecological research and education institution founded in 1983 whose scientist generate knowledge about ecological systems.
- IES scientists – 15 core scientific staff, over 80 post doctoral scientists + many dozen graduate and undergraduate students and visiting scientists – generate chemical data as part of their research.
- Research involves careful long-term monitoring of aquatic food webs, invasive species, native animal populations and environmental pollution.



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The Institute of Ecosystem

Studies (IES) – Case Study

- IES monitoring research projects average 5 to 40 years in length (some even longer).
- IES scientists often collaborate with other scientist and institutions worldwide.
- IES's central Analytical Laboratory (Rachel Carson Analytical Facility - AL) is the nexus for generating data and those data link collaborators together.
- Ten's of thousands of analyses from dozens of independent projects are run in the IES AL annually.





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Background on IES Case Study

- NSF (National Science Foundation) Grant – funding designed to help meet the goal of implementing a paperless laboratory that will capture, manipulate, distribute and preserve analytical data.
- IES used these funds in the 1999 to implement the Sample Master LIMS.
- Next Phase of automation was to implement the LabCORE LDMS to enable capture, preservation and sharing of all analytical information (including data and metadata) from a variety of sources (LIMS and lab instruments).





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Limitations of IES Quality

System Prior to Addition of

LDMS

- Managing and analyzing long term trends in analytical and associated metadata.
 - Retrieval or analysis of the data and associated documents is a very labor intensive exercise, at best.
 - Indexing and cross referencing information is not feasible.
 - More people need access than have computers running the proprietary software





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Limitations of IES Quality

System Prior to Addition of

LDMS

- Difficulties preserving the integrity of the data collected over time due to improvements in technology and staff turnover.
 - Turnover in personnel over time causes a loss of knowledge of analytical techniques, methods used are lost or not documented, reported or fixed.
 - Likely that when a critical piece of data is needed in the distant future, the data station hardware or operating system is obsolete and unavailable.





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Limitations of IES Quality

System Prior to Addition of

LDMS

- Tracking the details of the human instrument interface is a perennial problem.
 - Without appropriate searchable data it is difficult to offer assurances that an observed shift in long-term data is not the result of a change in instrument sensitivity or activities related to personnel change.
 - Without searchable and complete metadata, it is not possible to recreate instrument or method conditions.
 - Access to methods and data from the past is crucial as is the ability to check raw data from analytical runs.





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IES Goals of LDMS Project

1. Managing large volume of instrument data.
2. Manage laboratory protocols.
3. Store long term data.
4. Linking data results to metadata.
5. Verifying long term data trends.
6. Provide easy access to information.





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IES Required System Capabilities

- Automate capture of data/documents from a variety of sources across the lab network (LIMS and Lab instruments).
- Store, manage and retrieve documents.
- Categorize documents by keywords.
- Access documents via native applications.
- View and share instrument data without the software that created it.
- Common data formats, indexing and search.
- Data security (electronic signatures).





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IES Implementation of

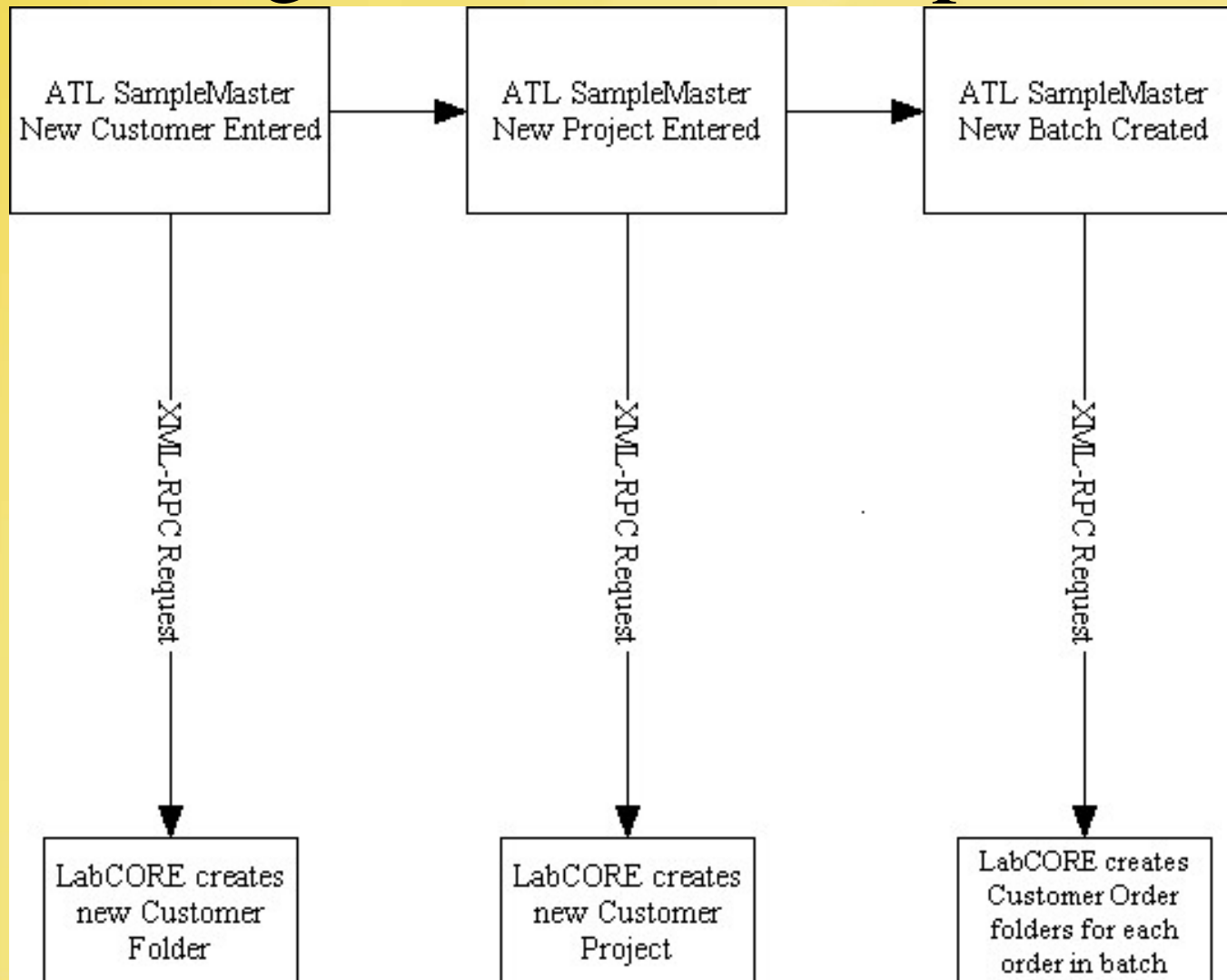
LabCORE LDMS and Sample

Master LIMS

- IES needed innovative solution that did not exist.
- Christine Paszko VP of Sales and Marketing for ATL suggested P-Wave's LabCORE as LDMS for IES.
- LabCORE's open architecture and LIMS API (application programming interface) enabled data integration to LIMS as well as lab instruments.
- P-Wave created API allowing ATL to update LabCORE database with customer specific projects and folders. Projects and folders are used to store document and data created by instrument runs.
- P-Wave created custom uploader to capture and upload data from instrument exports to LabCORE in the appropriate customer project and folder



Diagram of LabCORE (LDMS) Integration with Sample Master



min

Projects

Project List Browse Sharing Help





















Browse Projects Folder: Projects

- + [User Run](#)
- [Berkowitz, Alan R](#)
- + [Canham, Charles D](#)
- + [Caraco, Nina F M](#)
- + [Cole, Jonathan J](#)
- + [Denise Schmidt](#)
- + [Findlay, Stuart E G](#)
- [Groffman, Peter M](#)
 - + [Baltimore LTER](#)
 - + [CN Cycling](#)
 - + [Push-Pull Br Amber](#)
 - + [RI Groundwater](#)
 - + [WORM](#)
- + [Hogan, Kathleen](#)
- [Jones, Clive G](#)
- + [Likens, Gene E](#)
- + [Lovett, Gary M](#)
- [Ostfeld, Richard S](#)
- + [Pace, Michael L](#)
- [Pickett, Steward T A](#)
- + [Strayer, David L](#)
- + [Weathers, Kathleen C](#)
- [Winchcombe, Raymond J](#)

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 -  [0706006](#)
 -  [0709001](#)
 -  [Attachments for Baltimore LTER](#)
 -  [Calendar for Baltimore LTER](#)
 -  [Documents for Baltimore LTER](#)
 -  [Project Contacts](#)
 -  [Project Info](#)

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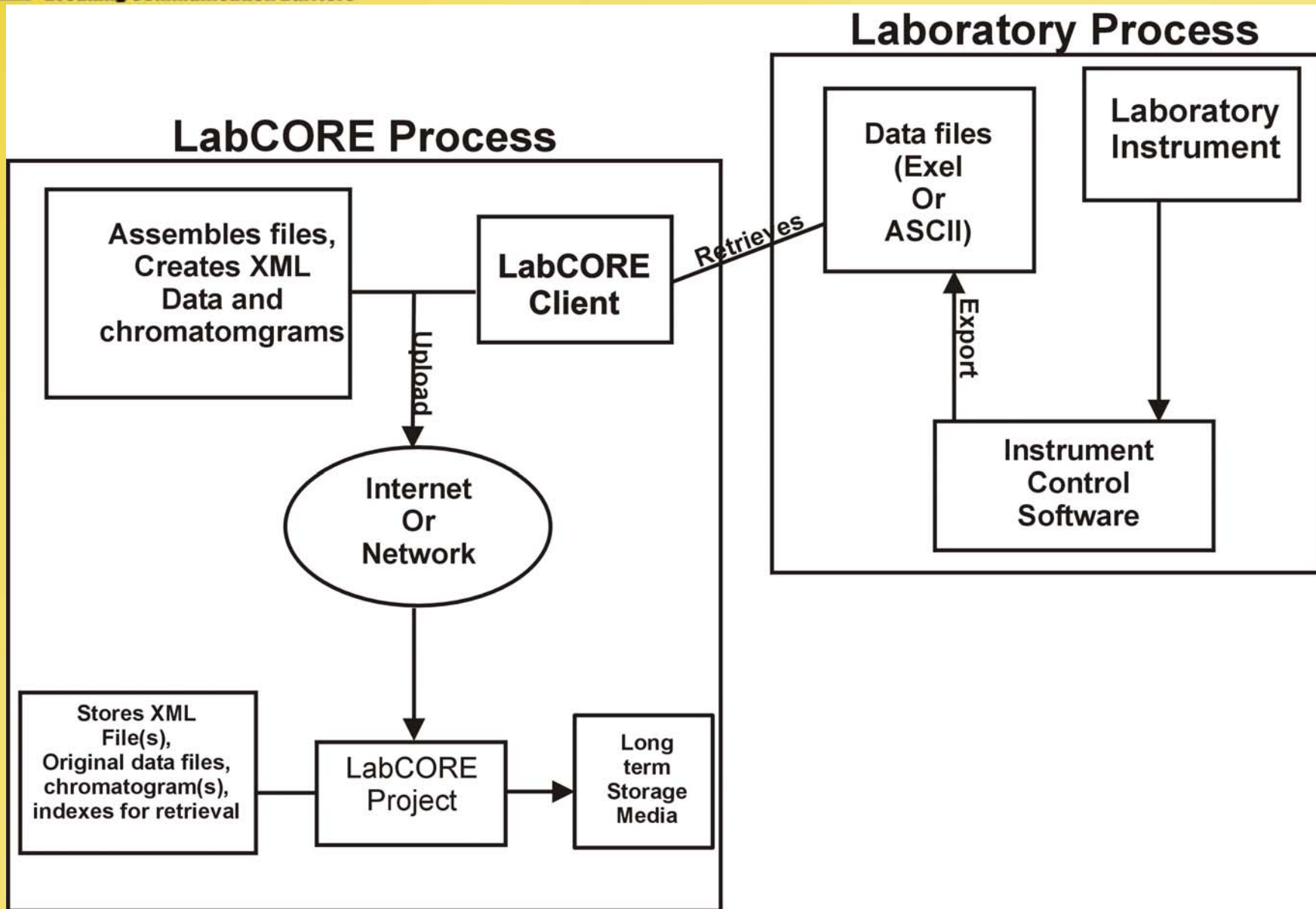
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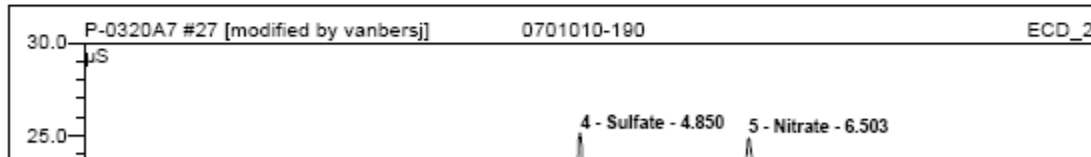
- 0701010-190
 - export summary
 - Integration
 - Calibration(Curr. Peak)
 - SST
 - Summary
 - Audit Trail

Operator:Administrator Timebase:Castor Sequence:C0225A4

5/14/21

27 0701010-190

Sample Name:	0701010-190	Injection Volume:	25.0
Vial Number:	27	Channel:	ECD_2
Sample Type:	unknown	Wavelength:	n.a.
Control Program:	Base Isocratic Pollux_Middle	Bandwidth:	n.a.
Quantif. Method:	BALT	Dilution Factor:	1.0000
Recording Time:	3/20/2007 17:04	Sample Weight:	1.0000
Run Time (min):	10.00	Sample Amount:	1.0000



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Summary

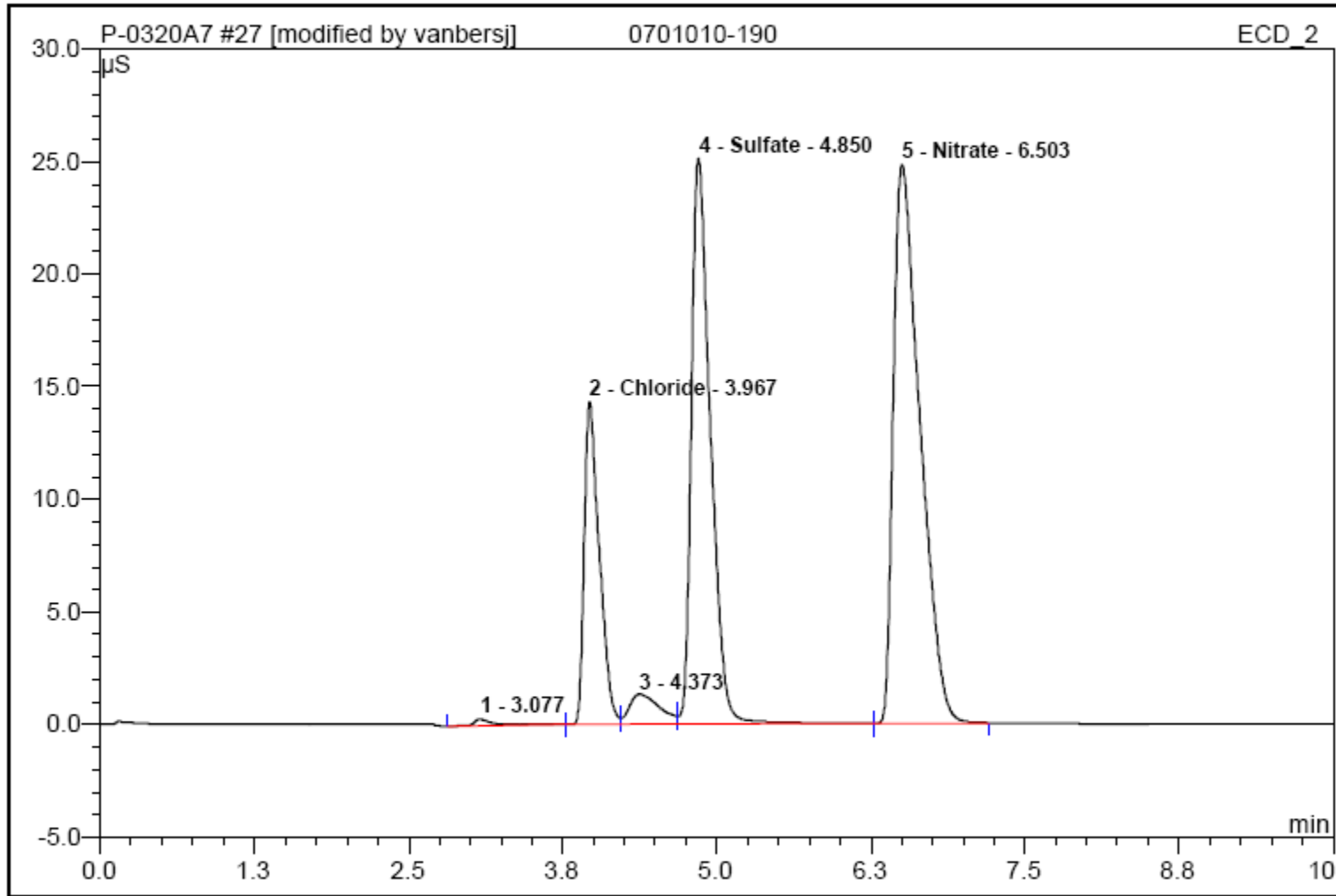
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Quantif. Method:	BALT	Dilution Factor:	1.0000
Recording Time:	3/20/2007 17:04	Sample Weight:	1.0000
Run Time (min):	10.00	Sample Amount:	1.0000



No.	Ret.Time min	Peak Name	Height μS	Area μS*min	Rel.Area %	Amount	Type
1	3.08	n.a.	0.323	0.068	0.51	n.a.	BMb*
2	3.97	Chloride	14.343	2.038	15.42	5.131	bM *
3	4.37	n.a.	1.342	0.385	2.02	n.a.	M*



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Key Performance Indicators at IEC

KPI	Pre- LDMS	Post - LDMS	Key Drivers
Retrieving Data and Correlated Documents	35 hour process per incident	Reduced process to 2 hours per incident (Significant gain in productivity)	* All data and correlated docs stored in searchable central repository
Automation of data and document capture	Each Lab tech spent at least 3.5 hours per week	Automated process = 0 hours = 10-15% time savings weekly	* Streamlined automated capture from lab instruments
Ease of Use/ Employee Acceptance		1-2 hours training for computer savvy lab technicians to max of 2 days for less savvy	* System very easy to learn and intuitive to the users
Access to Vital Data & Documents/ Collaboration	Limited access to docs/data; difficult collaboration/ data sharing	Full access to data via web - Correlating docs are avail in native applications; sharing and collaboration easy	* Access through simple UI in web browser - "Everything in one place"



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Final Key Performance Indicator

- Is this new automated process of the LIMS/LDMS improving your overall data quality?
 - Answer: “ABSOLUTELY! THIS IS OUR PRIMARY PURPOSE FOR IMPLEMENTING THE LDMS AND HAVING IT INTEGRATED WITH THE LIMS. WE NEEDED TO ADD STRUCTURE AND PROTOCOL TO OUR VERIFICATION PROCESS THAT INCLUDED LINKING RESULTS TO INSTRUMENT DATA”
 - Denise Schmidt, Manager of IES AL





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Thank You

Please visit www.lab-core.com

or or call Mark Ferrero

610-372-7890 ext. 22

The LABCORE logo features the word "LABCORE" in a bold, blue, sans-serif font. The text is centered within a white rectangular box that has orange diagonal lines on its left and right sides, creating a stylized, dynamic appearance.

LABCORE

