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GENERAL TERMS & CONDITIONS
REQUEST FOR QUOTATION (RFQ) AND REQUEST FOR PROPOSAL (RFP)

1. Awards will be made in the best interest of the State of West Virginia.

2. The State may accept or reject in part, or in whole, any bid.

3. All quotations are governed by the ***West Virginia Code*** and the ***Legislative Rules*** of the Purchasing Division.

4. Prior to any award, the apparent successful vendor must be properly registered with the Purchasing Division and have paid the required $125 fee.

5. All services performed or goods delivered under State Purchase Order/Contracts are to be continued for the term of the Purchase Order/Contracts, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise available for these services or goods, this Purchase Order/Contract becomes void and of no effect after June 30.

6. Payment may only be made after the delivery and acceptance of goods or services.

7. Interest may be paid for late payment in accordance with the ***West Virginia Code***.

8. Vendor preference will be granted upon written request in accordance with the ***West Virginia Code***

9. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.

10. The Director of Purchasing may cancel any Purchase Order/Contract upon 30 days written notice to the seller.

11. The laws of the State of West Virginia and the ***Legislative Rules*** of the Purchasing Division shall govern all rights and duties under the Contract, including without limitation the validity of this Purchase Order/Contract.

12. Any reference to automatic renewal is hereby deleted. The Contract may be renewed only upon mutual written agreement of the parties

13. **BANKRUPTCY:** In the event the vendor/contractor files for bankruptcy protection, the State may deem this contract null and void, and terminate such contract without further order.

14. **HIPAA BUSINESS ASSOCIATE ADDENDUM:** The West Virginia State Government HIPAA Business Associate Addendum (BAA), approved by the Attorney General, and available online at the Purchasing Division's web site (**http://www.state.wv.us/admin/purchase/vrc/hipaa.htm**) is hereby made part of the agreement. Provided that, the Agency meets the definition of a Cover Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.

15. **WEST VIRGINIA ALCOHOL & DRUG-FREE WORKPLACE ACT:** If this Contract constitutes a public improvement construction contract as set forth in Article 1D, Chapter 21 of the West Virginia Code ("The West Virginia Alcohol and Drug-Free Workplace Act"), then the following language shall hereby become part of this Contract: "The contractor and its subcontractors shall implement and maintain a written drug-free workplace policy in compliance with the West Virginia Alcohol and Drug-Free Workplace Act, as set forth in Article 1D, Chapter 21 of the West Virginia Code. The contractor and its subcontractors shall provide a sworn statement in writing, under the penalties of perjury, that they maintain a valid drug-free work place policy in compliance with the West Virginia and Drug-Free Workplace Act. It is understood and agreed that this Contract shall be cancelled by the awarding authority if the Contractor: 1) Fails to implement its drug-free workplace policy; 2) Fails to provide information regarding implementation of the contractor's drug-free workplace policy at the request of the public authority; or 3) Provides to the public authority false information regarding the contractor's drug-free workplace policy."

INSTRUCTIONS TO BIDDERS

1. Use the quotation forms provided by the Purchasing Division

2. **SPECIFICATIONS:** Items offered must be in compliance with the specifications. Any deviation from the specifications must be clearly indicated by the bidder. Alternates offered by the bidder as **EQUAL** to the specifications must be clearly defined. A bidder offering an alternate should attach complete specifications and literature to the bid. The Purchasing Division may waive minor deviations to specifications.

3. Complete all sections of the quotation form

4. Unit prices shall prevail in case of discrepancy

5. All quotations are considered F.O.B. destination unless alternate shipping terms are clearly identified in the quotation.

6. **BID SUBMISSION:** All quotations must be delivered by the bidder to the office listed below prior to the date and time of the bid opening. Failure of the bidder to deliver the quotations on time will result in bid disqualifications: Department of Administration, Purchasing Division, 2019 Washington Street East, P.O. Box 50130, Charleston, WV 25305-0130

LabWare Inc.
Three Mill Road, Suite 102,
Wilmington, DE, 19806

July 20, 2009

The State of West Virginia
Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV, 25305-0130

Dear Roberta Wagner:

LabWare, Inc. is pleased to submit the attached proposal for the commercial-off-the-shelf (COTS) Electronic Disease Surveillance System (EDSS) and Electronic Laboratory Reporting (ELR), in reply to the State of West Virginia, Division of Surveillance and Disease Control (DSDC) request for quotation. The proposal includes the LabWare EDSS COTS product, a pre-configured public health template solution, implementation services, training and ongoing technical support.

LabWare has been competing in the public health market for approximately 5 years. Our main focus, thus far, has been to provide LIMS solutions for the lab. It would seem to be a natural transition for LabWare to provide an Electronic Disease Surveillance and Electronic Laboratory Reporting (ELR) solution. The line between Epidemiology and the lab varies from State to State. LabWare believes that much of the functionality required by DSDC has already been configured through previous LabWare LIMS implementations. LabWare would open to visiting DSDC to provide a product demonstration to verify we can meet your requirements.

LabWare is offering DSDC a 100% web solution that is based on J2EE/JAVA technology. LabWare from a technical standpoint is a perfect fit for DSDC. LabWare EDSS makes use of the Tomcat Web Application server in our own development environment.

LabWare wishes the DSDC success in its endeavors to purchase and implement an EDSS and ELR system. LabWare is hopeful it will be the chosen vendor, and play a large role in the project's success.

Sincerely,

David Trottier

David Trottier
Address: Three Mill Road, Suite 102, Wilmington, DE, 19806
Email: trottier@labware.com
Fax Number: (302) 658-7894
Phone Number: (302) 658-8444 or (416) 769-2446

1. VENDOR REQUIREMENTS

The following are requirement's LabWare is offering a deviation from the specification.

1.3.2.16 System should be tested to mitigate the Top 25 Most Dangerous Programming Errors as developed by SANS (SysAdmin, Audit, Network, Security) Institute/Mitre Corporation. This may be found in the attached 2009 CWE/SANS (Common Weakness Enumeration) Top 25 Most Dangerous Programming Errors or on-line at http://cwe.mitre.org/top25 . Generate reports detailing any security issues from the top25 list.

A quick review of the Top 25 Most Dangerous programming Errors indicates LabWare will have issues in some areas. For example, one of the vulnerabilities is 'Dynamically generated code'. LabWare's Java tier, which renders the web interface, is based entirely on dynamically generated code. The LIMS tier feeds an XML file to the Java tier, which then dynamically generates the HTML and Javascript. We see this as one of the strengths of our architecture.

Another example where we may have an issue is Error Message Information Leak and Download of Code without Integrity Check.

LabWare recommends further investigation with the help of DSDC to determine if these issues present a significant security risk.

1.3.4.4.2 System must allow a user (ID) to consist of an e-mail address. User id and/or e-mail address should not be the primary key and/or foreign keys to any table.

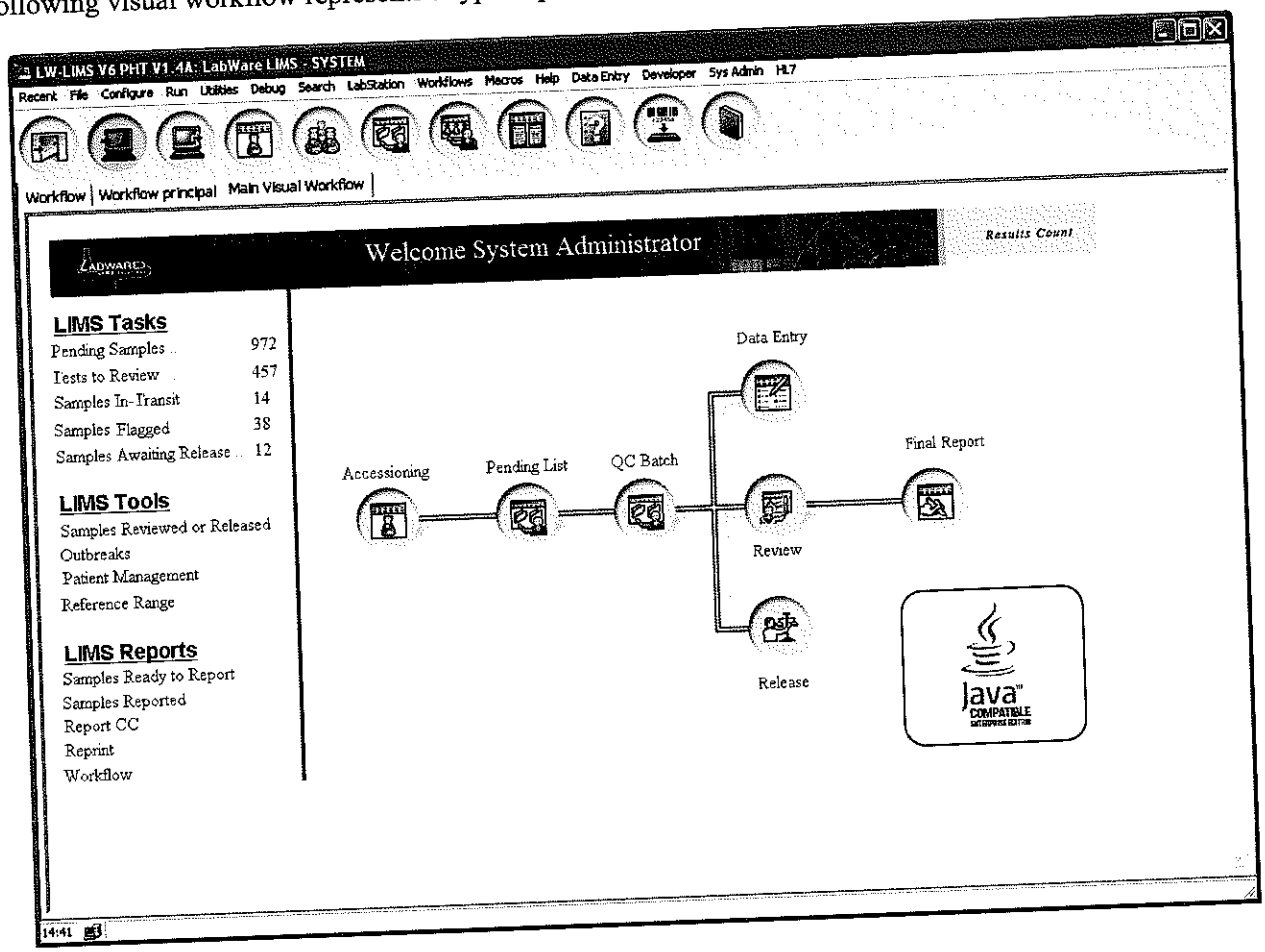
User accounts are managed by the LabWare EDSS application and stored in a LabWare EDSS table. The user ID is the primary key for this table and, therefore, cannot be an email address.

1.3.5.1 System must guide the user through the desired process by suggesting next steps.

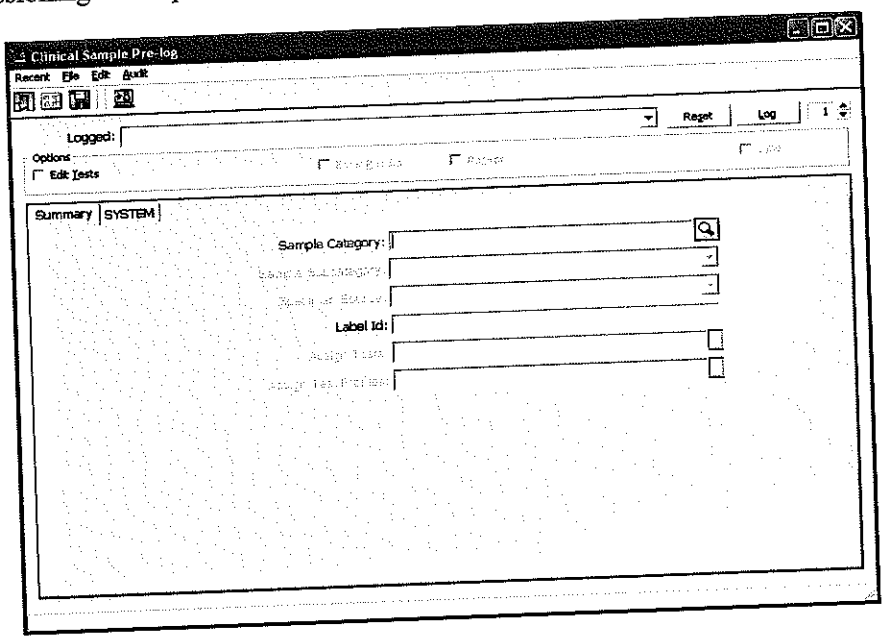
LabWare accomplished the equivalent functionality through a feature called visual workflows. A visual workflow is a graphical navigation tool depicting a user's desired process (workflow). The visual workflow is a series of web pages designed on a customer by customer basis. Defined hot spots on the visual workflow launch LabWare EDSS functionality.

Below are examples of visual workflows that have been used for product demonstrations:

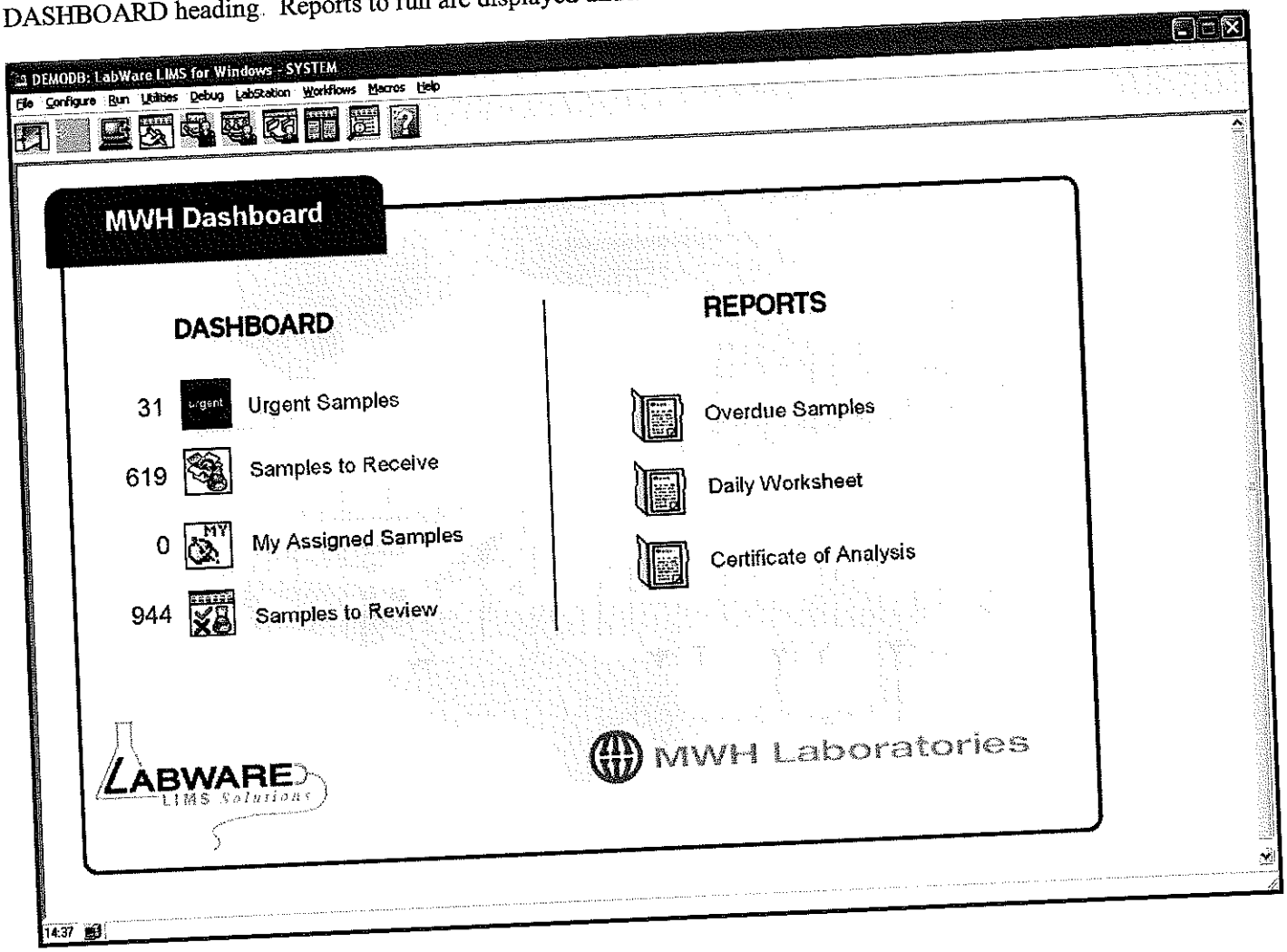
The following visual workflow represents a typical public health specimen workflow.



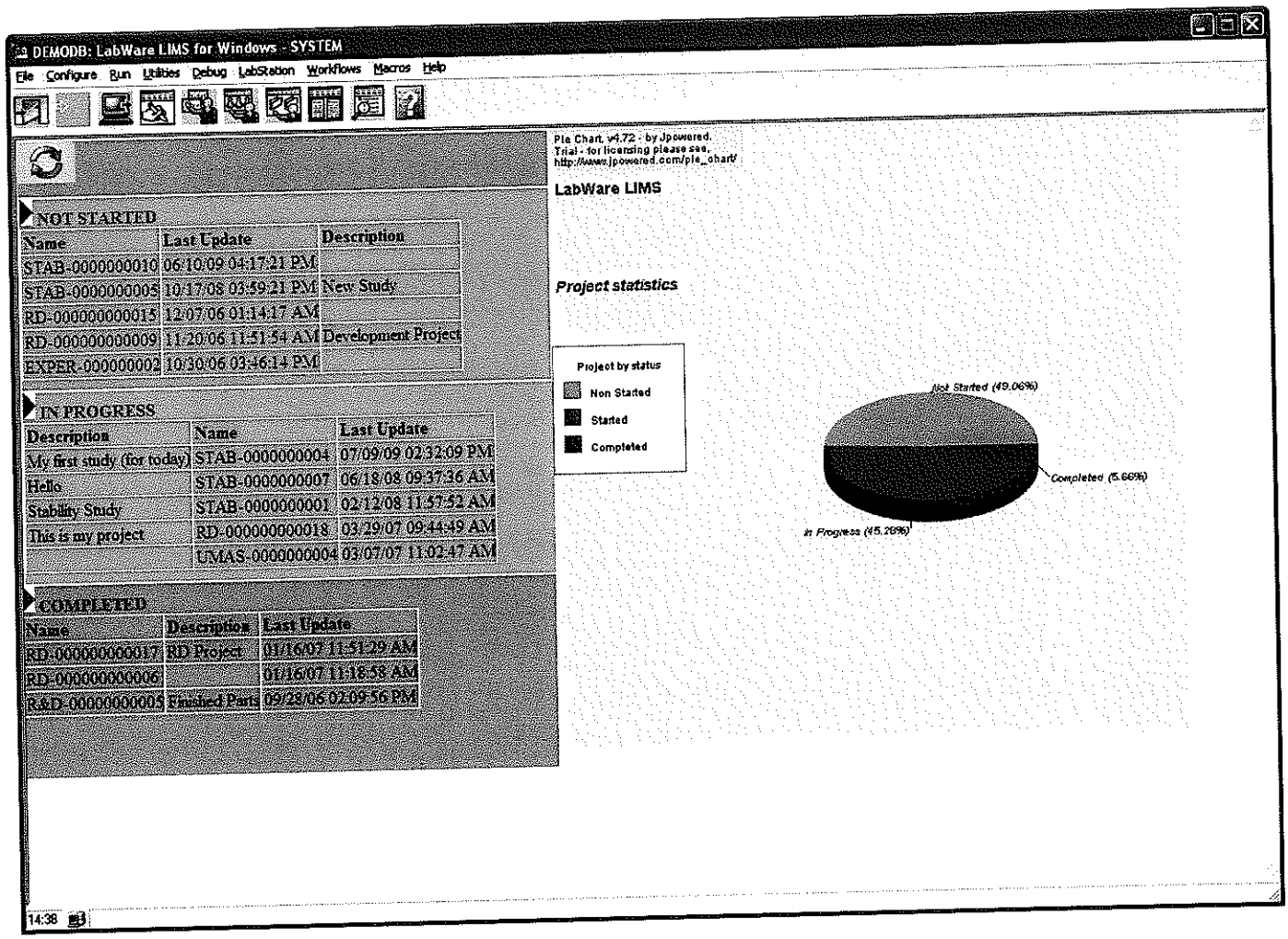
Clicking on the Accessioning bit map launches the LabWare EDSS sample login window.



The following visual workflow mimics a dashboard. Total counts of various sample statuses are displayed under the DASHBOARD heading. Reports to run are displayed under the REPORTS heading.



The following visual workflow displays a list of projects by status (not started, in progress, complete). The same data is rendered in a pie chart on the right side of the visual workflow.



1.3.5.17 System must be based on a visual model manager for easy configuration changes without source code changes.

LabWare EDSS configuration is mainly based on pre-populating static tables (facilities, practitioners, LONIC, SNOMED, test definition, organisms, templates, etc.). Populating these tables is typically done as part of the initial implementation. The DSDC EDSS Administrator will be trained on configuration and will be responsible for maintaining static data.

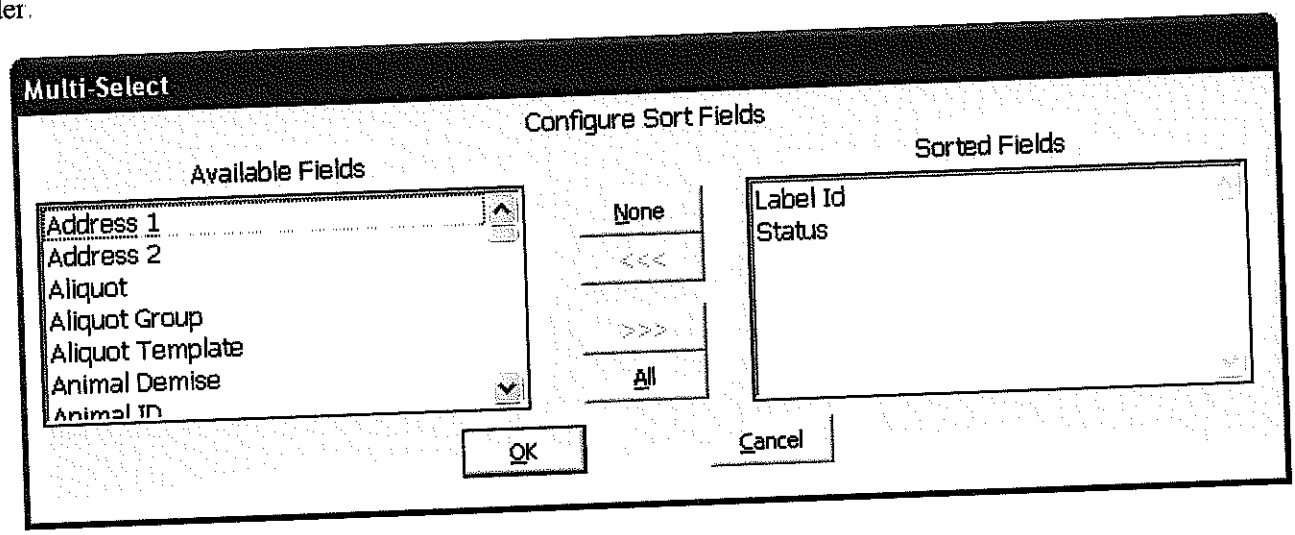
1.3.6.5.5 System must allow any list presented to the user to be sorted in ascending or descending order by any displayed field by clicking the column header.

One of the most commonly used features within LabWare EDSS is called Folder Manager. Folders are a list of specimens and associated test/results. Lists are created using a pre-defined query. End users can generate a list one of two ways:

1. The end user opens a particular folder, the pre-defined query is automatically executed and the specimen list is displayed.

2. The end user opens a particular folder, the user is prompted for a series of selection criteria, the query is executed, and the specimen list is displayed.

Sorting the list is accomplished by selecting a sort criteria menu option. The user selects what specimen fields are used to perform the sort. The list of specimens is sorted according to the selected fields. Below is a screen capture of the sort field window. The Label Id and the specimen status are used to determine the order of specimens in the folder.

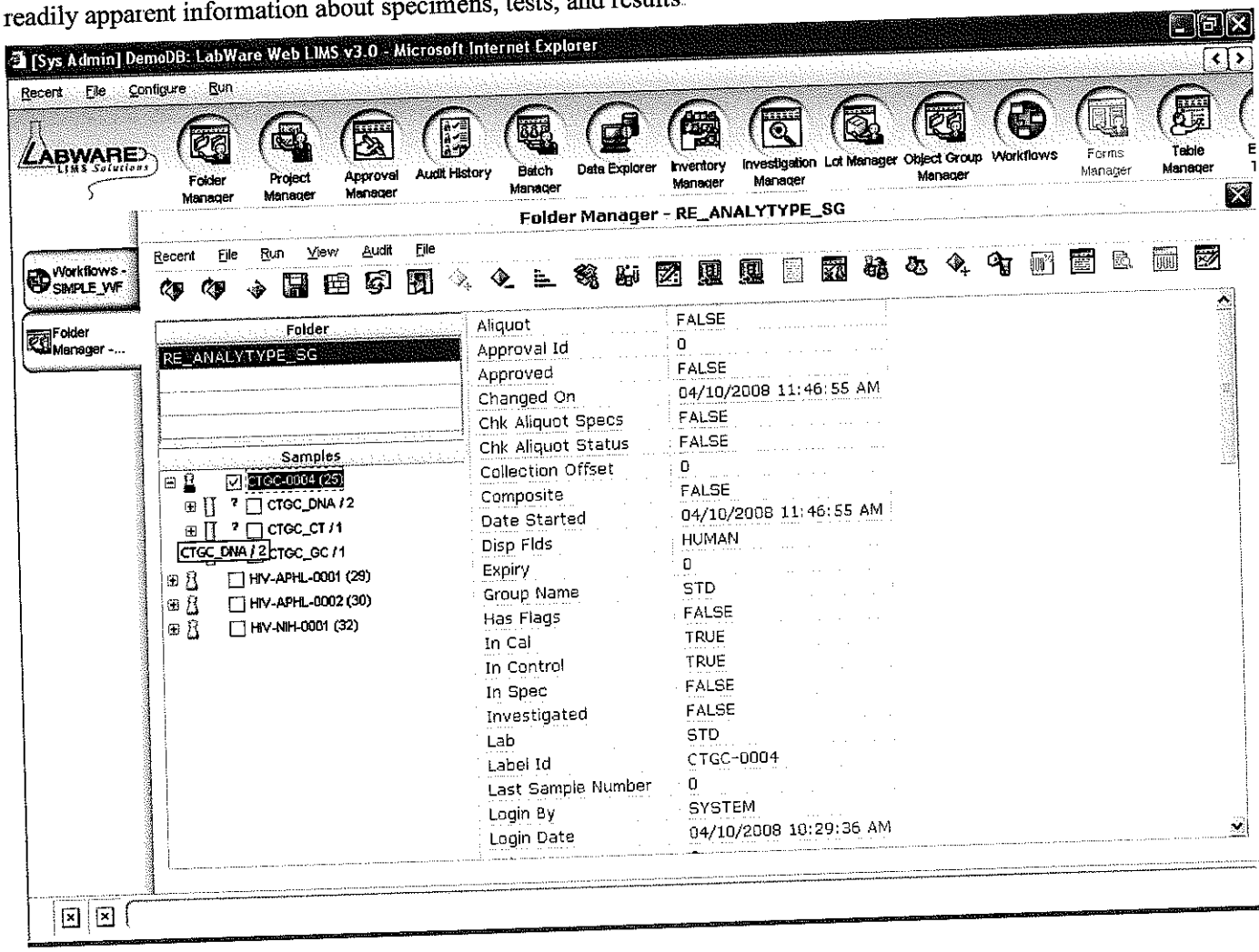


Below is a brief overview of Folder Manager.

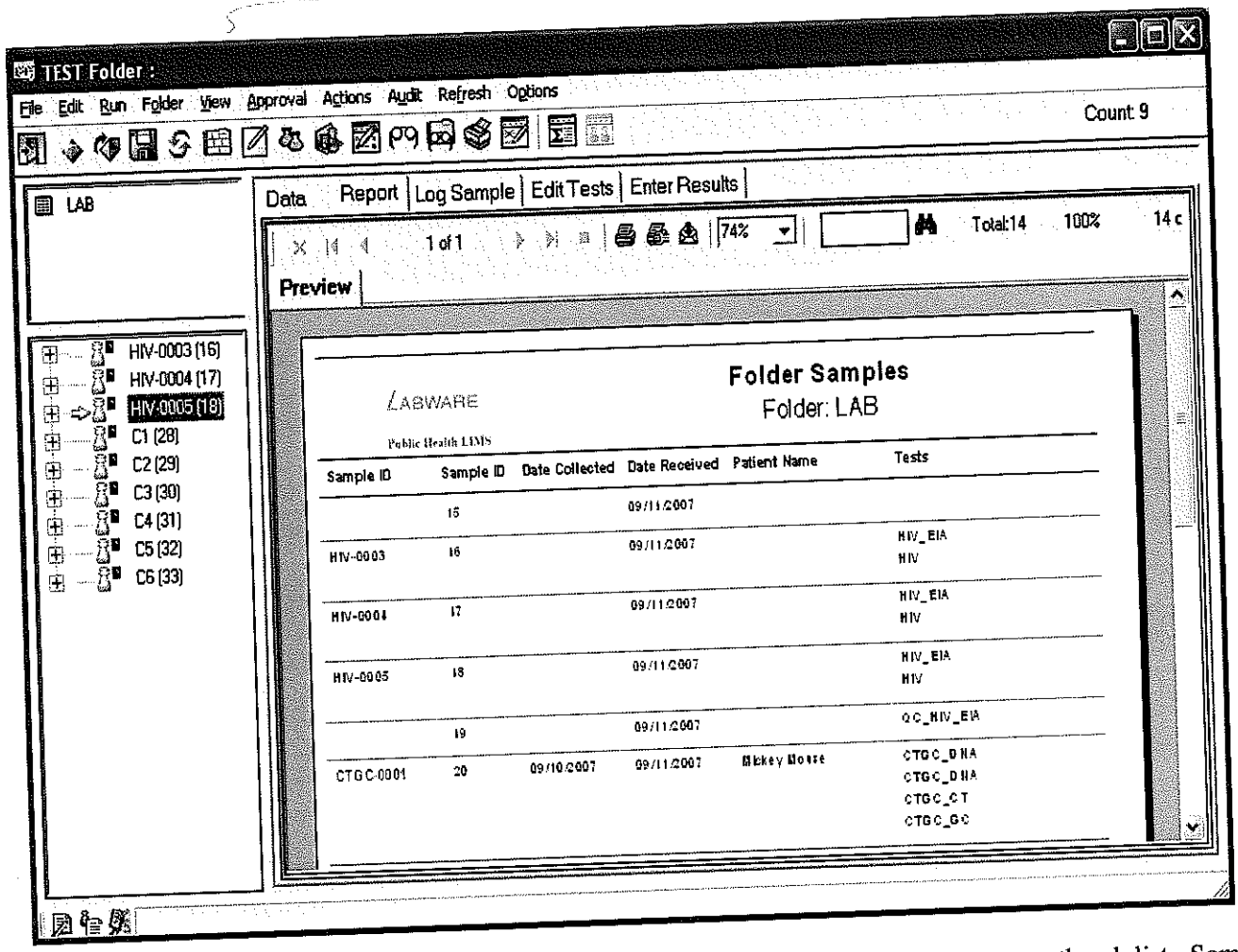
Folder Manager

Folder Manager presents a convenient way to work with multiple samples and tests. Folders are populated based on user-defined queries that allow selection of samples and tests based on any information (location, status, date range, analysis, etc.).

Folders enhance the view of samples, their assigned tests, and results. Visual cues such as icons and colors provide readily apparent information about specimens, tests, and results.



The classic view, as in the screen above, shows a familiar tree structure in the left-hand pane and tabular information relating to the selected sample/specimen, test, or result in the right-hand pane. LabWare EDSS provides an alternative view selectable by the user that toggles the right-hand pane view to a report format, either based on the chosen object or on all the samples/specimens in the folder, thus allowing the user full flexibility in what information is presented. Below is a folder with the sample summary report displayed in the right pane.



Folders play a large part in the workflow where they can be used, for example, to generate an outbreak list. Some of the major functions that are performed using folders include sample review/release, sample received, etc.

A folder can be refreshed at any time (and the selection criteria will be reapplied) or the folder can be "rebuilt" (which allows the user to choose new selection criteria). These events may be configured to happen automatically at a user-defined interval.

The creation of folders is configurable. A folder with its particular set of rules for displaying samples/specimens, test, results takes only minutes to setup. The folder manager window is out of the box functionality. All that is being configured is a query to determine the content of the particular folder.

The **File** menu on the Folder Manager interface provides the user with the following functions.

Open	Open folder
New	Create folder
New Ad-hoc	Create ad-hoc folder
Delete	Delete folder
Rebuild	Rebuild query

Refresh	Refresh query
Print	Print sample or test
Print All	Print content of folder
Save	Save content of folder
Save As	Save to a new folder
Exit	Exit Folder Manager

The **Edit** menu on the Folder Manager interface provides the user with the following functions.

Note	Add note to selected item
Add External Link	Add file to selected item
Delete Item	Delete sample or test from folder
Sort Criteria	Sort content of folder
Copy Test	Copy a selected test
Paste Test	Paste the previously select test

The **Run** menu and the **Folder** menu on the Folder Manager interface provide the user with the following functions.

Edit Tests	Edit test under a sample
Assign User	Assign a user to item
Print Sample Labels	Print sample labels
Cancel	Cancel an item
Release	Release a test
Un-Release	Un-release a test
Enter Results	Enter result for a given test
Review	Review tests

1.3.6.8.2 System must provide integrated, Web-based geographic information system (GIS) data visualization/mapping functionality to the end user.

One option is for LabWare to provide GIS data visualization/mapping using the existing State GIS product. An interface between LabWare LIMS and the existing GIS will be developed as part of this proposal.

Further investigation is required to determine the level of integration with the GIS. This may have an impact on the overall price submitted by LabWare.

1.3.9.2 The successful vendor must demonstrate the ability to import legacy NETSS data into the system.

1.3.9.3 The vendor must provide a mechanism to import and map existing WVEDSS data into the new system.

There are two approaches to data migration:

1. Re-created the existing table structure in the LabWare database, and copy the data into the new tables. Use the reporting tools to access the LabWare EDSS data, and the data from the old system. This approach will require a large emphasis be placed on the reports.

2. Migrate the existing data into the LabWare EDSS table structure. The data will likely have to be massaged before being transferred into the LabWare EDSS tables. It will be DSDC's responsibility to massage the data before LabWare can import it into the database. This approach will require a migration routine be written.

2. OTHER VENDOR REQUIREMENTS

1.4.1 The vendor must provide detailed evidence of other related experience with PHIN-compliant electronic disease surveillance/ELR systems and additional capabilities in providing the required services. The vendor must provide details of the background of the company/organization, the size and location of the company/organization, and the experience, capabilities, and resources of the company/organization which qualify and enable them to complete the project.

LabWare has been competing in the public health market for approximately 5 years. Our main focus, thus far, has been to provide LIMS solutions for the lab. It would seem to be a natural transition for LabWare to provide an Electronic Disease Surveillance and Electronic Laboratory Reporting (ELR) solutions. The line between Epidemiology and the lab varies from State to State. LabWare believes that much of the functionality required by DSDC has already been configured through previous LabWare LIMS implementations. For example, LabWare has built a patient management module (refer to section 5.1), contact management module (refer to section 5.2), a robust Final Report engine (refer to section 5.3), and HL7 integration (refer to section 5.4).

The following is a list of LabWare public health customers with a list of relevant functionality.

- State of Delaware Public Health Lab (Environmental & Clinical)
  - Morbidity report (by Agency, Agency Group, User's Agency)
  - AFB, ARBO, Flu, HIV, Rabies, Summary and statistics report
  - Micro Monthly, Micro monthly isolates
  - STD summary by age group and agency
  - Syphilis TPPA report
  - CDC Extract file
  - Clinics have online access to Final Report

- State of Florida Public Health Lab (Clinical)
  - Orders and results are transmitted via HL7
  - Configured HL7 interface for CDC LRN-BT
  - HL7 Pan Flu ELO and ELR interface between Florida and Texas public health labs
  - Using 2D barcode technology
  - Using Final Report engine

- State of New Mexico (Environmental, & Clinical)
  - Using Final Report engine

- State of Texas Public Health Lab (Clinical)
  - HL7 Pan Flu ELO and ELR interface between Florida and Texas public health labs
  - Accumulating Bioterrorism results from 11 LRN labs throughout the State
  - Using Final Report engine

- State of Utah Public Health Lab (Environmental, Clinical, & Newborn Screening)
  - HL7 bidirectional interface to ARUP reference lab for Newborn Screening specimens

- Province of Manitoba (Clinical, Newborn Screening)
  - Capturing all practitioner verbal communications using the Contact Manager module
  - Using Final Report engine

- Province of Ontario (Clinical)
  - Using Final Report engine

- Province of Saskatchewan (Environmental, Clinical, Newborn Screening)
  - Using Final Report engine

- Public Health Agency of Canada (Equivalent to the CDC)
- USDA Food Safety
- USDA Animal and Plant Health Inspection service (APHIS)

The State of Delaware has shared their success to the public health community through an article in the APHL Lab Matters magazine. Refer to section 5.6 Delaware Article.

LabWare Inc., a global supplier of Laboratory Information Management Systems (LIMS) was founded in 1987 and entered the LIMS market in 1994. With most of our growth taking place in the last 7 years, LabWare has become the largest supplier of LIMS. LabWare had sales of $70M in 2007, and $84M in 2008. Over 400 companies have purchased LabWare LIMS over the last five years.

The LabWare head office is in Wilmington, Delaware, USA. The LabWare software development team, accounting, management, and support reside from this location.

The success and strength of LabWare has generated some very impressive metrics:

- LabWare is privately owned, has zero debt, and is profitable.
- Over 1000 installations with over 20,000 concurrent user licenses deployed globally. All are using the same product. Over 500 people attended user meetings in 2008.
- LabWare's dedicated team of over 300 professionals is all focused on developing, implementing and supporting one LIMS product. Eliminating the duplication of development effort that a multi product vendor experiences

Key differentiators for LabWare are as follows:

- As a general rule LabWare is not a sales and marketing focused company. LabWare strategy is simple; successful implementations will in turn generate growth. We rely on our customer base to disseminate their success to others.
- LabWare has been capable of adding current technology without abandoning its existing customer base. LabWare's strategy is one of rendering new technology into the existing product as opposed to rewriting the product from scratch. A good example is our web solution. We've been able to add web capability to LabWare EDSS without causing our existing customer base any re-configuration or complex migration. Refer to section 5.5.

- LabWare stores the entire configuration in the database. The benefit of this approach is to simplify upgrades. A typical major version upgrade can take as little as one day of effort to install.

- LabWare EDSS is a customer configurable solution. A key factor to long-term success with EDSS is by having an organization that is self reliant and knowledgeable at keeping their EDSS up to date with respect to their changing business environment. Our entire business model is to develop superior yet customer-friendly solutions and to teach our customers how they can configure those solutions effectively without requiring an unnecessary reliance on LabWare services.

- LabWare has a proven solution for large multi-site implementations. Deploying a solution in a large multi-site environment should not be taken for granted. Products perform quite differently when put under large volumes. Examples of customers with large deployments using a single data base are as follows:

    - Province of Ontario
      250 concurrent users, 12 sites

    - Province of Saskatchewan
      125 concurrent users, 1 site

    - State of Florida
      115 concurrent users, 5 sites

    - Apotex Pharmaceutical
      300 concurrent users, 4 sites

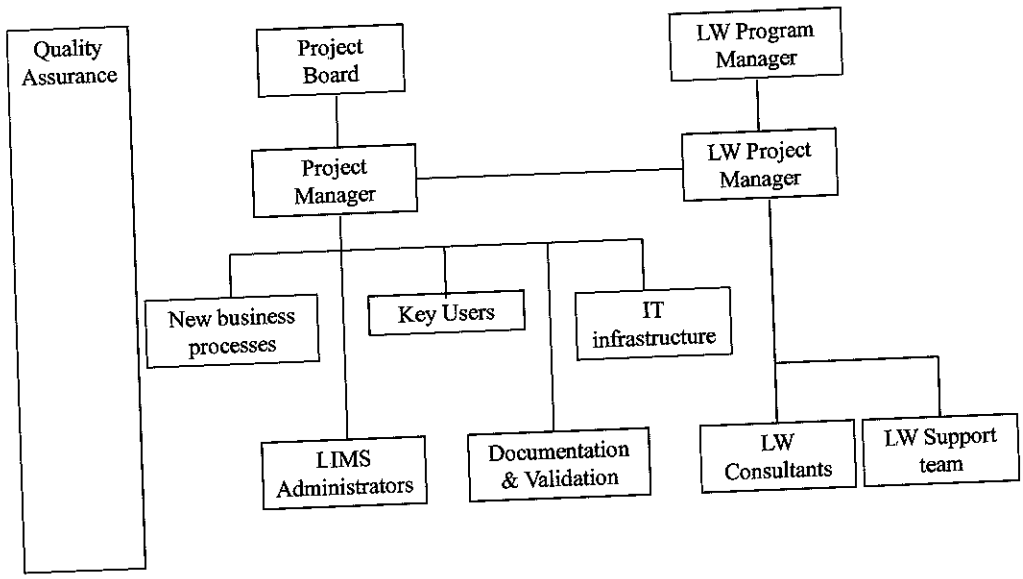
    - Silliker
      250 concurrent users, >20 sites

    - Pfizer corporation
      450 concurrent users, > 7 sites

1.4.2 The vendor must provide a functional organizational chart indicating the proposed project structure. The vendor should provide job descriptions and resumes for the key project staff and any other staff who will work on any part of this contract, specifying experience with the vendor and relevant education, experience, and training. The vendor should describe the process if any key project staff is replaced.

2.1 Project Organization

The proposed project organization and resource requirements are defined as follows. Roles and Responsibilities for each position are defined below:



Role	Provided by	Responsibility	%
Project Board	DSDC and LabWare	Has the ultimate responsibility for the successful outcome of the project. Board members have limited time, so the day to day responsibility for managing the project is delegated to the DSDC project manager. The board retains responsibility for approving the business case, securing the agreed resources required to undertake the project, and approving all Change Management requests. The board creates the environment required for the project to succeed and serves as a point of escalation for prompt and decisive issue resolution. The DSDC project manager, LabWare project manager, LabWare program manager and business sponsor are required members of the Project Board. The board meets monthly. The agenda is prepared jointly by both project managers, with an emphasis towards risk identification and issue escalation.	<5%
DSDC Project Manager	DSDC	Manages the scope of the project to ensure it is delivered on time and on budget. Plays a key role in simplifying and standardizing business processes and getting the business to benefit from using a more "standard package". Raises exceptions to the board and manages the project controls, deliverables and risks. The DSDC	not less than 50%

Role	Provided by	Responsibility	%
		project manager should be empowered to make challenging decisions when needed, because this is often the key to on-budget, on-time delivery. Plans daily work activities for DSDC team resources. Works with Project Board to ensure project is adequately staffed and roadblocks are removed. Coordinates schedules with managers and DSDC resources to ensure availability to the consultants. Works closely with the LabWare project manager to ensure scope remains within agreed upon boundaries.	
LabWare Project Manager	LabWare	Responsible for all LabWare deliverables and provides general leadership on EDSS issues and advice to DSDC. o A certified LabWare consultant with proven experience of leading projects o Works alongside the DSDC project manager and helps prepares the project schedule. o Organizes and schedules activities for other LabWare consultants o Responsible for risk identification and escalation to Project Board. o Activity is usually intense at the start of the project and near major milestones. o may also serve as a technical consultant	approx. 30%
EDSS Administrator	DSDC	As a critical part member of the development team, the EDSS administrator is responsible for supporting the configuration, enhancing the system and supporting users when the EDSS has gone live. As such, the importance of this role should not be underestimated. The EDSS administrator must have a central role during the implementation process, coordinating configuration changes, user reviews, testing and the specific activities allocated to her/him in the project plan. Personnel that undertake this role will need to successfully complete the EDSS administrator exam. This person needs to be very enthusiastic about making EDSS work and should be knowledgeable about EPI and IT. This role plays an integral part in collecting, verifying, entering and maintaining the necessary static data for the system, and conducting end-user training.	100%
Deputy EDSS Administrator	DSDC	Similar responsibilities to the EDSS administrator. Serves as a back-up in the absence of the EDSS administrator. Also takes on much of the support responsibilities of early roll outs while the EDSS Administrator is working with the development team on the next section to be implemented.	not less than 50%

Role	Provided by	Responsibility	%
Business Analyst	DSDC	Business Analyst – Responsible for the creation of the workflows and collecting requirements that will serve as the basis for pilot development. Plays a key roll in harmonizing requirements across sections and across locations and incorporating business changes and decisions into the local procedures and/or the user guides. Along with the DSDC project manager, instrumental in keeping project focused on base needs and managing scope.	25-50%
Key Users	DSDC	These are individuals who work in one or more of the areas that will use EDSS and who are very knowledgeable about those areas. • Key users have a good understanding of the business requirements and are empowered to make decisions • provide detailed requirements to LabWare for their section; work with other key users and the DSDC project manager to harmonize on requirements • must attend Key User Training • mandatory participation in requirements discussions, configuration reviews and acceptance testing of their area of expertise • usually assist the EDSS Administrator with static data collection, clean-up, entry, validation and maintenance	numerous – not less than 20% while their section is active
Documentation & Testing	DSDC	This role is responsible for creating customer specific documentation and testing activities (test scripts, SOP's and SOP revisions, etc.) This activity may be completed by the key users or the EDSS Administrator in addition to other assignments.	25 – 50%
IT infrastructure	DSDC	Assistance from Information Technology staff is needed at various stages of the project. Internal IT staff will also have ownership of processes and documentation for disaster recovery, archiving, etc. Typical roles include the following: • Database Administrator (DBA) – Responsible for setting up the database, tuning it, and maintaining it. Most projects do not warrant a full-time DBA. However, getting timely access to a part-time DBA is very important. LabWare develops the initial pilot system in Microsoft Access, in order to allow the core team members to add tables and columns themselves. The database can be moved to a different database product (using tools provided by LabWare) once the data model stabilizes. • Server Administrator – Responsible for setting up the various computers that are needed for the implementation and for back-ups of all environments, including Web services. In larger organizations, this role may be filled with multiple individuals, each one specializing in a certain area, such as	As required

Role	Provided by	Responsibility	%
		application servers, file servers, terminal servers, and desktops. • Network Administrator – Provides assistance in determining whether DSDC's network can support the chosen implementation architecture. • Other – to complete local desktop installations and printing support • Support for multiple locations must also be available.	
LabWare Consultant	LabWare	Responsible for architecting the configuration, ensuring the overall system design satisfies the requirements, and mentoring the EDSS administrator and key users. It's a technical "hands on role". All consultants will be certified LabWare consultants.	50-200% depending on project stage.
LabWare Support	LabWare Support	The LabWare support team provides the support services as defined in the maintenance agreement.	N/A
LabWare Program Manager	LabWare	LabWare program manager is responsible for all services delivered by LabWare on the project. The program manager has responsibility for the Public Health Template and all public health projects within LabWare.	<10%
LabWare Services Manager	LabWare	The LabWare services manager is responsible for the assignment of LabWare consultants.	<5%

1.4.3 The vendor must provide at least three (3) vendor references from similar projects within the past three (3) years that include a description of the work performed for each reference.

(1) Firm/Government Agency (Name):	Contact Person Name: **Elizabeth Delamater**
State of Texas Department of State Health Services	Address: **1111 N Loop, Austin, TX** Phone: **512 634-6734** E-mail Address: **elizabeth.delamater@dshs.state.tx.us**
Types of Supplies/Services Provided and Dates Provided/Contracted: **60 concurrent users, 11 sites, 1 database** **There are 3 state labs using LabWare LIMS for clinical and 8 LRNs using LabWare LIMS for BT. Project started in August 2007 and is ongoing with an estimated completion date of September 2008. They have been in production for 1 year.**	

(2) Firm/Government Agency (Name): **State of Florida Department of Health**	Contact Person Name: **Susanne Crowe** Address: **P. O. Box 210** **Jacksonville, FL 32231-0042** Phone: **904-791-1550** E-mail Address: **susanne_crowe@doh.state.fl.us**
Types of Supplies/Services Provided and Dates Provided/Contracted: **150 concurrent users, 5 sites, 1 database** **All sites are clinical. Project started in August 2006 and completed in August of 2007**	
(3) Firm/Government Agency (Name): **State of Delaware Division of Public Health**	Contact Person Name: **Dr. Jane Getchell** Address: **1901 North DuPont Highway** **New Castle, DE 19720** Phone: **(302) 223-1520** E-mail Address: **jane.getchell@state.de.us**
Types of Supplies/Services Provided and Dates Provided/Contracted: **50 concurrent users, 1 site, 1 database** **Environmental & clinical. Project started in October 2003 and completed in June 2006**	

1.4.4 The vendor must provide a proposed work plan, discussing its approach to providing the products and services required to fulfill the terms of this RFQ. The work plan must demonstrate a clear grasp of the overall project and services to be provided with specific action steps that will guarantee the successful provision/completion of the project.

1.4.5 The vendor must use a formal and documented project management method to develop the work plan that includes the tasks, completion criteria for the tasks and a comprehensive project plan.

1.4.6 The project management method must provide the State with a means of determining if the statement of work is being accomplished as scheduled with acceptable deliverables.

1.4.7 The vendor must provide a schedule of proposed project milestones, tasks and deliverables to support each phase of the project.

Phase I: Software acquisition and if necessary tweaking of current hardware/network/software.

Phase II: Vendor on-site to work with state staff to system installed and do state personnel train the trainer (administration, configuration and usage)

Phase III: User acceptance testing done by Infectious Disease and Epidemiology Program (IDEP) staff, regional epidemiologists, Information

Systems Manager II (ISM II) and others. After system usage and any necessary minor system adjustments are done, signoff occurs and projects transitions into maintenance.

1.4.8 The work plan must list all tasks needed to accomplish the statement of work. The tasks to be included are:

Project management
Project status review
Change management
Application development
Programming and unit testing
System testing
User acceptance testing
Technical documentation
Technical training and skills transfer
Transition plan
Data conversion
Data exchanges
Capacity planning
Change control process
Service level agreement methodology and review process
On-going support during the warranty period
System issues reporting and resolution process
Risk Management

LabWare Philosophy

LabWare strongly believes that it is in DSDC's best interest to be able to support their implementation themselves. A key factor to long-term success is by having an organization that is self reliant and knowledgeable at keeping their system up to date with respect to their changing business environment. Our entire business model is to develop superior yet customer-friendly solutions and to teach our customers how they can use those solutions effectively without requiring an unnecessary reliance on LabWare.

Below are three reasons why LabWare has been successful at delivery and is confident this project can be delivered within the specified timeframes:

Out of the Box Functionality

It has been the experience of LabWare's staff that the biggest reason why projects fail is large amounts of site-specific customization. We've seen it time and again where the cost of customization and testing become excessive and customers give up on their project. This problem is prevalent in the software market. Too often the gap between the vendor's out-of-the-box functionality and what is required is too large to overcome.

LabWare has solved this problem by eliminating site-specific customization or site-specific changes to source code. Gaps in functionality are filled by LabWare developers, incorporated into the base product, and added to LabWare EDSS at no cost to DSDC. In fact, LabWare is so committed to this philosophy that all enhancements to LabWare EDSS have to be first identified through a customer or require customer sponsorship.

Developing out of the box Public Health functionality has already been done through existing Public Health customers. The State of Florida and the State of Texas, in particular, contributed substantially to the Public Health solution.

Public Health Template

LabWare provides a pre-configured template for Public Health. Most of the required functionality already exist in the Public Health Template. The public health template is the basis for the project implementation.

Implementation Methodology

A commercial, packaged based approach will be used. Standard LabWare functionality will be used as much as possible, with changes requiring justification based on business value. Our implementation consulting effort is focused on configuration. Configuration is defined as follows:

- Populating the static tables where differences exist between the Public Health Template and DSDC requirements. Some of the relevant tables include analysis, antibiotics, CPT codes, patient template, sample login template, SNOMED codes, specimen source, and users.
- Crystal Reports, interface to third party applications, configuring the gap defined in the functional spec.

Methodology

Based on work with many major international customers, LabWare has developed a remarkably successful and proven solution that we call Goal Oriented LIMS Delivery (GOLD). GOLD takes the best ideas from the IT industry and applies them to LabWare products. It embraces effective project management techniques that fully utilize an evolutionary, participatory approach while maintaining tight time scales and regulatory compliance. Our approach is based on high productivity tools, clear objectives, and small, very skilled teams. GOLD has been developed using the experience of hundreds of successful projects.

The GOLD methodology consists of four key stages, which are summarized below.

Pre-project Activities:

In order to effectively initiate a project it is recommended DSDC meet the following prerequisites before a project start.

- Prepare workflows of the "as-is" process for all sections and sites.
- Staff the project with named participants as defined in the Project Organization section. Particularly, a project manager, a EDSS Administrator, an overall business leader, key users and a Project Board
- Establish the development environment with secure, remote access for LabWare. This environment will host the development and dev-test instances. LabWare will install the application once the project has started.
- Complete sufficient architectural planning such that a test and production environment may be purchased, installed, tested and stabilized by DSDC within 12 weeks of project start

LabWare will also conduct a pre-project Gap Analysis. The purpose of this Gap Analysis is to assess the general gap between LabWare's public health template and the general workflows. The analysis includes a demonstration of the template to the project management team. The gap also provides an opportunity to collect additional details about the requirements and the requested system interfaces.

Stage 1 – Project Initiation Stage

The key objective of the Project Initiation stage is to establish the complete project team, and to ensure that all team members understand the scope of work and speak the same language. Two key knowledge transfer activities occur: (1) DSDC's EDSS Administrator and back-up are trained in LabWare's product by completing the EDSS Administration 1 training course. (2) LabWare's team members gain a clear understanding of DSDC's current work processes through review of customer-provided workflows and high-level workflow review meetings.

The major deliverables for the Project Initiation Stage include:

- Project Kick-off – The primary purpose of the meeting is to ensure that all key participants and stakeholders have the same common understanding about the project and its scope. Having all applicable parties attend the meeting and hear the same message is the best way to ensure this common understanding, even though many of the participants may already be familiar with parts of the content being discussed.
- Administrator Training – All of DSDC's team members who will participate in configuration activities attend our EDSS Administration I training class. Minimally, this includes the EDSS Administrator, and back-up administrator (see Project Organization section). This is an intensive, weeklong class that covers the essentials of how information is processed by EDSS. It also covers the configuration activities, including administration of business rules, static data, and reports. The on-site class offered in this proposal is limited to eight attendees. A second course may be offered on-site.
- Workflow Reviews – LabWare uses a two-step approach to gain an understanding of DSDC's workflows. The first step is a joint review of DSDC provided "as-is" workflows with key staff members from each functional area. The major workflows are discussed to provide a common understand and assess the project workload as input into project planning. The second step, completed in stage 2 of the process, consists of more detailed reviews of each area.
- Development Environment – LabWare consultants install LabWare EDSS in the development environment previously provided by DSDC. The database supplied with the product is a Microsoft Access database. Initial development work will be completed in Access, because of the ease with which tables and columns can be added to the data model. Tools for moving the database to a different platform are supplied with the product.
- Testing Plan and Documentation Requirements: Testing and acceptance is a critical part of the project and must be planned and considered from the beginning. Testing and acceptance is the responsibility of DSDC. LabWare offers a draft acceptance test plan which DSDC may choose to use as a starting point.
- System Architecture Plan (a.k.a. Environment Plan) – design, specifications and purchase orders for the testing and production environments are documented and executed by DSDC. LabWare consultants provide input, but as LabWare EDSS imposes minimal restrictions on architecture, DSDC is responsible for the definition and build of the environments.
- Project Schedule – The LabWare project manager reviews all information gathered during this stage and prepares a comprehensive Project Schedule for the remainder of the project. Project schedule emphasizes the first set of sections to be addressed.

Stage 2 – Pilot Stage (repeated for each set of sections to be implemented)

Note - Each set of areas to be launched (i.e., each phase) requires the execution of Stage 2 through Stage 4. The first section is typically the longest to implement. Much of what was identified and configured during the implementation of the first section will be reused by other labs. Therefore, subsequent sections will require shorter implementations.

Each implementation phase starts with a review of process workflows and example documents, reports, forms, etc. provided by DSDC. Interviews are conducted by LabWare certified implementation consultant(s) with area experts to clarify and understand the business processes and workflows. The standard LabWare EDSS product functionality and the public health template are demonstrated and reviewed with the relevant experts to communicate how the public health template has addressed requirements common at other states/provinces. A gap analysis is conducted. The gap analysis identifies the discrepancies between existing LabWare functionality and desired functionality as determined during these discussions.

Next, LabWare documents the gaps and assesses the impact of potential changes. The determination of what activities can be undertaken without jeopardizing the schedule or budget is a collaborative effort between LabWare and DSDC. Those functions that withstand the gap impact analysis go into a Functional Specification that is reviewed and approved by the project team prior to starting configuration. This specification becomes the basis for system development and acceptance during the phase in question. Subsequent changes to approved specifications are managed via the Change Management process.

The public health template configuration is modified to meet the needs of DSDC within the boundaries of the functional specification and a pilot system is built in a development environment. Gaps may be filled by a change to core software, a change to the public health template, or a local change specific to this customer only. It is important to note that the closer the system remains to the template, the easier it will be for DSDC personnel to maintain, evolve, and share information about the system with their colleagues in other states and provinces using LabWare. Close adherence to the template also allows the DSDC EDSS administrator to take advantage of future enhancements to the template. Reducing the amount of site-specific customizations will make it easier for DSDC to support the system, and will reduce the risk of project delays. Therefore, the LabWare proposal assumes the public health template is the basis for system implementation and LabWare consultants will continually emphasize the importance of sticking to core system functionality and pre-configured objects.

Configuration of the pilot takes place in an iterative manner. Configurations are reviewed with the key users. Involvement of key individuals from DSDC, those knowledgeable in the current process and those willing and able to implement improvements to the process, is critical to project success. The flexibility of the LabWare EDSS product means the team will be presented with hundreds of decisions throughout the project. LabWare will offer recommendations based on our experience in public health, but timely decisions will be required from DSDC. LabWare will look to the DSDC project manager to facilitate and expedite the decision making process.

During the configuration process, key users and the EDSS administrator will be using the development system on a daily basis. This is critical to the mentoring process. They will be evaluating the configuration for proper function as well as assessing whether they believe the requirements are met and if the system will eventually be accepted by the user community. All the while, the key users and EDSS administrator are improving their skills and knowledge of the system. Over time, the team members start to feel comfortable with the tools and are ready to take on some of the configuration tasks (data loading). The purpose of performing configuration is to become proficient with the product. LabWare still has responsibility for delivering the functional solution.

Based on feedback from the key users and wider user audiences, the pilot is established as an acceptable design. At this point, the pilot is fleshed out to incorporate additional analyses, sample types, reference ranges, interfaces, etc. until a full system is available. The EDSS administrator and key users will contribute to this effort by collecting, entering and verifying static data (submitter information, etc.). The key users continue to challenge and evaluate the system against the functional specifications previously recorded. Eventually, the full system for the section under

development comes together and is ready for acceptance testing. The speed with which the configuration is completed is a function of the complexity of the section, adherence to the public health template, and the ability for the EDSS Administrator and key users to absorb and apply their training.

Key deliverables for the Pilot Stage include:

- Requirements Refinement:
    - Workflow Reviews (part 2)–The second step of workflow reviews consists of one-on-one sessions in each area. This allows the team members to understand the various work processes in more detail and review the forms, and other materials that are being used.
    - Data Collection – DSDC submits more detailed requirements for areas not fully explained in the RFP (for example, report outlines, mark-ups of existing forms, etc.). Additionally, DSDC gleans static data from existing databases for eventual entry into EDSS (for example, submitter information, reference ranges for specific tests, list of analyses, etc.). This step includes clean-up and harmonization across various databases. These activities are coordinated by DSDC's project manager, and are typically executed by the business experts and the EDSS Admin.
- Review Existing LabWare EDSS Functionality and the Public Health Template – Once the LabWare consultants have an understanding of the current processes, the public health template is reviewed with key users and the decision-making body. All gap requirements then undergo an impact analysis to determine if they will be in that phase's requirements specification.
    - Gap Analysis – The LabWare team will identify the gaps between the template and DSDC's requirements. This isn't a formal deliverable, but a project tool to direct gap activities to the best source for resolution. Gaps in product functionality are escalated to the LabWare product development team for consideration as product changes. Gaps in standard configuration are escalated to the LabWare Public Health Program Manager for possible inclusion in the public health template. Remaining gaps are addressed by the LabWare consultants on the DSDC project. Acceptance of the template and minimizing the gaps will lead to a faster project completion, with the ability to leverage existing testing, training, user guides, etc.
    - Gap Impact Analysis – All gap requirements are assessed for their impact on budget and schedule. This isn't a formal deliverable, but a project tool to rate the gaps. As defined by DSDC, requirements will fall into one of three categories of importance: High, Medium, and Low. These levels will be taken into consideration when conducting each phase's gap impact analysis, where gap requirements are categorized by complexity: High, Medium, and Low. Sorting through the combinations of importance and complexity will result in the material for the Functional Specification and what will actually be undertaken during that phase.
    - Functional Requirements Specification – LabWare will author a Functional Requirements Specification. The functional specification defines those requirements necessary to fill the gaps in the gap impact analysis. The functional specification is approved by LabWare and DSDC and defines the basis for user acceptance. Once approved, changes fall under the realm of Project Change Management. Those key participants who will accept the system for this section are required approvers of the Functional Requirements Specification.
- Key User Training – Team members who will not configure but will provide testing, business insight and acceptance decisions attend our Public Health Key User Training, a 2.5 day class that focuses on system use within the public health arena, rather than detailed system configuration. The intent is to provide trainees with the means to navigate the system and to establish a common EDSS terminology. Key Users who will become trainers for this section or will be involved in user acceptance are required to attend. As a phased implementation is planned, this course will be offered two or three times throughout the duration of the project. Each on-site class offered in this proposal is limited to eight attendees. Additional courses may be offered on-site at standard rates.

- Iterative Configuration and Reviews – Particular attention is paid to items identified during the gap analysis. The team configures the system in an iterative manner, building on the previously reviewed configuration. Critical interfaces are established. Reports are defined and created. Key users and the EDSS administrator participate by evaluating the iterations and supplying feedback to the consultants. The EDSS administrator and key users load data as part of the mentoring process. The DSDC project manager ensures meetings are promptly scheduled and attended by key participants. Those key participants who will accept the system for this section are required attendees for configuration reviews and are required to attend key user training.

- Static Data – While the configuration is being completed, the loading of static data can begin. Static data encompasses items such as analyses, reference ranges, templates, supplier information, organisms, test profiles, etc... The EDSS administrator and key users collect static data, ensure the data is clean and matches the requirements, enter the data into EDSS, verify the data in EDSS, and maintain it. File transfers can also be used to import the data. Entering and managing the static data is an important learning opportunity for the EDSS Administrator and key users.

- Final Configuration Review – LabWare consultants and the EDSS administrator review the final configuration with those key participants who will accept the system for this section. The purpose of this review is to lock the configuration prior to investing in test scripts and documentation of the configuration. As reviewers have participated during previous reviews, there should be a good understanding of the system by this time. All user-acceptance approvers are required to attend.

- Testing and Production Environment: Before proceeding to the System Completion Stage, DSDC has installed and tested the necessary servers, network connections database, etc in both the test and production environments. When this is completed, LabWare consultants install LabWare EDSS in the test and production environments following the standard LabWare manual.

Stage 3 – System Completion Stage (repeated for each set of section to be implemented)

The purpose of this stage is to formalize the system and complete user acceptance.

User acceptance is completed in a testing environment. Provided the key users have been involved throughout the configuration and review process and are in a position to represent and make decisions, user acceptance should not produce any surprises and should require minimal documentation. LabWare will provide direction and test scripts used at other public health sites as examples. DSDC creates and executes the testing scripts.

The following items are completed during the System Completion stage.

- Move Objects to Testing Environment – LabWare delivers a set of files and step-by-step instructions to move configuration objects from development to formal testing, and later from testing to production. This set of files is called an Installation Package, and it ensures that what was reviewed in the final configuration review is moved to the test environment. LabWare consultants execute the package instructions to move the objects from development to testing.

- User Acceptance Test Scripts – DSDC is responsible for creation and execution of user acceptance test scripts. LabWare can provide example scripts upon request. The scope of test scripting is limited to documented requirements and the functional requirements specification. The testing focuses primarily on testing of the actual system configuration. The testing procedure and documentation depends on DSDC interpretation of applicable regulations.

    - Regression testing – once a set of test areas has been implemented (i.e., a Phase has been launched), subsequent development phases will cause the configuration to change. Regression testing is necessary to ensure that new additions do not impact previously tested and accepted

functions. DSDC will be required to complete regression testing to ensure system integrity for prior functionality.

- User Guide – The LabWare EDSS User Manual and supporting documentation provide a comprehensive description of all functions, as delivered out of the box. LabWare will work together with DSDC to create role-based user guides for DSDC prior to user acceptance testing. LabWare provides a draft user guide covering the functions in the base workflow for the section. The draft guide is turned over to DSDC around the time the new objects are loaded into the test environment. DSDC takes ownership of the draft user guide and adds detail, format and additional examples as necessary to meet the needs of the end user. The User Guide becomes a living document which DSDC can enhance as they gain more experience with the system.

  User guides provide step-by-step instructions on how to complete the most common activities for the roles within DSDC configuration. The user guide defines how to use the configuration and satisfies those functions covered in the functional specification and the template. User guides cover a typical workflow session, not an exhaustive test suite. Once fleshed out by DSDC, they serve as an end-user training guide and a day-to-day reference manual. User guides are a supplement to the LabWare EDSS User Manual, not a replacement for it. Several public health customers formally run through the user guides as part of their user acceptance testing. This gives them the opportunity to review the guides as well as capture formal documentation of testing.

- Complete formal testing & corrections – Installation by LabWare of the configuration in the testing environment is LabWare's notification to DSDC that configuration for this section has been completed and is ready for user acceptance – See Training Section for details. The test scripts are executed by DSDC to verify that the EDSS, as configured, implements the agreed upon functional requirements. It is expected that key users and the EDSS administrator execute user acceptance testing, thereby leveraging the key user training and the mentoring that comes from the various configuration reviews. Given the opportunity for the testers to see and interact with the system during the pilot stage, issues are expected to be minimal.

- Initiate DSDC Issues Log. The log is maintained by the DSDC EDSS Admin. The issues log captures enhancements, issues, change requests, wish-list and other items outside the scope of the original system requirements. Items in the log are addressed by the EDSS Admin as negotiated and prioritized with business owners, typically after go-live.

Stage 4 – Rollout Stage (repeated for each set of sections to be implemented)

The Rollout stage covers all training and deployment activities prior to releasing the system for production use. DSDC completes roll out activities. LabWare is available in a technical support role. The following are the key activities:

- Train the Trainer – The key users for the section and the EDSS administrator will have learned enough during training, configuration review and user acceptance to train the end-users.
- End User Training – The key users for the section and the EDSS administrator conduct end user training. The user guides are used as the basis for training. Any training materials in addition to this are completed by DSDC (i.e., short-cut guides, quick references, etc.).
- Move Objects to Production Environment – DSDC uses the Installation Package previously delivered by LabWare and moves the configuration objects from testing to production.
- Release the System for Production Use - Once all tasks have been performed the system is ready for production use. Any customer required documentation (SOP updates, system release forms, etc.) is completed by DSDC. Additional features are configured on an ongoing basis, based on defined change management procedures.

- Deployment – Site preparations (training schedules, workstation installations, scanners, etc.) are completed on site. End-user training occurs at each location

By the end of the project, DSDC has become self-supporting. LabWare continues to support DSDC with online information, an email discussion forum, and assistance from our technical support staff via the telephone or if DSDC prefers via email. DSDC will ultimately have to maintain, support and enhance the final LabWare EDSS solution and be in a position to take over responsibility from the LabWare consultants. This can only happen if the EDSS team has gained extensive product knowledge during the project by completing the assigned deliverables.

Infrastructure

Minimally, three database instances are required: development, testing and production. A fourth instance for training may also be necessary, depending on the desires of DSDC. Additional instances may be created at the discretion of the team (dev-test, install, sandbox, etc.)

- The development environment is installed by DSDC prior to project kick-off. Secure, remote access with full access rights is also established for the consultants. This ensures that the project initiation activities can occur as efficiently as possible. Requirements for a development system are minimal – the hardware is separate from the testing and production hardware. LabWare will install LabWare EDSS in the development environment following project kick-off. The development database is started in Microsoft Access.
- An understanding of the product and the requirements, combined with an understanding of DSDC infrastructure, allows the team to choose the most appropriate implementation architecture. The primary choice relates to thin client versus thick client. DSDC is largely responsible for putting together an architectural plan for the testing and production systems during the initiation stage. The plan details design, specifications and purchase orders for the testing and production environments, as well as a build schedule consistent with the overall project schedule. LabWare consultants provide input while DSDC is responsible for the definition and build of the environments.
- At some point during configuration, the LabWare consultants will determine when the database should move to a database matching production (i.e., Oracle, SQL Server).
- Build Test and Production Environments – DSDC IT personnel will need to create the test and production environments based on the agreed upon architecture. In order to allow for sufficient lead-time, architecture decisions must be made before the pilot system is complete. Depending on the project schedule, it may be necessary to decide on the system environment earlier in the project. The project cannot proceed to stage 3 (System Completion) without a testing environment in operation. The project cannot proceed to stage 4 (Roll Out) without a production environment in operation.

Quality Assurance and Testing

The EDSS application is produced by configuring the LabWare EDSS product and not by changing the products standard software as delivered and validated by LabWare.

- The configuration will be completed in accordance with LabWare's guidelines on configuring LabWare EDSS.
- The configuration will be based on the LabWare public health template – a preconfigured database that serves as the basis for all public health projects.

- A requirement necessitating a large amount of configuration, configuration through scripting, or significant deviation from the template will be raised with the project managers to provide the opportunity to look at requirements simplification.
- A requirement necessitating a change to LabWare EDSS code will be reviewed with the program manager and escalated to LabWare via existing product enhancement processes.

Conformance to business needs will be initially controlled through review of the template, identification of gaps, iterative configuration by LabWare, reviews with the development team, and undocumented testing by DSDC.

Testing:

LabWare has been assessed by many customers and confirmed as a "configured software package". Due to this and the large number of environmental and clinical customers using the same software, no further testing will be conducted on the standard product or released modules.

Reuse of configuration items taken directly from the template also carries minimal risk, as they have been tested at previous sites. Minimal testing will be applied to these areas.

The consultant performing the configuration will execute undocumented unit testing on the configuration. The purpose of this unit testing is to challenge subroutines, etc. that may be created during the course of the project. The consultant may choose to keep his own records of testing for efficiency purposes, but these will not be included as a project deliverable.

Working closely with the LabWare consultants, the EDSS administrator and key users will evaluate the configuration prior to formal user acceptance testing. The objective of this testing is to build user confidence with both LabWare EDSS and the configuration, and confirm the general operation of the system. Early evaluation of the configuration has proven to be very effective, as operational issues can be resolved before investing in writing user test scripts. Configuration evaluation is continual throughout the pilot stage and is undocumented. Configuration evaluation takes place in the development environment.

User acceptance testing is the responsibility of DSDC. LabWare offers a draft acceptance test plan which DSDC may choose to use as a starting point. User acceptance testing takes place in the test environment.

Having gone through this process many times, LabWare recommends a practical, efficient approach to user acceptance testing. Rather than spend considerable time and effort writing tests scripts that will only be used once, LabWare suggests a more pragmatic approach. The user guides provide step-by-step actions for the most commonly used functions for the given role and will match to the functional specifications approved earlier in the project. LabWare customers have experienced good success with employing these user guides as the basis for user acceptance, as they reflect the day-to-day activities of the end user. Key users execute the user guides in a formal manner in a test environment. A cover letter or acceptance sheet is completed upon successful execution of the test. A successful test not only indicates system acceptance of the tested functions, but also acceptance of the guide itself and the guide as a training document.

Completion of user acceptance testing shall be indicated in writing from DSDC to LabWare by either an approved test report indicating acceptance of the software, or by a list of all non-conformances of the software to DSDC's prescribed functional specifications.

In the event that DSDC provides to LabWare a list of non-conformances, LabWare will have defined time period to resolve the non-conformance(s) or to provide a written plan to resolve the non-conformance.

DSDC is responsible for regression testing. Since there will be several roll outs over the course of the project, regression testing is necessary to ensure that new additions do not impact previously tested and accepted functions. DSDC shall apply their own risk-based analysis to determine what additional testing is warranted prior to user acceptance of the new configuration. Regression testing is usually limited to a high-level check of major functions, possibly re-execution of a fraction of the original acceptance tests. Regression testing takes place in the testing environment.

Targets

The elapsed time for the Pilot stage is driven by the extent to which the requirements deviate from the provided public health template, and new functionality is introduced.

The elapsed time of the System Completion stage is driven by the amount of static data to be verified, the efficiency with which test scripts are written and executed, and the extent to which the system has been customized.

The single most significant factor driving the elapsed time of the Rollout stage is simply the extent to which the team is prepared. Finishing the configuration is not the only prerequisite for starting the roll out. The production hardware needs to be available and training needs to be scheduled. If these items are not properly managed by the DSDC project manager during the System Completion stage, the rollout will be delayed. The duration of the Rollout stage also depends on the number of sites to which EDSS will be rolled out.

Project Change Management

A "new requirement" for a developer is often a "clarification to an existing requirement" for a user. To avoid "open ended developments" a change will be considered anything that requires a change to an existing component that is not specifically stated in a pre-agreed specification. The functional specifications created during the pilot stage will be the base document for Change Management once approved. A change is also defined as a request for a new deliverable, a change in project scope, or a change to any previously recorded decision, prerequisite, or commitment.

If a requested change exceeds the LabWare project manager's margin of tolerance (i.e., it places in jeopardy the project schedule or budget), or it involves amendment to a completed deliverable that has already been approved, the DSDC project manager together with the LabWare project manager will need to obtain Project Board agreement and sign-off to the revised plan. Escalation will include an impact assessment. The impact assessment will describe the amount of work necessary to complete the request, the impact to the timeline, and the potential additional cost to DSDC. Together, the DSDC and LabWare project managers offer a recommendation to the board. The Project Board may then make a determination on the request. The change request is not acted upon without board approval.

Project Communication

Communication between LabWare and DSDC will be addressed as follows:

Project Team Meetings	A tactical, weekly meeting coordinated and documented by DSDC project manager. LabWare project manager helps define the agenda. Attendees include the core project team (project manager, the LabWare project manager, the LabWare consultant(s), the EDSS Administrator(s)) and other key persons involved with the project at the current stage. Meeting purpose is to communicate deliverables to the team, assign tasks, and track the detailed project deliverables, making sure that all team members are effectively contributing to the goal. Agenda typically includes task review, project decisions, and action items for project team.
Project Board Meetings	A strategic, monthly meeting coordinated and documented by DSDC project manager under the authority of the Project Board. Attendees include the Project Board. Meeting purpose is to communicate issues and risks, and to report on high-level scope, schedule and budget status. Resource needs and change requests are also raised to this forum.
Status Report	The LabWare Project Manager will provide a status report for review by the Project Board. Frequency will be twice monthly. Each project manager has developed a format and level of detail that works for them. However, common elements include an executive summary, future milestones, and progress towards next milestone. The status report summarizes current, issues, risks and change requests.

Communication throughout the organization and across locations regarding the project status and upcoming milestones is the responsibility of DSDC project manager. The DSDC project manager will also be responsible for communicating project activities to the organization and scheduling meetings, review sessions, and testing as required.

It is strongly recommended that DSDC establish an FTP site or other common repository for project information.

Support

DSDC resources will be required to undertake application support and enhancements. To achieve this, the EDSS administrator will form part of the implementation team and proactive knowledge transfer will be conducted during the project to enable the following support model to be adopted:

Level 1	General help desk support for the site (i.e., IT help desk). This resolves standard infrastructure type issues (e.g. printers not working). The aim is to forward calls to the dedicated business system support team when required (e.g. EDSS, Citrix, etc)
Level 2	Support is provided by staff very familiar with the EDSS (key users and the EDSS Admin). This team

	will resolve all end-user day-to-day issues and prioritize qualified reported issues. This team will be responsible for resolving all issues; however they are supported by the standard LabWare Support agreement.
Level 3	Support for the EDSS administrators. This service includes; new products and services to meet future needs, bug fixes/ workarounds to LabWare EDSS; and providing assistance as required to enhance the system or resolve issues. The process model by which the above services are provided is detailed in the "Engaging LabWare Support" document. Updates to the Public Health Template will also be provided.

1.4.10 The vendor must provide a mechanism whereby all system source code is the property of or can be accessed by the State of West Virginia. Vendor shall include a description of the source code ownership/access provision, prior to award.

LabWare can provide an Escrow account.

3. QUOTATION FORM

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

REQ NUMBER: EHP90097

PAGE: 1

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SHIP TO
HEALTH AND HUMAN RESOURCES
BPH - IMMUNIZATION PROGRAM
350 CAPITOL STREET, ROOM 125
CHARLESTON, WV
25301-3719 304-558-2188

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
06/23/2009				

BID OPENING DATE: 07/23/2009 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
0001	1	JB		099-00		

TO PROVIDE A PUBLIC HEALTH INFORMATION NETWORK

(PHIN) COMPLIANT ELECTRONIC DISEASE SURVEILLANCE SYSTEM THAT WILL ALSO SUPPORT ELECTRONIC LABORATORY REPORTING (ELR), PER THE ATTACHED SPECIFICATIONS.

TERM SHALL BE FOR A ONE YEAR PERIOD WITH THE OPTION OF TWO (2), ONE YEAR PERIODS.

EXHIBIT 3

LIFE OF CONTRACT: THIS CONTRACT BECOMES EFFECTIVE ON AWARD..... AND EXTENDS FOR A PERIOD OF ONE (1) YEAR OR UNTIL SUCH "REASONABLE TIME" THEREAFTER AS IS NECESSARY TO OBTAIN A NEW CONTRACT OR RENEW THE ORIGINAL CONTRACT. THE "REASONABLE TIME" PERIOD SHALL NOT EXCEED TWELVE (12) MONTHS. DURING THIS "REASONABLE TIME" THE VENDOR MAY TERMINATE THIS CONTRACT FOR ANY REASON UPON GIVING THE DIRECTOR OF PURCHASING 30 DAYS WRITTEN NOTICE.

UNLESS SPECIFIC PROVISIONS ARE STIPULATED ELSEWHERE IN THIS CONTRACT DOCUMENT, THE TERMS, CONDITIONS AND PRICING SET HEREIN ARE FIRM FOR THE LIFE OF THE CONTRACT.

RENEWAL: THIS CONTRACT MAY BE RENEWED UPON THE MUTUAL WRITTEN CONSENT OF THE SPENDING UNIT AND VENDOR, SUBMITTED TO THE DIRECTOR OF PURCHASING THIRTY (30) DAYS PRIOR TO THE EXPIRATION DATE. SUCH RENEWAL SHALL BE IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE ORIGINAL CONTRACT AND SHALL BE LIMITED TO TWO (2) ONE

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 3026588448 DATE 7/21/09

TITLE VP FEIN 20-8696880 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
EHP90097	2

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SHIP TO
HEALTH AND HUMAN RESOURCES
BPH - IMMUNIZATION PROGRAM
350 CAPITOL STREET, ROOM 125
CHARLESTON, WV
25301-3719 304-558-2188

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
06/23/2009				

BID OPENING DATE: 07/23/2009 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT

(1) YEAR PERIODS.

CANCELLATION: THE DIRECTOR OF PURCHASING RESERVES THE RIGHT TO CANCEL THIS CONTRACT IMMEDIATELY UPON WRITTEN NOTICE TO THE VENDOR IF THE COMMODITIES AND/OR SERVICES SUPPLIED ARE OF AN INFERIOR QUALITY OR DO NOT CONFORM TO THE SPECIFICATIONS OF THE BID AND CONTRACT HEREIN.

OPEN MARKET CLAUSE: THE DIRECTOR OF PURCHASING MAY AUTHORIZE A SPENDING UNIT TO PURCHASE ON THE OPEN MARKET, WITHOUT THE FILING OF A REQUISITION OR COST ESTIMATE, ITEMS SPECIFIED ON THIS CONTRACT FOR IMMEDIATE DELIVERY IN EMERGENCIES DUE TO UNFORESEEN CAUSES (INCLUDING BUT NOT LIMITED TO DELAYS IN TRANSPORTATION OR AN UNANTICIPATED INCREASE IN THE VOLUME OF WORK.)

BANKRUPTCY: IN THE EVENT THE VENDOR/CONTRACTOR FILES FOR BANKRUPTCY PROTECTION, THE STATE MAY DEEM THE CONTRACT NULL AND VOID, AND TERMINATE SUCH CONTRACT WITHOUT FURTHER ORDER.

THE TERMS AND CONDITIONS CONTAINED IN THIS CONTRACT SHALL SUPERSEDE ANY AND ALL SUBSEQUENT TERMS AND CONDITIONS WHICH MAY APPEAR ON ANY ATTACHED PRINTED DOCUMENTS SUCH AS PRICE LISTS, ORDER FORMS, SALES AGREEMENTS OR MAINTENANCE AGREEMENTS, INCLUDING ANY ELECTRONIC MEDIUM SUCH AS CD-ROM.

REV. 05/26/2009

INQUIRIES:
WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF BUSINESS ON 7/7/2009. QUESTIONS MAY BE SENT VIA USPS, FAX, COURIER OR E-MAIL. IN ORDER TO ASSURE NO

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
EHP90097	3

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SHIP TO
HEALTH AND HUMAN RESOURCES
BPH - IMMUNIZATION PROGRAM
350 CAPITOL STREET, ROOM 125
CHARLESTON, WV
25301-3719 304-558-2188

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
06/23/2009				

BID OPENING DATE: 07/23/2009 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT

VENDOR RECEIVES AN UNFAIR ADVANTAGE, NO SUBSTANTIVE QUESTIONS WILL BE ANSWERED ORALLY. IF POSSIBLE, E-MAIL QUESTIONS ARE PREFERRED. ADDRESS INQUIRIES TO:

ROBERTA WAGNER
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON STREET, EAST
CHARLESTON, WV 25311

FAX: 304-558-4115
E-MAIL: ROBERTA.A.WAGNER@WV.GOV

NOTICE

A SIGNED BID MUST BE SUBMITTED TO:

DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
BUILDING 15
2019 WASHINGTON STREET, EAST
CHARLESTON, WV 25305-0130

PLEASE NOTE: A CONVENIENCE COPY WOULD BE APPRECIATED.

THE BID SHOULD CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPE OR THE BID MAY NOT BE CONSIDERED:

SEALED BID

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
EHP90097	4

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE
LabWare Inc
3 Mill Rd ste 102
Wilmington De 19806

SHIP TO
HEALTH AND HUMAN RESOURCES
BPH - IMMUNIZATION PROGRAM
350 CAPITOL STREET, ROOM 125
CHARLESTON, WV
25301-3719 304-558-2188

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
06/23/2009				

BID OPENING DATE: 07/23/2009 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT

BUYER:----------RW/FILE 22----------

RFQ. NO.:----------EHP90097----------

BID OPENING DATE:----------7/23/2009----------

BID OPENING TIME:----------1:30 PM----------

PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID:

3026587894

CONTACT PERSON (PLEASE PRINT CLEARLY):

David Trottier

****** THIS IS THE END OF RFQ EHP90097 ****** TOTAL: 3174900

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 302 658 8444 DATE 7/21/09

TITLE VP FEIN 20-8696880 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

4. BID QUOTATION

West Virginia Electronic Disease Surveillance System (WVEDSS)

BID QUOTATION SHEET

Qty	Description		Unit Cost	Total Cost
1 ea.	*Software Application*			
	Based on 250 concurrent users		$4,720	$1,180,000
	Guide To Reporting With Labware LIMS		$1,000	$1,000
160	*Technical Services*			
Hours	Implementation Planning	135 Days	$1,750	$236,250
	Installation	15 Days	$1,750	$26,250
	Configuration and Customization	575 Days	$1,750	$1,006,250
	Documentation Development	25 Days	$1,750	$43,750
40	*On-Site Training*	Administration 1 (4 courses)	$12,000	$48,000
Hours		Advanced Configuration Using LIMS Basic	$7,500	$7,500
		Reporting Using Crystal Reports (4 courses)	$5,000	$20,000
		Key User Training for Public Health (4 courses)	$7,500	$30,000
	Documentation (in paper and electronic format)			
1 ea.	System Installation Manual			$0
1 ea.	System Administration Manual			$0
1 ea	User Manual			$0
1 ea.	Data Dictionary			$0
1 ea.	Entity Relationship Diagram			$0
	Software Maintenance			
	Year 2	Annual Software Maintenance Plan	$286,450	$286,450
	Year 3	Annual Software Maintenance Plan	$286,450	$286,450
		Escrow per year	$1,000	$3,000
	Technical Support			
	Year 2	LabWare Technical Support	$2,000	$2,000
	Year 3	LabWare Technical Support	$2,000	$2,000
		Grand Total		$3,174,900

BASIS OF AWARD

David Nixon VP LabWare Inc

Contract will be awarded to lowest bidder that meets the requirements.

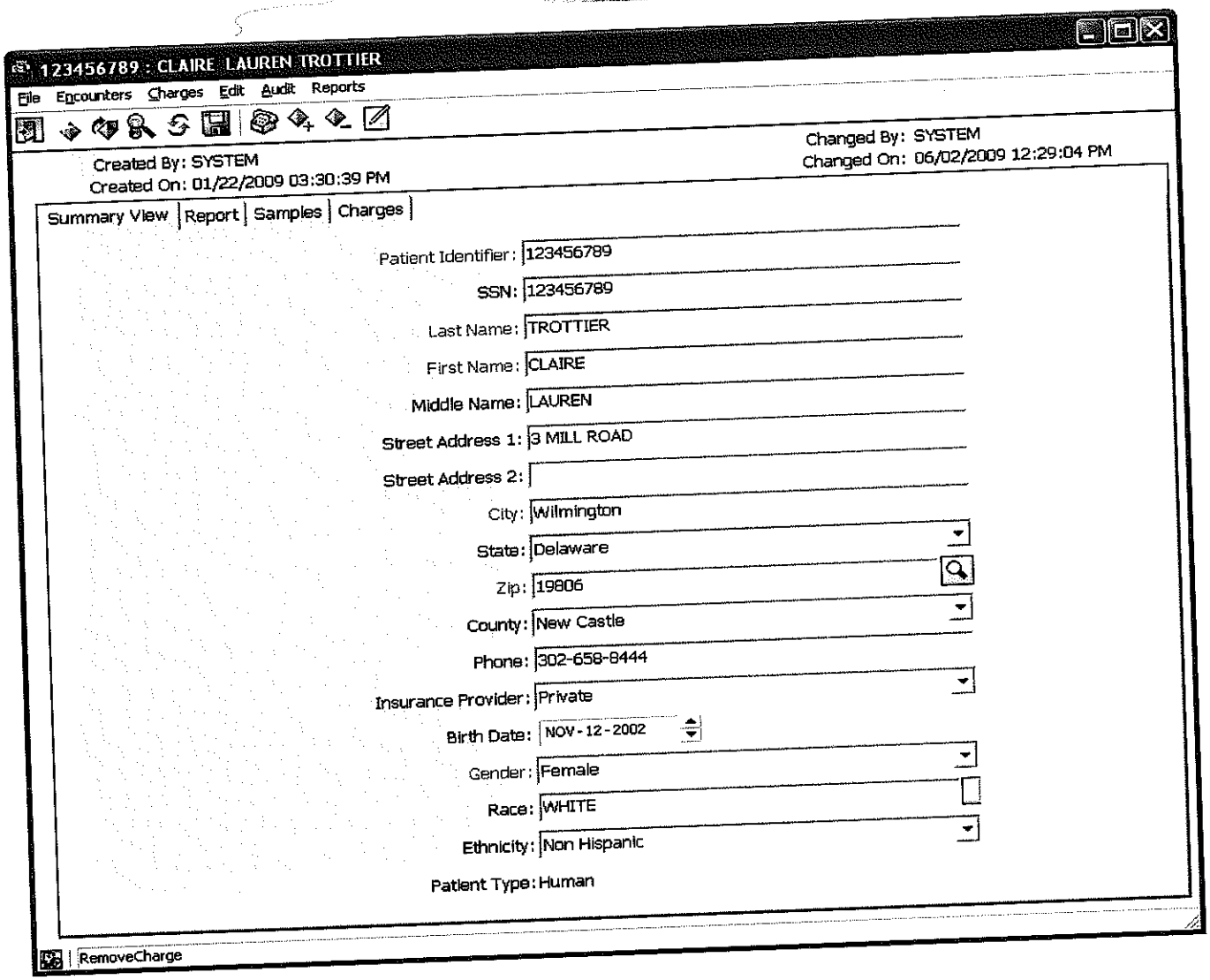
5. RELEVANT FUNCTIONALITY

5.1 Patient Manager

The LabWare Patient Manager module provides for the management of patient information. Information is collected in three areas:

1. Patient Demographics (name, SSN, address, birth date, gender, etc.)
2. Patient History
   A Crystal Report summarizing all patient samples and final reports
3. Sample Summary
   A list of samples/tests/results displayed in a tree structure

Summary View
Below is the Patient Manager summary view. It provides the patient's detailed demographic information.



Detail Information

Field level data is organized through pre-defined templates. Different roles can be set up to access different patient templates. The purpose is to provide information access to the individual users as needed to perform their jobs as well as to control access to protected health information in compliance with HIPAA requirements.

The **File** menu on the Patient Manager interface provides the user with the following functions.

Open	Open patient dialog window to search for a patient
Find	Browse on patients
New	Create new patient
Refresh	Refresh content of window
Remove	Remove a patient
Merge	Merge two patients
Un-Merge	Un-merge two patients

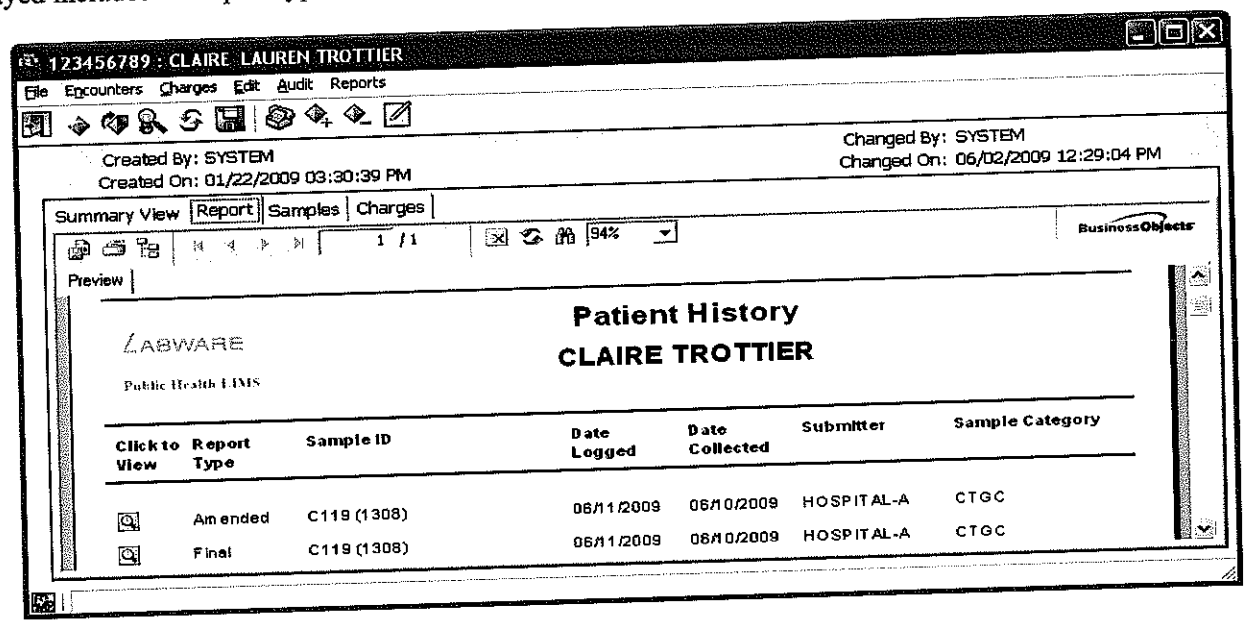
Save	Save patient information to the database
Exit	Exit Patient Manager

The **Edit** menu on the Patient Manager interface provides the user with the following functions.

Note	Add a note to patient
Contact Manager	Capture verbal communication about patient
Log Samples	Log a sample linking it to the patient

Report View

An imbedded Crystal Report is used to display a summary of specimens for a particular patient. Information displayed includes the report type, sample id, date logged, date collected, submitter, and sample category.



Selecting the icon drills down to the external report that was sent to the client.

LABWARE
Public Health LIMS
CLIA: 9999999

3 Mill Road
Suite 102
Wilmington, DE 19810

LIMS Report #: 249

Patient: CLAIRE TROTTIER
3 MILL ROAD
Wilmington, DE 19806

Provider: Hospital A
Russell Robertson
3 Mill road
Wilmington, DE 19806

Local Patient Id:
Date of Birth: 11/12/2002
Social Security #: 123456789 **Gender:**

Sample #: G090011 (1305)
Source: Cervix
Outbreak:
Specimen Note:

Date Collected: 06/10/2009
Date Received: 06/11/2009
Date Reported: 06/11/2009

Test	Result	Reference Range	Date Approved
GC Culture ID	Culture positive for Neisseria gonorrhoeae		06/11/2009
Penicillin 10.0 U	30mm - Intermediate		06/11/2009
Tetracycline 30.0 mcg/ml	0mm - Resistant		06/11/2009
Ceftriaxone 30.0 mcg/ml	0mm - Resistant		06/11/2009
Ciprofloxacin 5.0 mcg/ml	50mm - Susceptible		06/11/2009

Final

X_SingleSamplePHT.rpt

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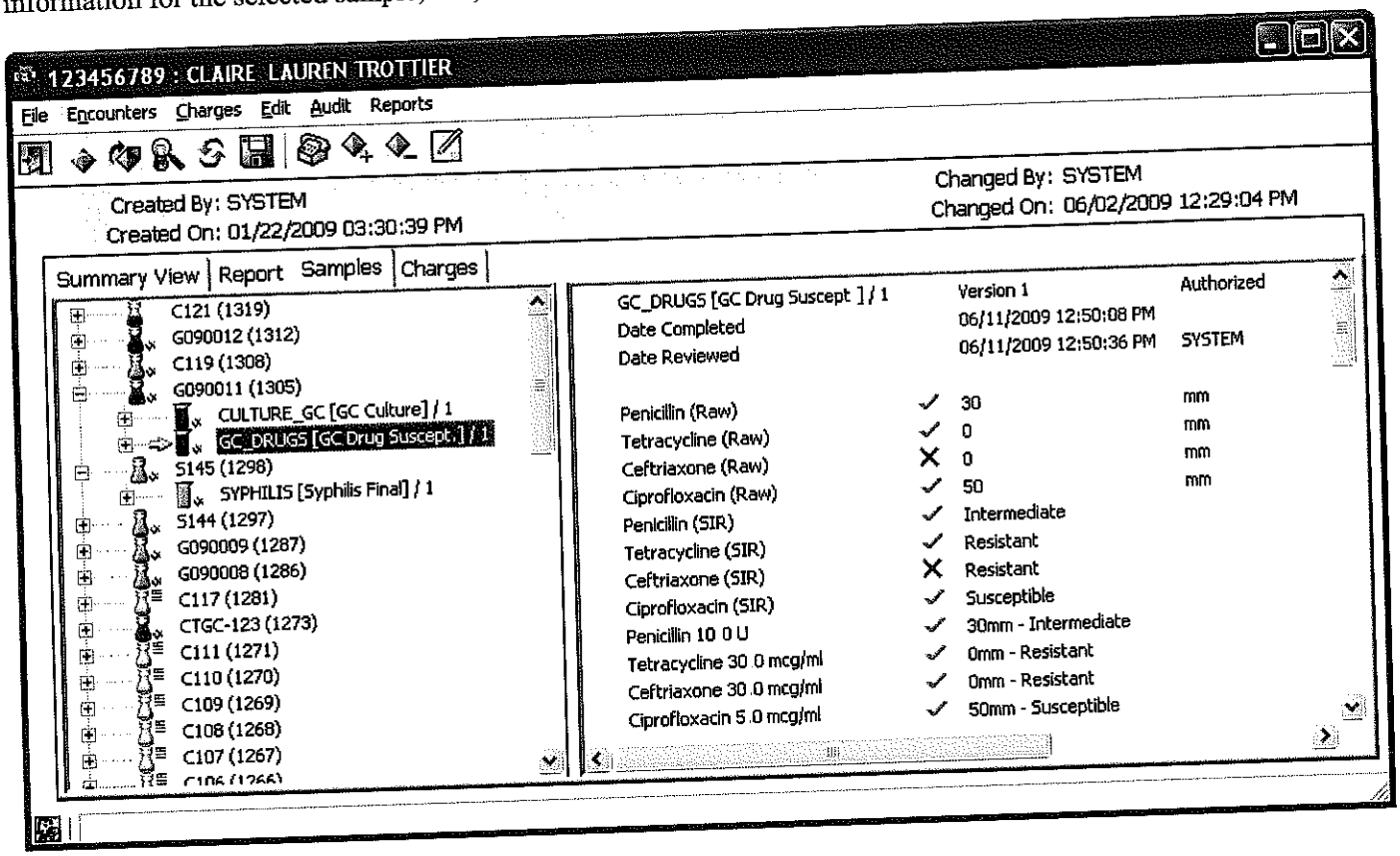
Print Date: 06/11/2009

Samples View

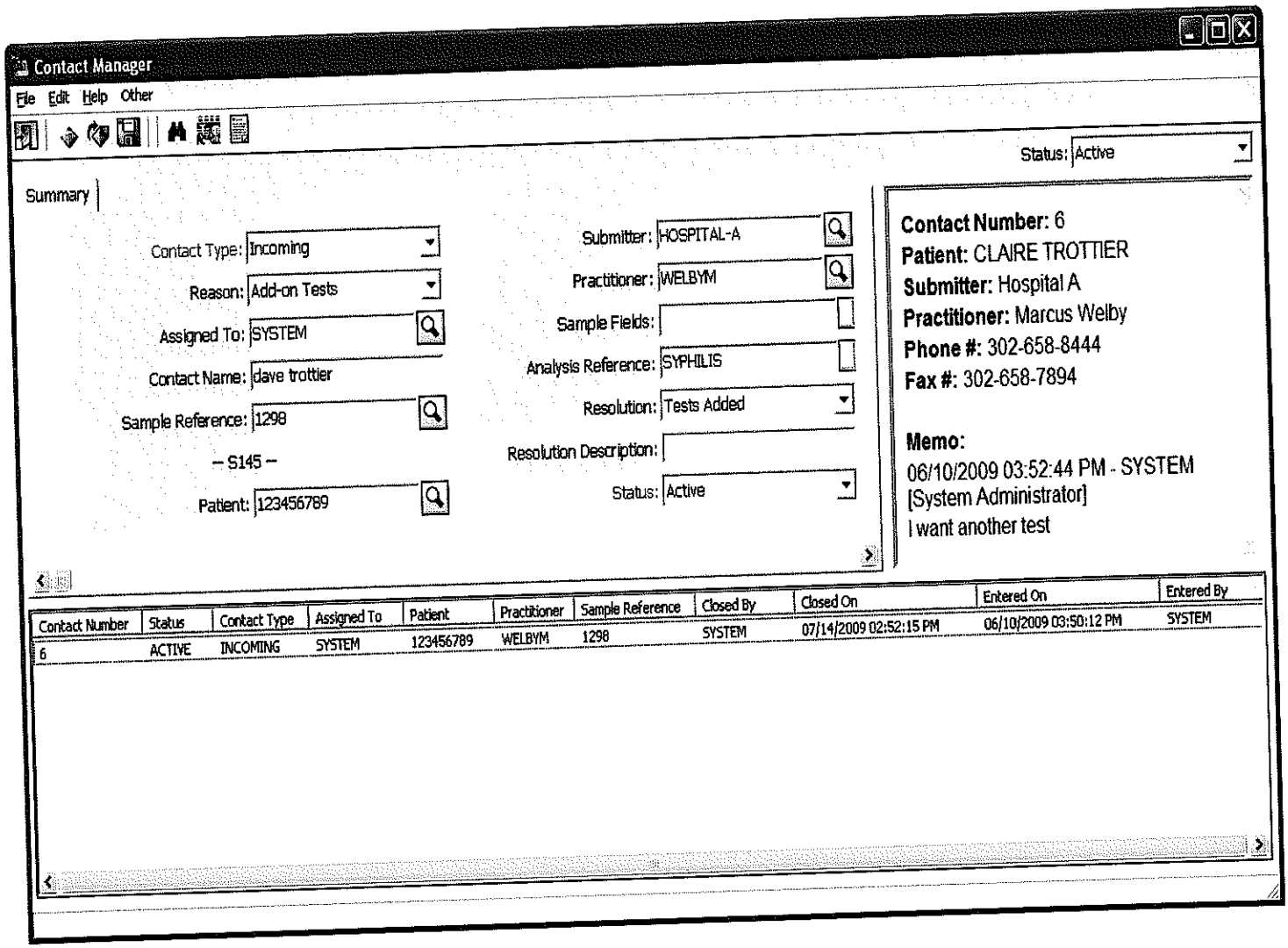
Sample/Test/Result information is displayed in an explorer type interface. The right pane displays attribute information for the selected sample, test, or result.



5.2 Contact Manager

Contact Manager provides functionality to capture and track any contact between EPI and the practitioner. One example of contact is incoming and outgoing calls. Each time a call occurs the call center captures the summary details of the call, and a memo indicating the purpose of the call.

Below is the Contact Manager interface. The top left pane displays contact summary information. The fields displayed are based on a predefined contact template. More than one template can be defined depending on the type of contact. In the example below the contact type is an incoming call. The top right pane displays general information about the sample referenced and a memo added by the call center. The memo indicates, in this case, the practitioner has requested another Syphilis test. The bottom pane displays a list of previous contacts.



Fields capture the following information:

- Contact type (i.e. incoming, outgoing, etc.)

- Reason for the call (i.e. add-on test, call referral, clarification of test ordered, illegible information, missing information, etc.)
- Contact name
- Sample reference (unique id of sample)
- Patient (unique id of patient)
- Submitter (facility)
- Practitioner (unique name of practitioner)
- Sample fields (sample field information)
- Analysis reference (test name)
- Resolution (i.e. canceled sample, gave verbal results, report re-faxed, results confirmed, test added, etc.)
- Resolution description (free format text)
- Contact status (i.e. active or closed).

The **File** menu on the Contact manager interface provides the user with the following functions.

Search	Displays search dialog to capture contact search information
Open for Customer	Open contact list for a submitter
Open for Sample	Open contact list for a sample
Open Active	Open contact list for active contacts
New Contact	Add contact
Delete Contact	Delete contact
Save	Save contact
Exit	Exit contact manager

The **Edit** menu on the Contact Manager interface provides the user with the following functions.

Edit Note	Add memo
Contact Notified	Update closed by and closed on fields
Add Alert	Send a message
Delete Alert	Delete a message
Modify Alert	Modify a message
Drill Down	Display sample details
Sample External Notes	Add memo that will appear on Final Report

The **Other** menu on the Contact Manager interface provides the user with the following functions.

Patient Manager	Display patient demographics
Sample Report	Display Final Report

5.3 Final Report

One of the more complex functional areas within a public health lab is the Final Report. Incorporating business rules, rendering patient information, tracking report status, and permanently retaining reports all contribute to a very challenging reporting requirement. A huge differentiator for LabWare is our ability to offer a Final Report solution that is out of the box. A public health organization could in effect change the logo on the Final Report and be in a position to go into production.

LABWARE

Public Health LIMS

CLIA: 9999999

3 Mill Road
Suite 102
Wilmington, DE 19810

LIMS Report #: 179

Patient: Michelle Trottier
3 Mill Road
Wilmington, DE, 19806

Provider: Hospital A
Russell Robertson
3 Mill road
Wilmington, DE 19806

Local Patient Id: X-00010
Date of Birth: 01/01/1963
Social Security #: 987654321 **Gender:** Female

Report Copied to: Ron Mueller

Sample #: CTGC-0005 (872)
Source: Conjunctival Swab
Outbreak:
Additional Info: Information on the submitted requisition
Specimen Note: **Used for Lab Note**

Date Collected: 02/22/2009
Date Received: 02/23/2009
Date Reported: 02/23/2009

Test	Result	Reference Range	Date Approved
Chlamydia by DNA Amplification	No Chlamydia trachomatis detected		02/23/2009
Gonorrhoeae	No Neisseria gonorrhoeae		02/23/2009

Final

X_SingleSamplePHT.rpt

Page 1 of 1

Print Date: 02/23/2009

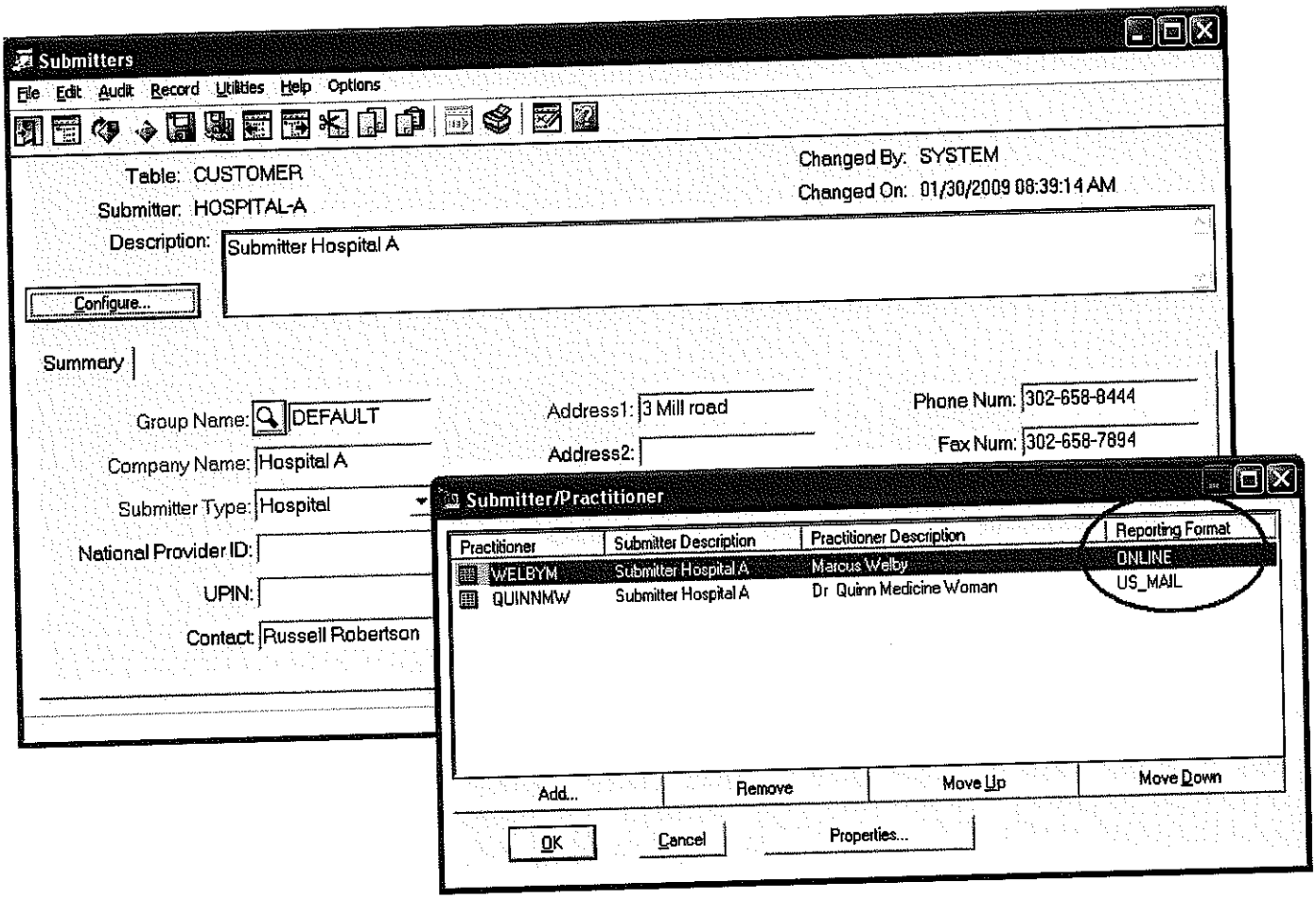
The following white paper is a detailed description of the LabWare Public Health Final Report as it exists from day one of the implementation. In addition, public health customers have the ability to extend or change the Final Report functionality through the use of several LabWare EDSS data driven configuration tools.

Business Rules

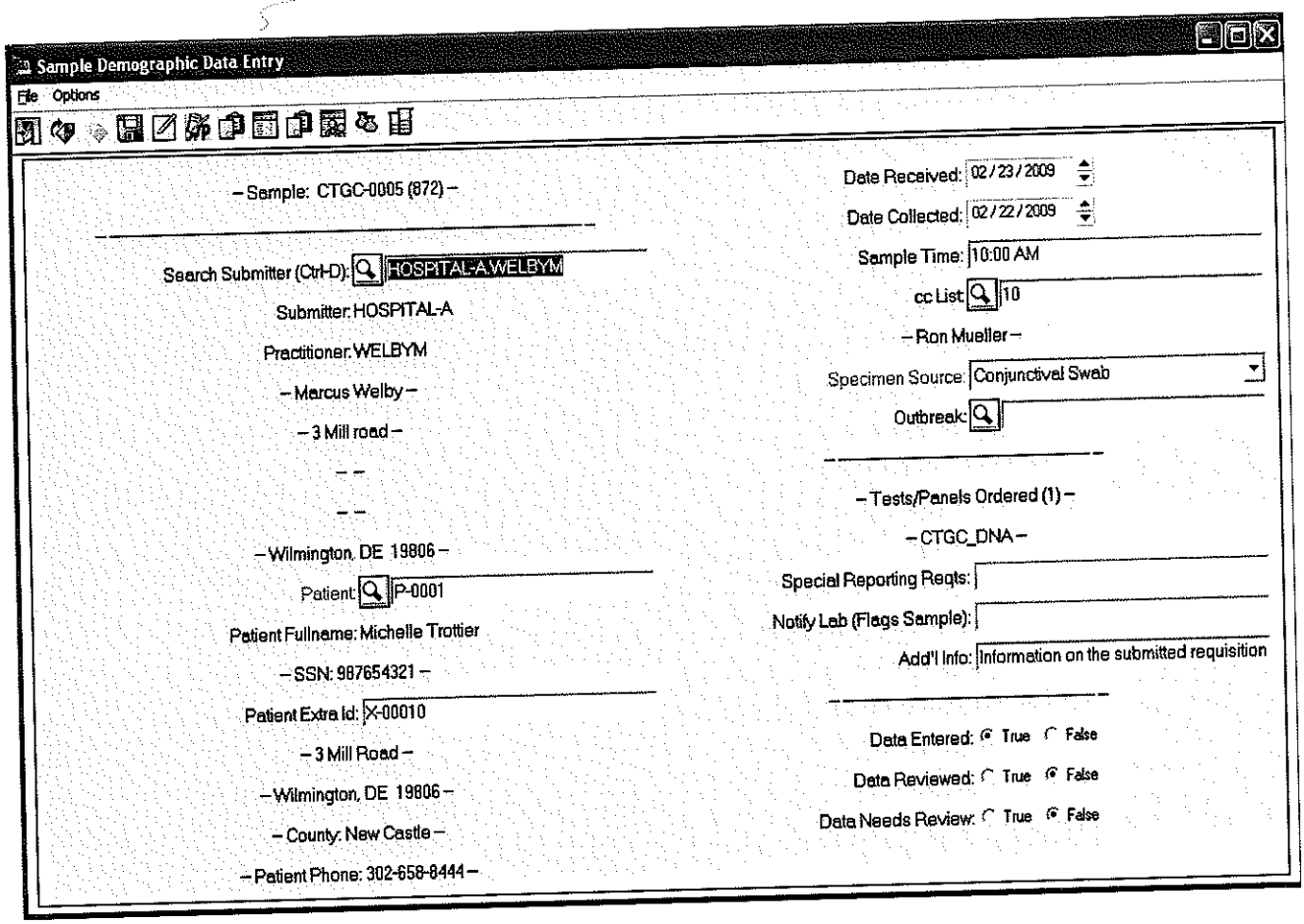
The following section summarizes the current business rules incorporated into the Final Report.

Submitter/Practitioner

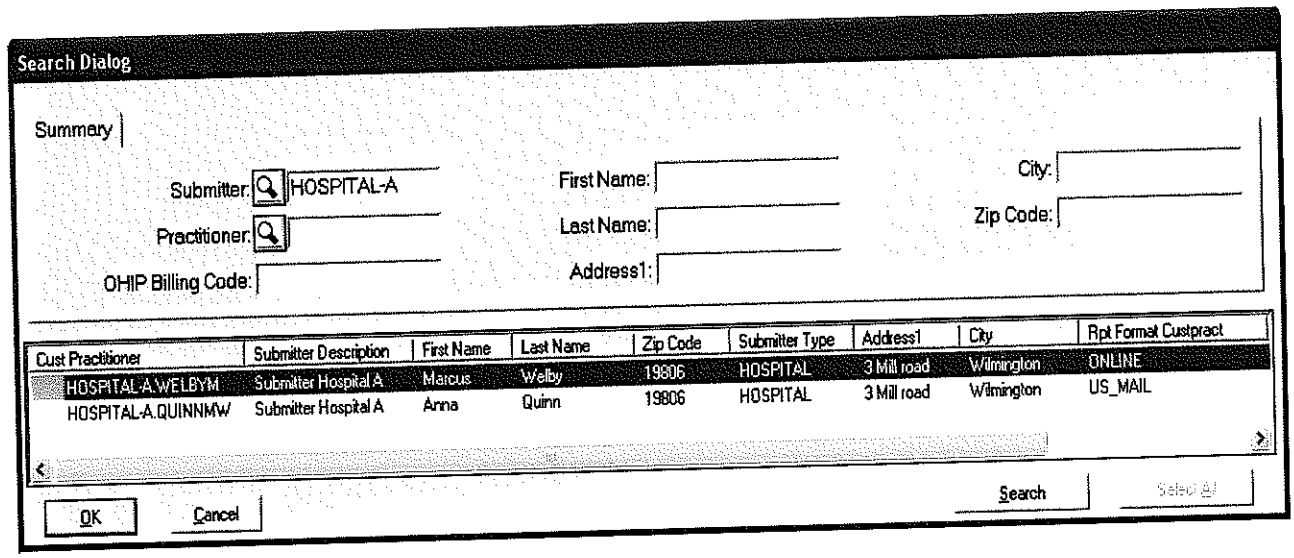
A combination of Submitter and Practitioner identifies the reporting method (courier, mail, email, online, fax). A Submitter is used to represent a facility (hospital, clinic, etc.). A Practitioner is used to represent the individual (physician, provider, doctor) responsible for the patient. The combination of a Submitter and Practitioner alleviates the problem of when practitioners are working at multiple facilities. For example, one Submitter may have multiple practitioners and one practitioner may work at multiple submitter facilities.



Both the submitter and practitioner are associated with the sample through entry on the sample demographic data entry window. The Search Submitter field allow the user to select and display a combination of submitter/practitioner. Subsequent fields display information on the submitter (Submitter id) and the practitioner (Practitioner id, Name, Address, City, State, Zip).

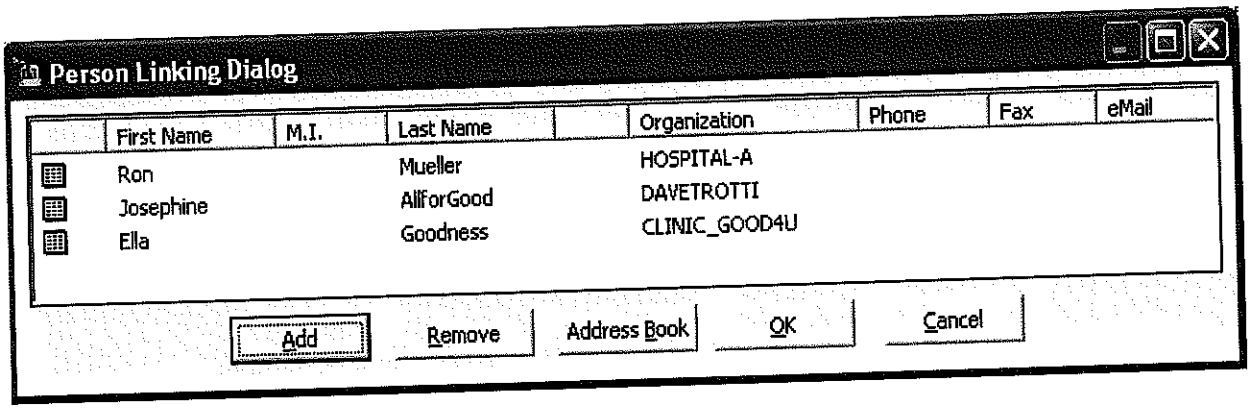


Browsing on the Search Submitter field displays a submitter/practitioner search dialog shown below. The Search Dialog window provides an efficient way to find the appropriate Submitter/Practitioner. Entering field information in the Summary tab and then selecting the search button will display a list of valid submitters/practitioners.

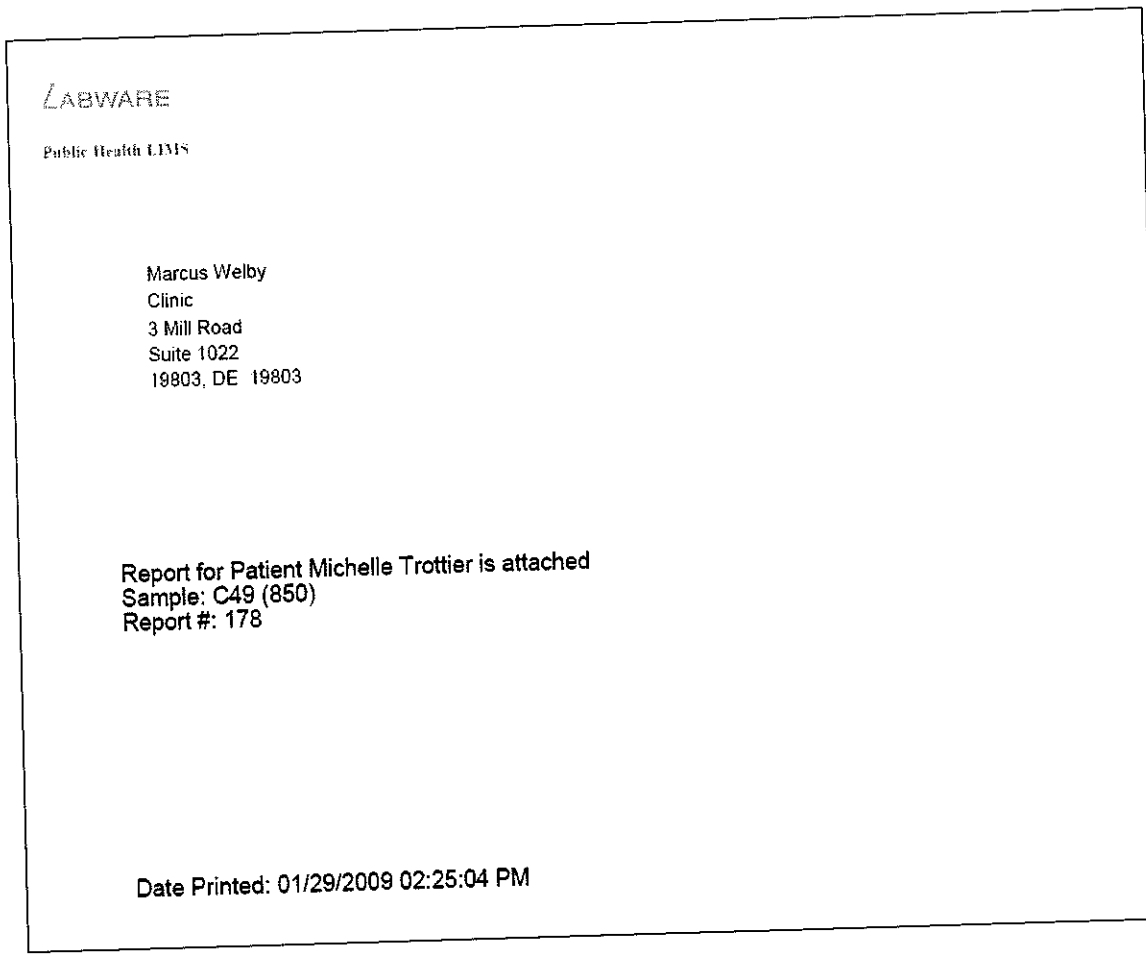


Carbon Copy (CC)

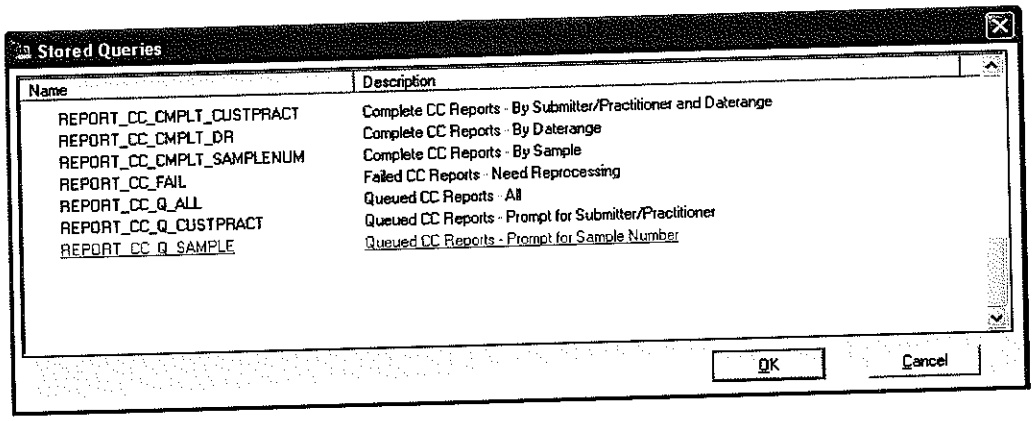
A sample can be assigned a list of individuals who are sent a copy of the Final Report. The cc'd individuals are assigned as part of Sample Demographic Data Entry. Below is a window listing the individuals that have been selected to receive a copy of the Final Report.



During Final Report generation a cover page containing the cc'd individual is automatically attached to the front of the Report. Below is an example of a cc cover page.



Several stored queries are used to summarize and track CC reporting. Queued CC report queries are a list of samples that have an assigned CC name, but the CC Final Report has not been generated. The Failed CC report query is a list of samples where the generation of the CC Final Report failed. Complete CC report queries are a list of samples where the CC Final Report was generated.

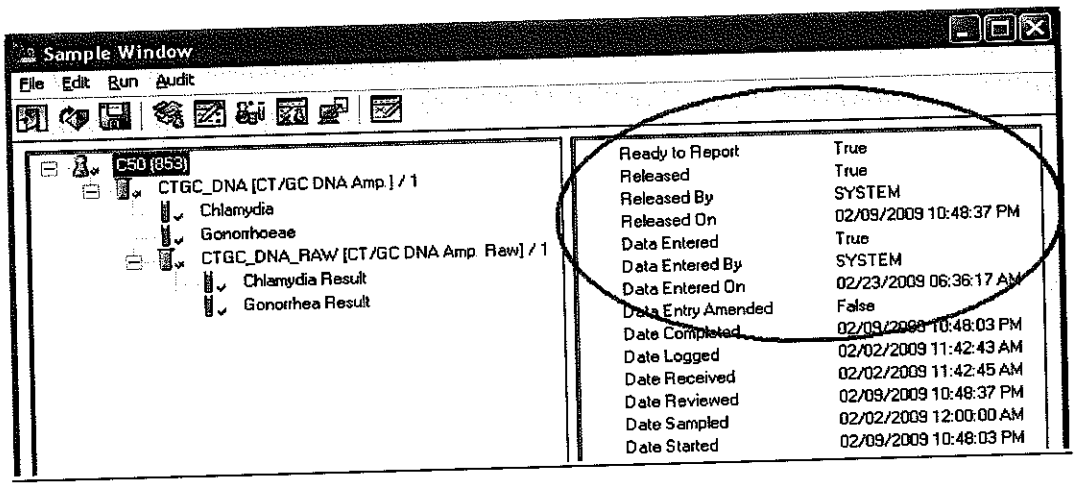


Ready to Report

Samples and/or tests must be released and the demographic data entered before the Final Report can be generated. Once both activities have occurred the test "Ready to Report" flag is automatically set to True. The following is a list of scenarios where tests are ready to be reported. In all cases the demographic data must be entered.

1. Sample is released
2. An individual test designated as preliminary reportable is released
3. All tests in a defined release group are released. Common release groups are hepatitis, syphilis, etc.

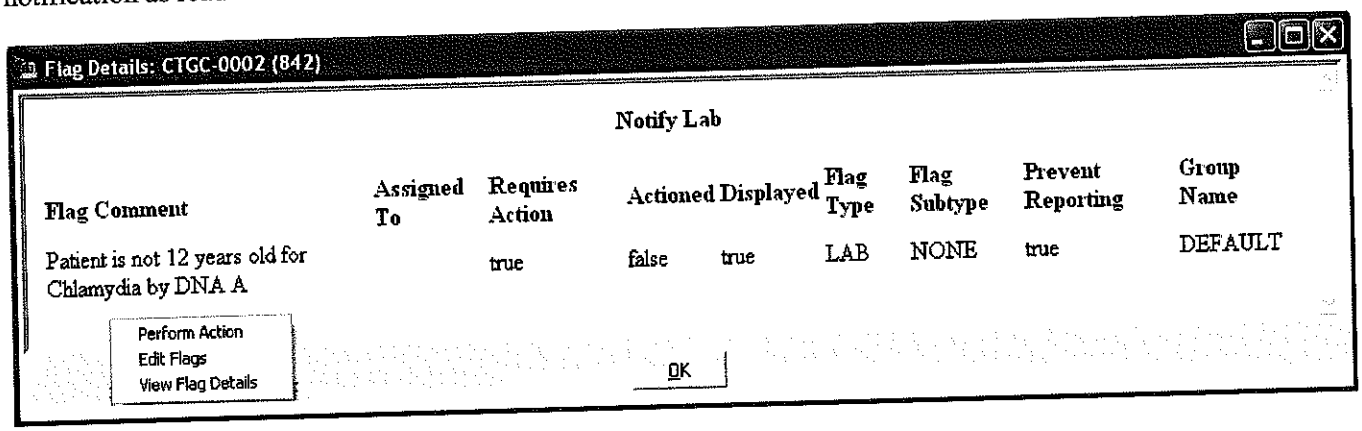
Released indicates testing is completed and reviewed. The check mark symbol next to the sample CTGC-00002 in the left pane indicates the sample has been released. The Released, Released By, and Released On attributes in the right pane show the relevant release information.



Notification

For communication purposes a sample can be assigned an internal notification. For example, during sample demographic data entry a notification can be assigned such as "Patient is not 12 years old for Chlamydia by DNA Amplification". A user will see the notification whenever the sample is viewed. In addition, Folders are used to create a list of samples with an assigned notification. Users can access the appropriate folder to view a list of samples where the notification has not been accepted. In some cases a LabWare EDSS Alert message is automatically sent to the appropriate users to inform them of the notification.

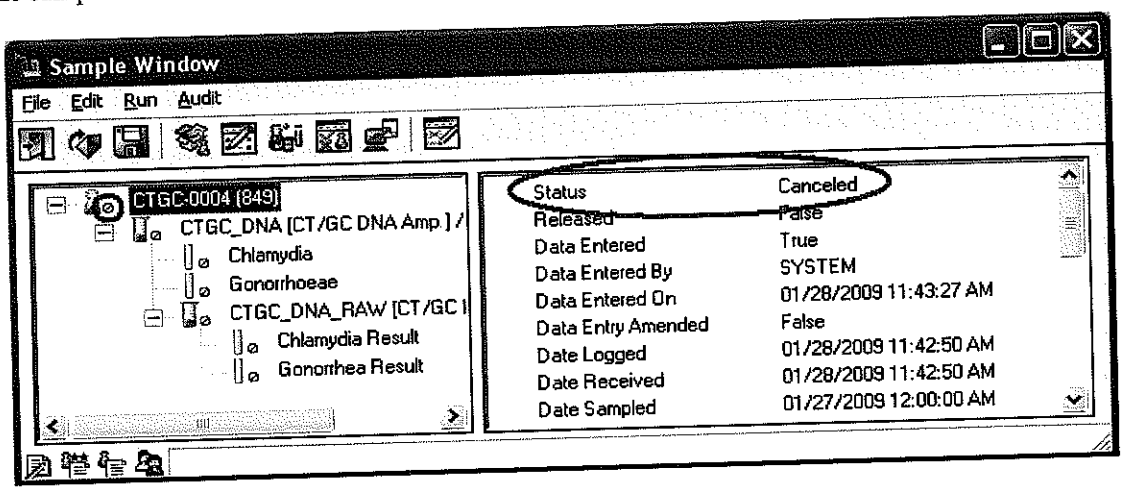
The window below is an example of a notification. The menu option "Performing Action" is used to mark the notification as read



If the "prevent Reporting" flag is set the notification has to be read and accepted before the Final Report can be generated.

Cancel Sample/Test/Result

Samples, tests, and/or results can be cancelled prior to Final Report generation. The symbol in the left pane below indicated the sample is cancelled. The status of the sample is shown in the right pane.



Below is the Final Report for sample CTGC-00004 (849). The specimen note displays the cancel reason entered by the end user during cancellation.

LABWARE

Public Health LIMS

CLIA: 9999999

3 Mill Road
Suite 102
Wilmington, DE 19810

LIMS Report #: 177

Patient: Michelle Trottier
3 Mill Road
Wilmington, DE, 19806

Provider: Clinic
3 Mill Road
Wilmington, DE 19803

Local Patient Id: X-00005
Date of Birth: 01/01/1963
Social Security #: 987654321 **Gender:** Female

Sample #: CTGC-0004 (849)
Source: Genital
Additional Info:
Specimen Note: Cancel Sample Reason: DEMO CANCEL

Date Collected: 01/27/2009
Date Received: 01/28/2009
Date Reported: 01/28/2009

Test	Result	Reference Range	Date Approved
Chlamydia by DNA Amplification	Canceled		
Gonorrhoeae	Canceled		

Features of Final Report Generation

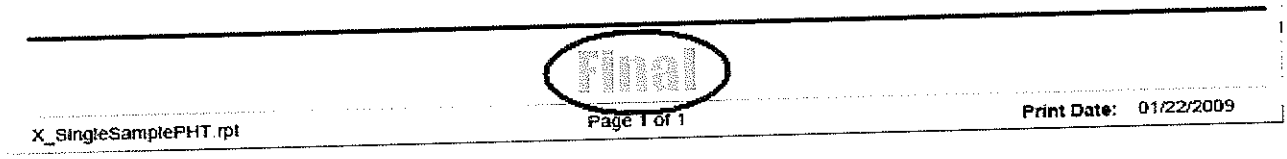
The following section summarizes the current features of Final Report generation.

PDF

The Final Report is automatically rendered and saved in PDF. A LabWare specific security algorithm is applied to the PDF, which permanently prevents the report from being altered.

Report Status

A Report is assigned a status of either "Preliminary, Final, or Amended". The Status appears at the bottom center of the Report as shown below.



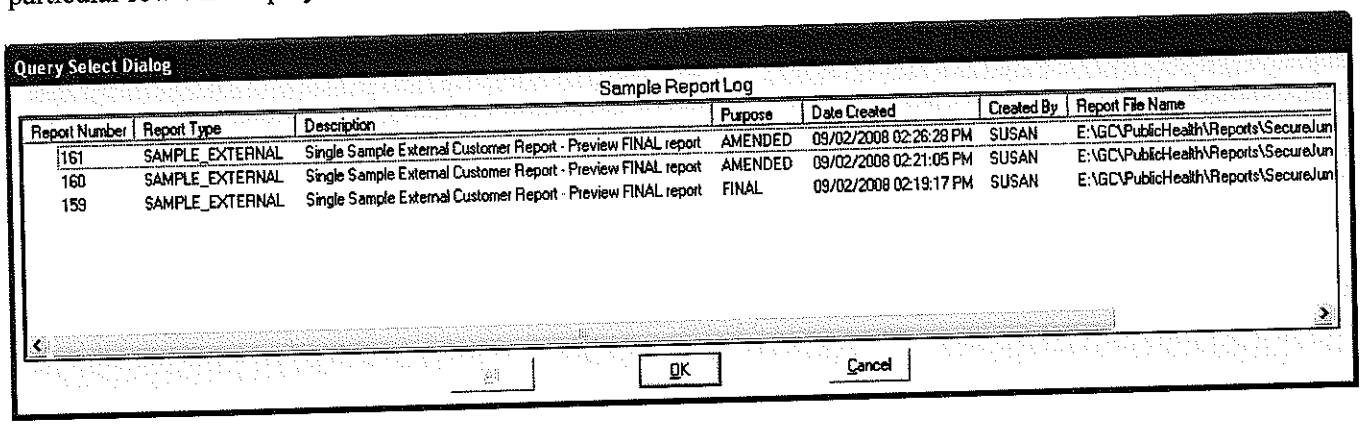
A Preliminary status represents a Report where at least one of the tests is released, but the sample is not released, and other test on the sample are pending completion, or review. Only released tests appear on the report.

A Final status represents a Report where the sample is released. All tests appear on the report.

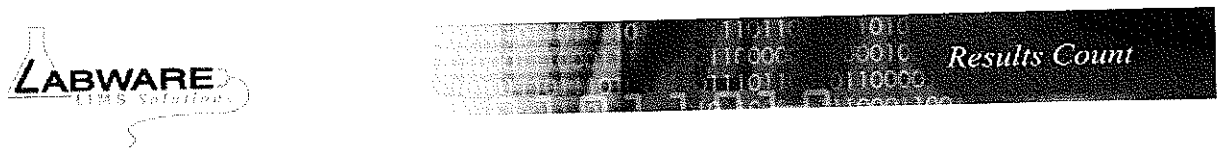
An Amended status represents a Report where a change is made to at least one of the test results. The sample is manually un-released and then re-released resetting the sample for Report generation.

Modification of Demographic Data after the sample has been reported will also cause an amended report.

Below is a list of the Final Reports generated for sample 530. Report number 159 is the Final Report with a status of "FINAL". Report numbers 160 and 161 are each Final Reports with a status of "AMENDED". Double clicking a particular row will display the associated Final Report PDF.



A Report with status AMENDED includes the results from the Report with status Final. The Report below shows the Amended results along with the previous results. In addition, the Specimen Note indicates the demographic data was amended.



Sample #:	CTGC-0002 (842)	**Date Collected:**	01/21/2009
Source:	Vaginal Swab	**Date Received:**	01/23/2009
Additional Info:	Report has been Amended	**Date Reported:**	01/27/2009
Specimen Note:	Demographic data updated on 01/23/2009: ok		

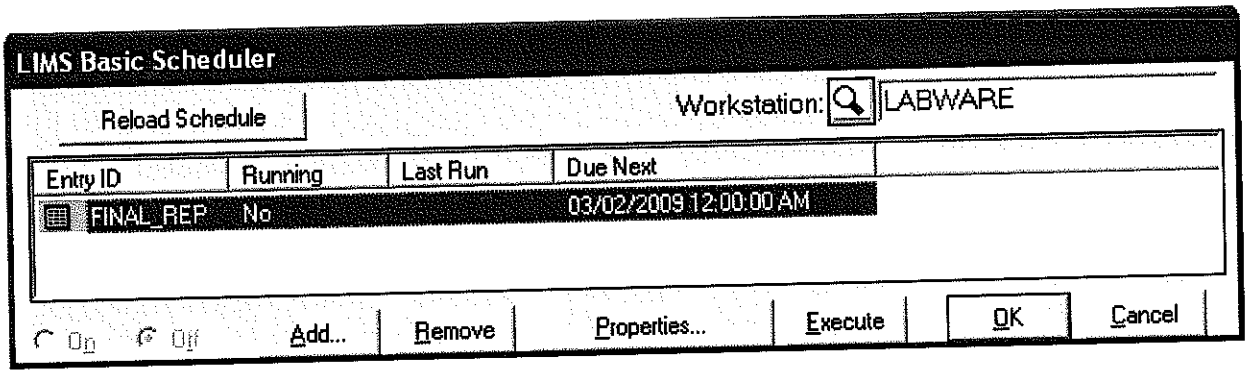
Test	Result	Reference Range	Date Approved
Chlamydia by DNA Amplification	Indeterminate by genetic probe		01/27/2009
Corrected: Previously Reported As:	No Chlamydia trachomatis detected		
Gonorrhoeae	Indeterminate by genetic probe		01/27/2009
Corrected: Previously Reported As:	No Neisseria gonorrhoeae		

Corrected

X_SingleSamplePHT rpt | Page 1 of 1 | **Print Date:** 01/27/2009

Schedule Final Report Generation

Generation of the Final Reports can be scheduled (once per day, every hour, etc.) using the LabWare EDSS Schedule Reports utility. In the window below the report REPORT_AUTO is schedule to run every day at midnight.



Manual Generation of Final Report

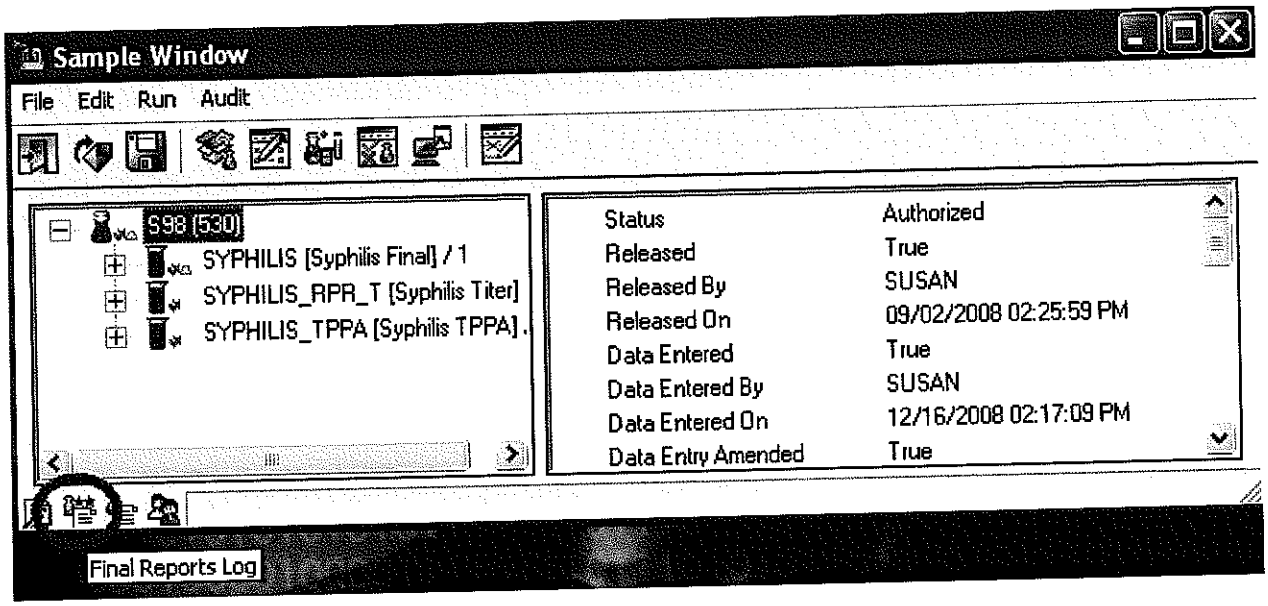
a. A user with appropriate security can manually generate single Final Report. The user is prompted for either the sample internal id or external id.

b. A user with appropriate security can manually re-print a Final Report.

c. A user with appropriate security can manually generate all Final Reports where the samples are marked as ready to report.

Online Access to Final Reports

Each time a Final Report is generated an electronic copy of the PDF is stored in a secure directory on the file server. Accessing the icon at the bottom of any sample view window will allow a user to view the final report online.



Each Final Report is assigned a unique identifier called the Report number. The Report number simplifies the identification of a Final Report. The Final Report below displays a report number of 171.

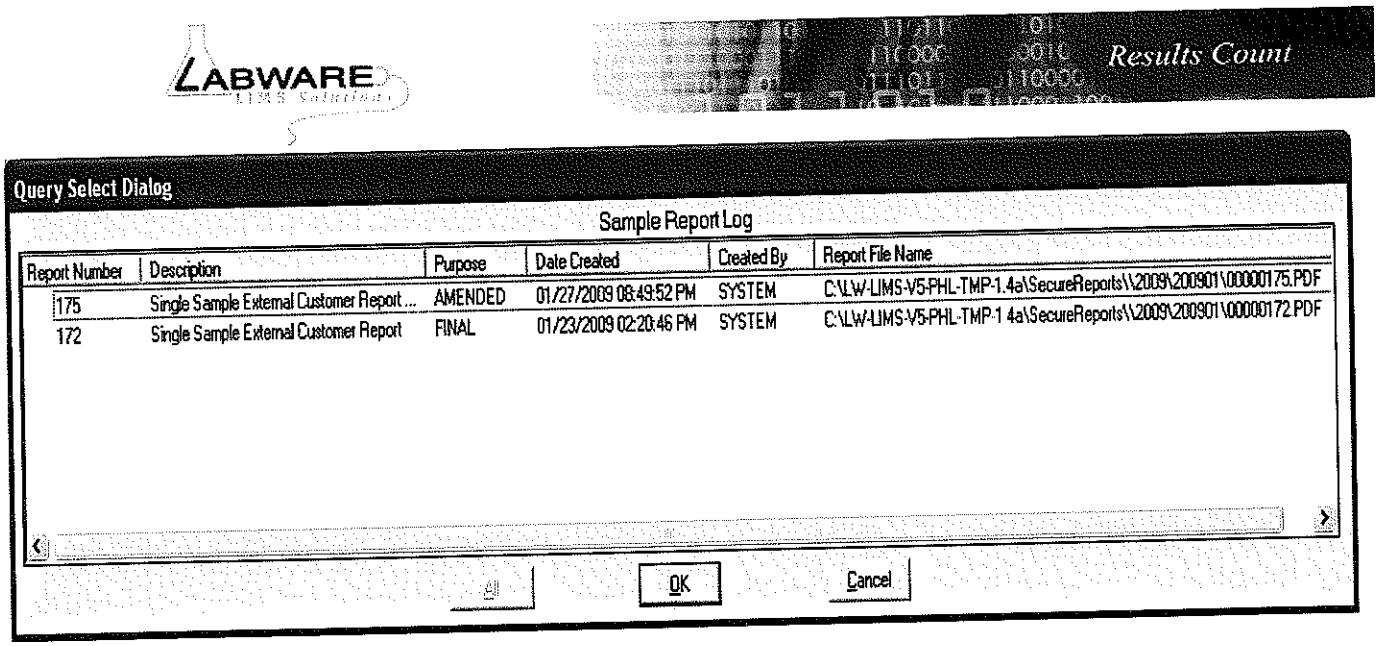
LABWARE
Public Health LIMS
CLIA: 9999999

3 Mill Road
Suite 102
Wilmington, DE 19810

LIMS Report #: 171

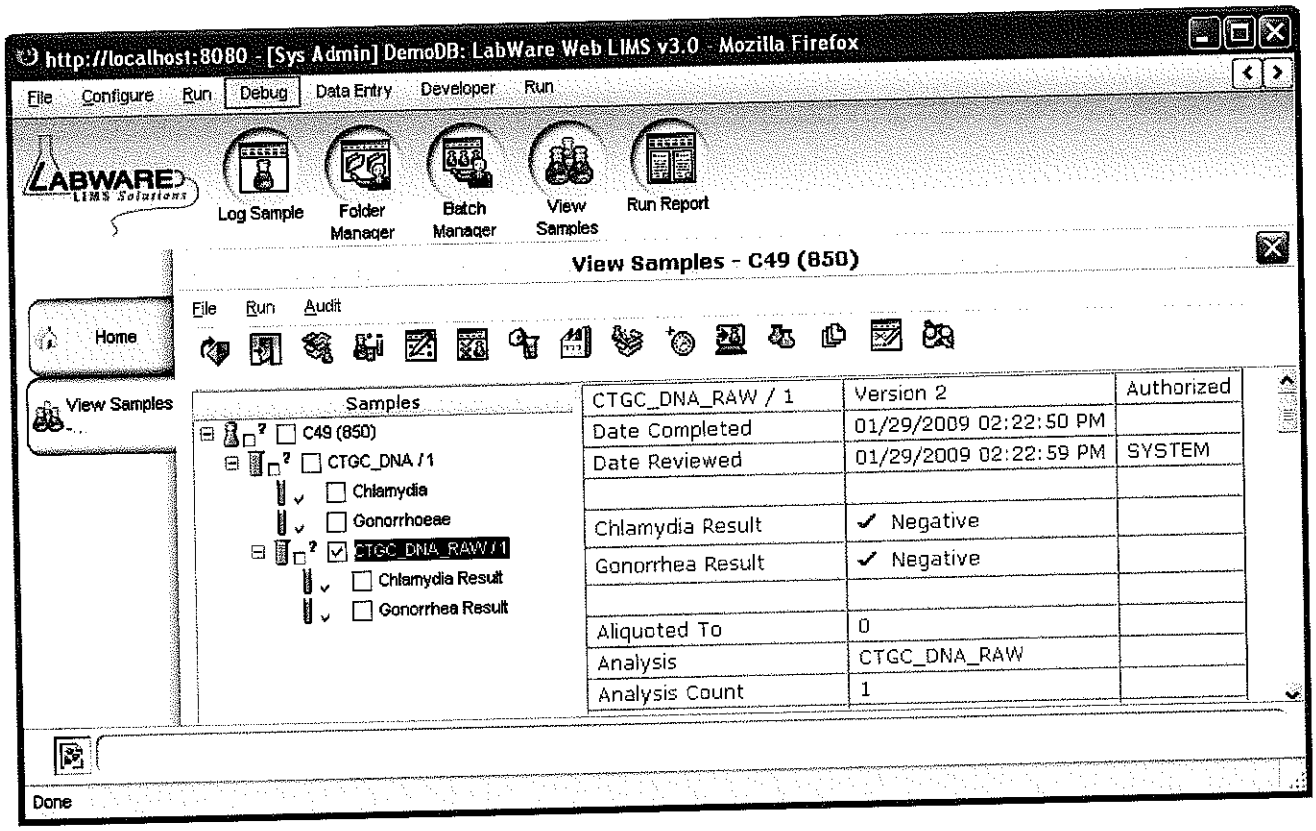
Patient: RENEE TROTTIER
3 MILL ROAD
Wilmington, DE, 19806

Accessing a Final Report when more than one Report exists will display a list. The user can view the appropriate report by selecting the row. The Report File Name column in the Sample Report Log view below displays the location of the Final Report PDF (i.e. C:\LW-EDSS-V5-PHL-TMP-1 4a\SecureReports\\2009\200901\...).

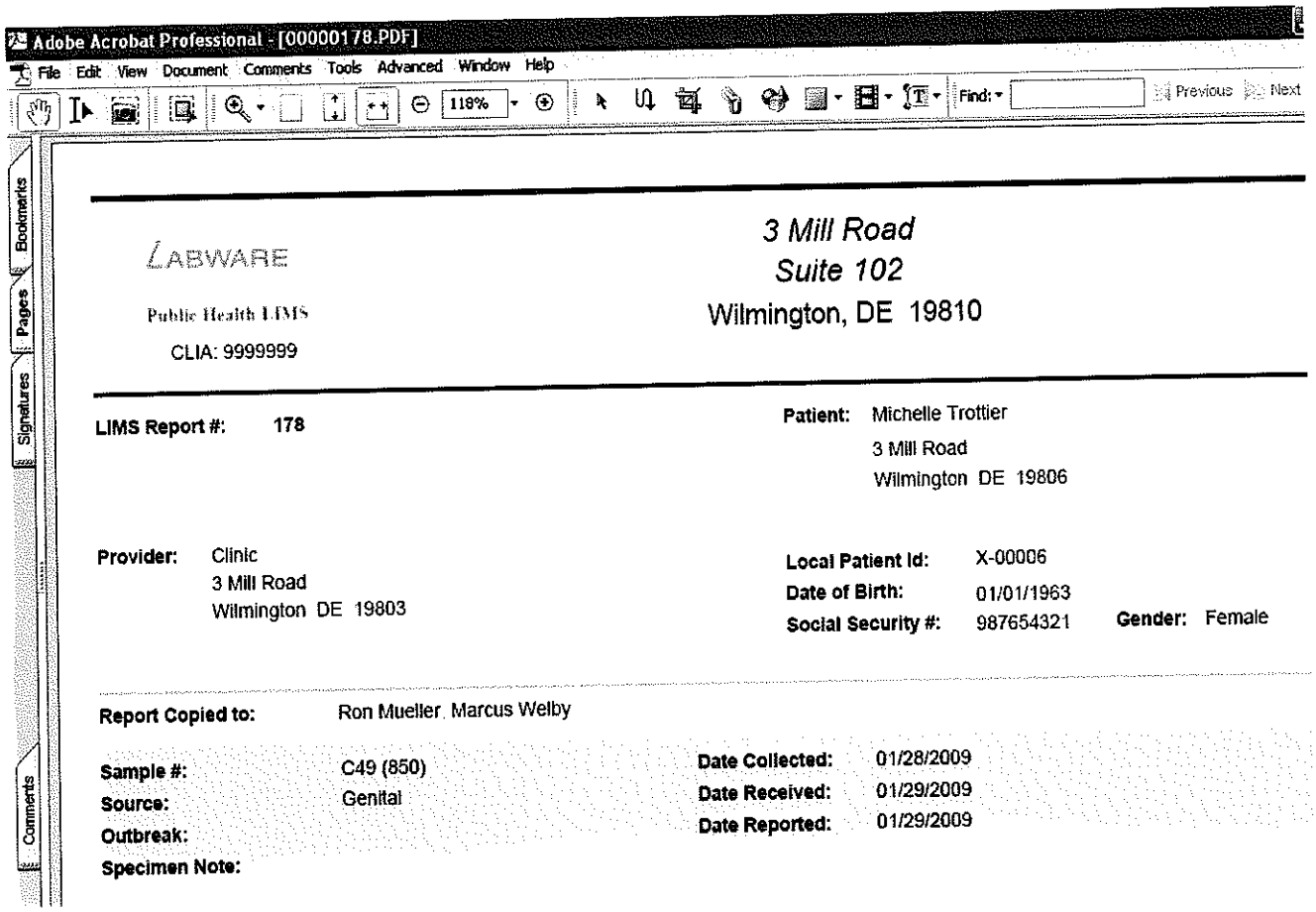


External User Online Access to Final Reports

External users can access LabWare EDSS via the web. Below is a screen capture of LabWare's WebEDSS running within Mozilla / Firefox. LabWare EDSS can run in any browser including Internet Explorer. In this case the sample view feature is displaying sample number C49 (850). To access the Final Report the sample is highlighted and the icon at the bottom left corner is selected. The Final Report is displayed within a PDF viewer.



Below is the Final Report displayed from within WebEDSS using the PDF browser plug-in.

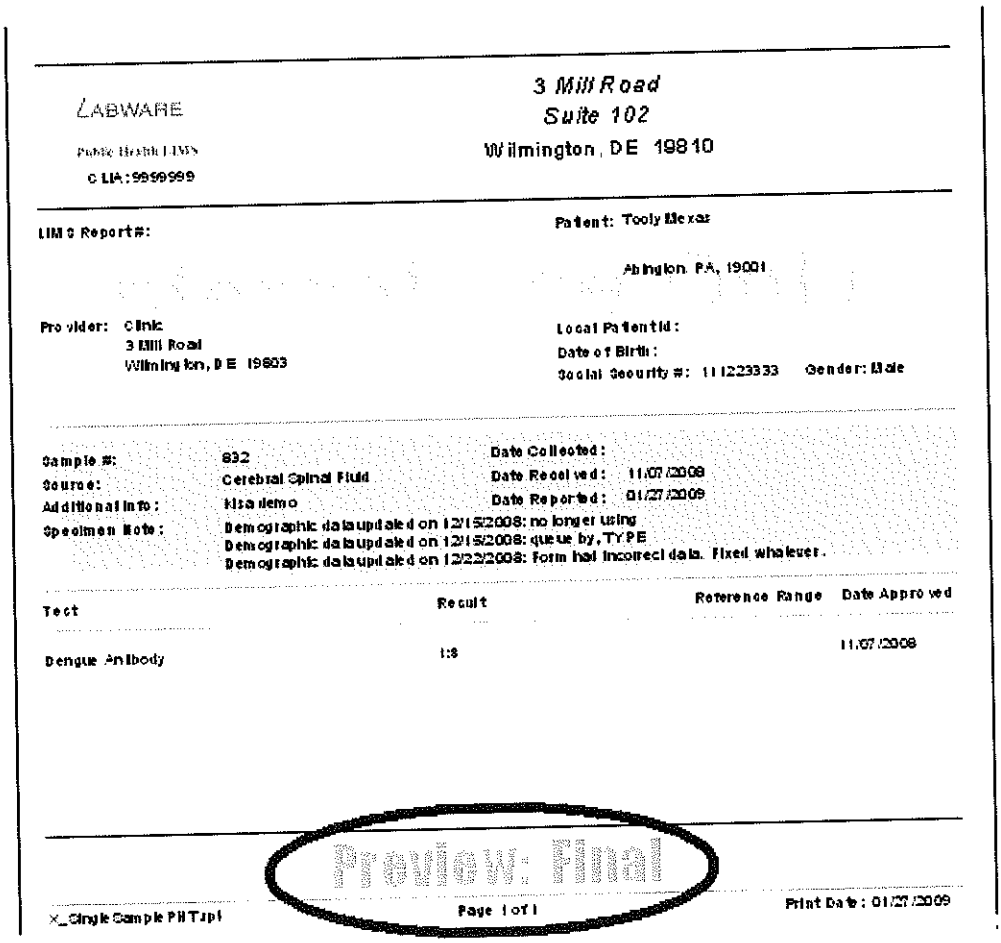


Report Information

The following section provides an overview of a few internal reports used to summarize Final Report information.

Preview Final Report

A user at anytime can preview a Final Report. The user is prompted for either the sample internal id or external id; once entered the report is generated. Only results marked reportable appear on the Preview Final Report. The Status at the bottom of the Final Report indicates it is a preview. Also, the report uses a water mark to indicate the Final Report is for internal use only.



LABWARE
Public Health LIMS
CLIA:9999999

3 Mill Road
Suite 102
Wilmington, DE 19810

LIMS Report#:

Patient: Tooly Mexar
Abington PA, 19001

Provider: Clinic
3 Mill Road
Wilmington, DE 19803

Local Patient Id:
Date of Birth:
Social Security #: 111223333 Gender: Male

Sample #:	832	Date Collected:	
Source:	Cerebral Spinal Fluid	Date Received:	11/07/2008
Additional Info:	kisa demo	Date Reported:	01/27/2009
Specimen Note:	Demographic data updated on 12/15/2008: no longer using Demographic data updated on 12/15/2008: queue by, TYPE Demographic data updated on 12/22/2008: Form had incorrect data. Fixed whatever.		

Test	Result	Reference Range	Date Approved
Dengue Antibody	1:8		11/07/2008

Preview: Final

X_Single Sample PHTxpl

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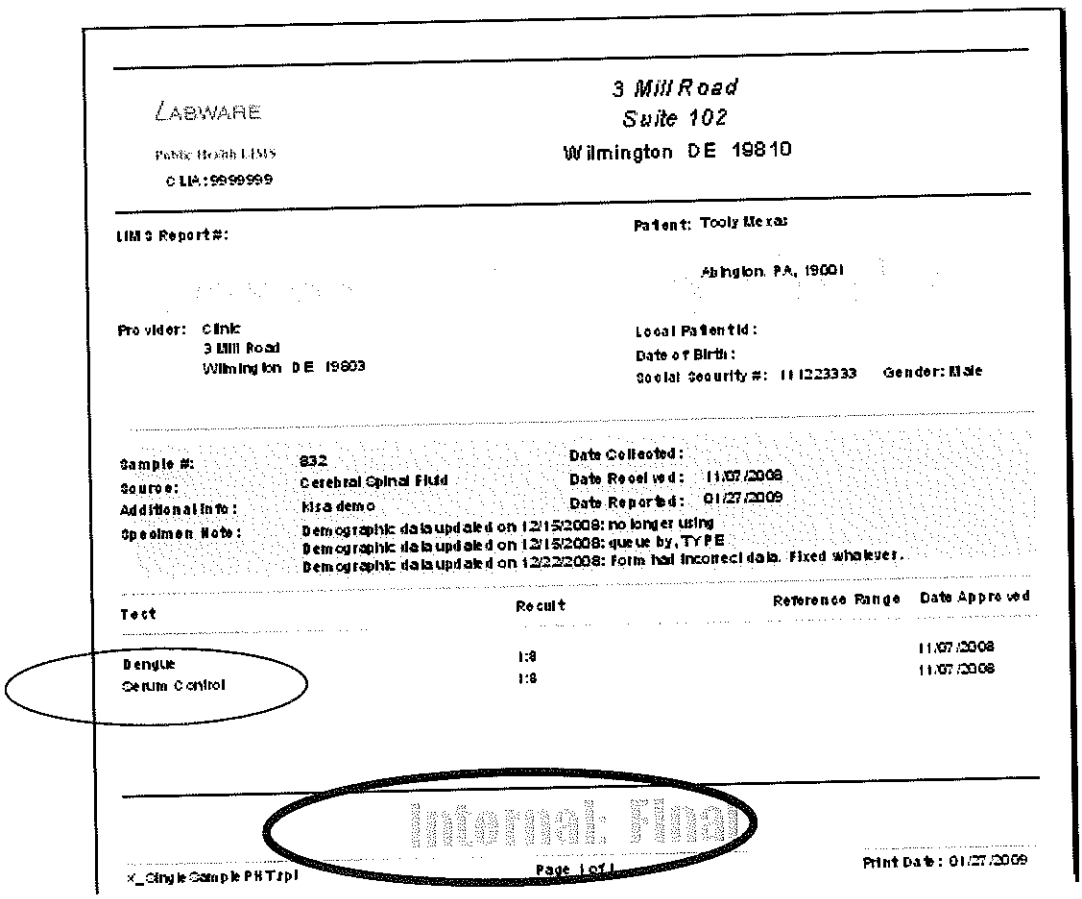
Print Date: 01/27/2009

Preview Internal Final Report

A user at anytime can preview the internal final report. The user is prompted for either the sample internal id or external id; once entered the report is generated. Both reportable and non-reportable test results appear on the Preview Internal Final Report. The Status at the bottom of the Final Report indicates it is internal. Also, the report uses a water mark to indicate the Final Report is for internal use only.



LABWARE
Public Health LIMS
CLIA:9999999

3 Mill Road
Suite 102
Wilmington DE 19810

LIMS Report#:

Patient: Tooly Mexas
Abington PA, 19001

Provider: Clinic
3 Mill Road
Wilmington DE 19803

Local Patient Id:
Date of Birth:
Social Security #: 111223333 Gender: Male

Sample #: 832
Source: Cerebral Spinal Fluid
Additional Info: lisa demo
Specimen Note: Demographic data updated on 12/15/2008: no longer using
Demographic data updated on 12/15/2008: queue by, TYPE
Demographic data updated on 12/22/2008: Form had incorrect data. Fixed whatever.

Date Collected:
Date Received: 11/07/2008
Date Reported: 01/27/2009

Test	Result	Reference Range	Date Approved
Dengue	1:8		11/07/2008
Serum Control	1:8		11/07/2008

Internal: Final

x_Single Sample PRT.rpt Page 1 of 1 Print Date: 01/27/2009

List samples ready to report

A report is included to display a summary of samples ready to be reported. The samples on the report are grouped according to report status Preliminary, Final, Corrected (Amended)).

LABWARE
Public Health LIMS

Samples Ready to Report
Submitter: DAVETROTTI
Lab: STD

Lab: STD

Corrected Reports

Submitter	Sample ID	Sample #	Date Collected	Patient
DAVETROTTI	S81	438	05/27/2008	Michelle Trottier
DAVETROTTI	S98	530	09/02/2008	RENEE TROTTIER

Final Reports

Submitter	Sample ID	Sample #	Date Collected	Patient
DAVETROTTI	S114	624	09/20/2008	Jerry Jones
DAVETROTTI	S115	625	10/01/2008	Julia Jones

Preliminary Reports

Submitter	Sample ID	Sample #	Date Collected	Patient
DAVETROTTI	S116	626		Too Mexas
DAVETROTTI	S113	623		Too Mexas
DAVETROTTI		274		Too Me

List of samples already reported

A report is included to display a summary of samples that have been reported. A sample is marked as Reported as part of the Final Report generation. The samples on the report are grouped by lab.

LABWARE
Public Health LIMS

Samples Reported

Date Reported: 01/01/2009 - 01/27/2009

Lab: Serology

Corrected

Submitter	Sample ID	Sample #	Date Reported	Patient Full Name
DAVETROTTI		832	01/27/2009	Tooly Mexas

Lab: STD

Final

Submitter	Sample ID	Sample #	Date Reported	Patient Full Name
DAVETROTTI	CTGC-0001	839	01/22/2009	RENEE TROTTIER
HOSPITAL-A	CTGC-0003	846	01/27/2009	Michelle Trottier

Corrected

Submitter	Sample ID	Sample #	Date Reported	Patient Full Name
HOSPITAL-A	CTGC-0002	842	01/27/2009	RENEE TROTTIER

5.4 HL7 Interface

Included with the LabWare application is the ability to send and receive HL7 messages. For public health HL7 has been used to receive orders, send orders, receive results and send results. The State of Florida Public health Lab has the most advanced deployment of LabWare HL7 functionality. Florida is using HL7 functionality for the following two purposes:

1. The majority of orders received by the lab from the clinics and results sent to their downstream partners (EPI, clinics, CDC) are via HL7. Receiving orders and sending results occur on an hourly basis.
2. Florida and Texas have formed a partnership for surge capacity utilizing electronic data exchange. A bi-directional ordering and resulting HL7 interface has been developed for use under surge conditions. Thus far, the interface is being used for interstate interoperability for real-time polymerase chain reaction (RT-PCR) analysis of seasonal and potentially pandemic influenza strains.

The processing of orders and results is typically an automated activity (in the background) with no user interaction. Only when an error occurs is a user required to manually process the HL7 message. Although rare, the processing of HL7 message can be done interactively. Processing of HL7 messages is the same whether it is done interactively or in the background. Below is a description of the interactive HL7 Interface.

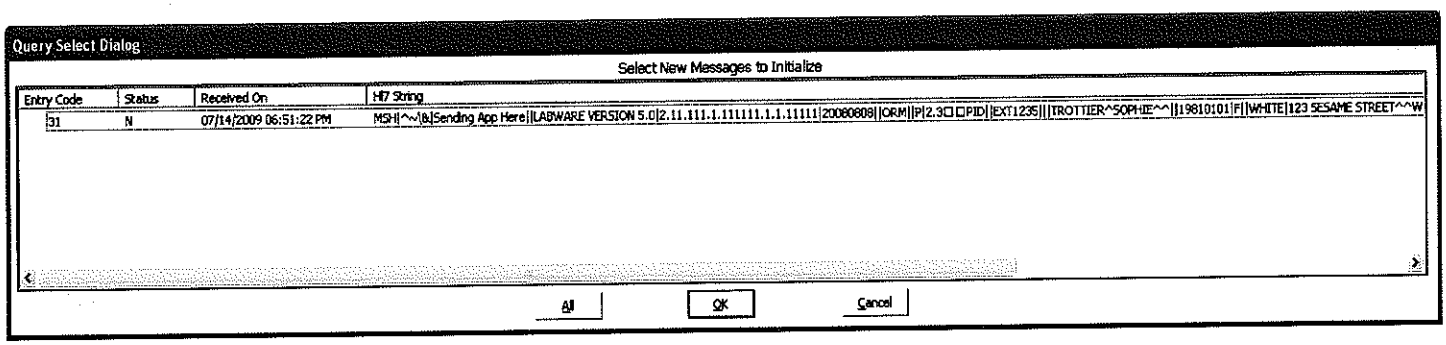
Receiving Orders

Initialize

The first step in receiving an order is called "Initialize". The purpose of initialization is to validate the content of message. A few examples are listed below.

- Validate receiving facility id
- Verify unique tube id
- Validate specimen source
- Ensure test ordered exists for each OBR segment

Manually selecting the initialize menu option will display the following dialog. Each row within the dialog represents an order. The selected order will be initialized. The status of the order when initialized will change from "N" to "P".



If an error occurs the status of the order changes from "N" to "E" and the order is queued for manual processing. A

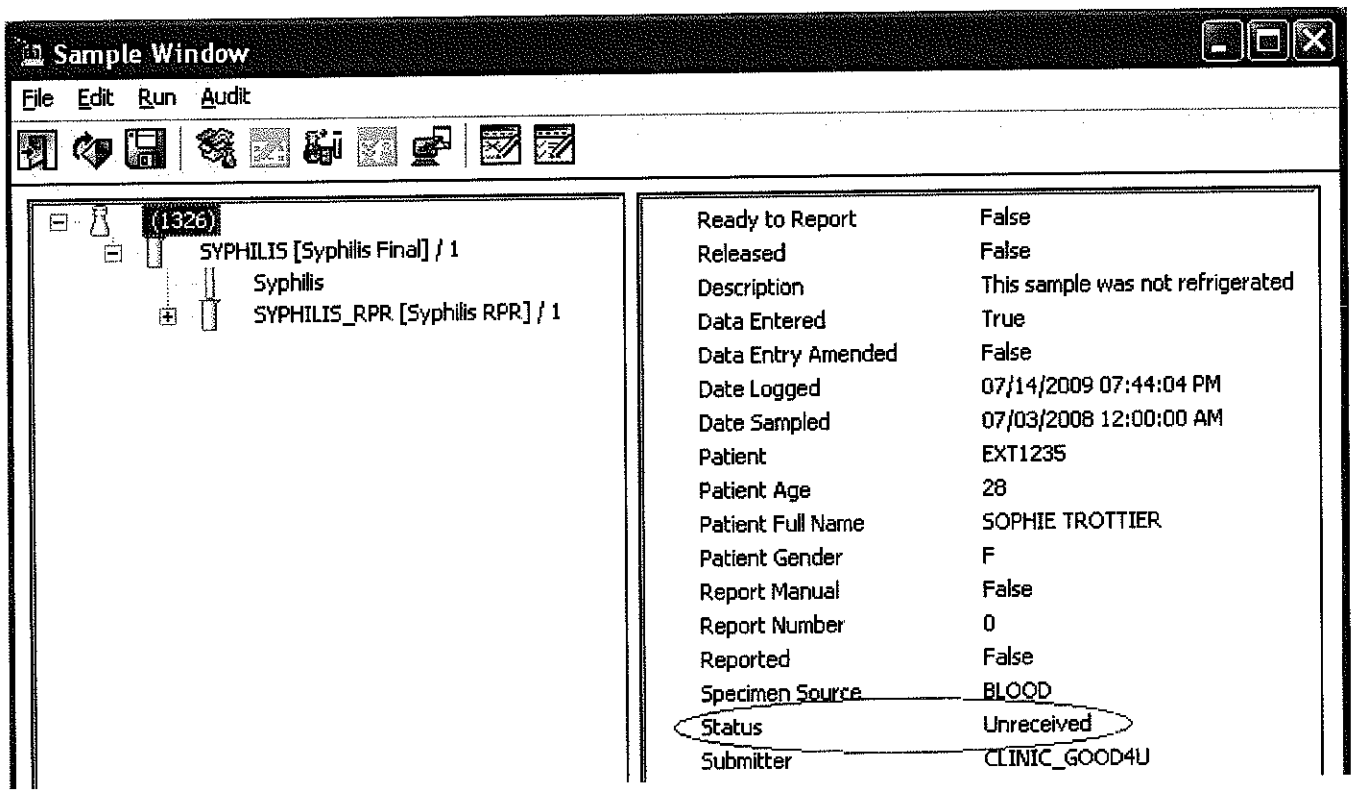
user has to view the error and determine if the order should continue to be processed or be rejected.

Process

The second step is called "Process" and is where the order is parses and the sample is logged. As part of sample login a patient is found that matches the Social Security Number (SSN), Date Of Birth (DOB), Last Name (LN), and First Letter of First Name (FLFN). If the SSN matches and the LN does not match then a partial match exists and the status of the order changes from "P" to "Q". If the SSN does not match and the LN does match then the same is true.

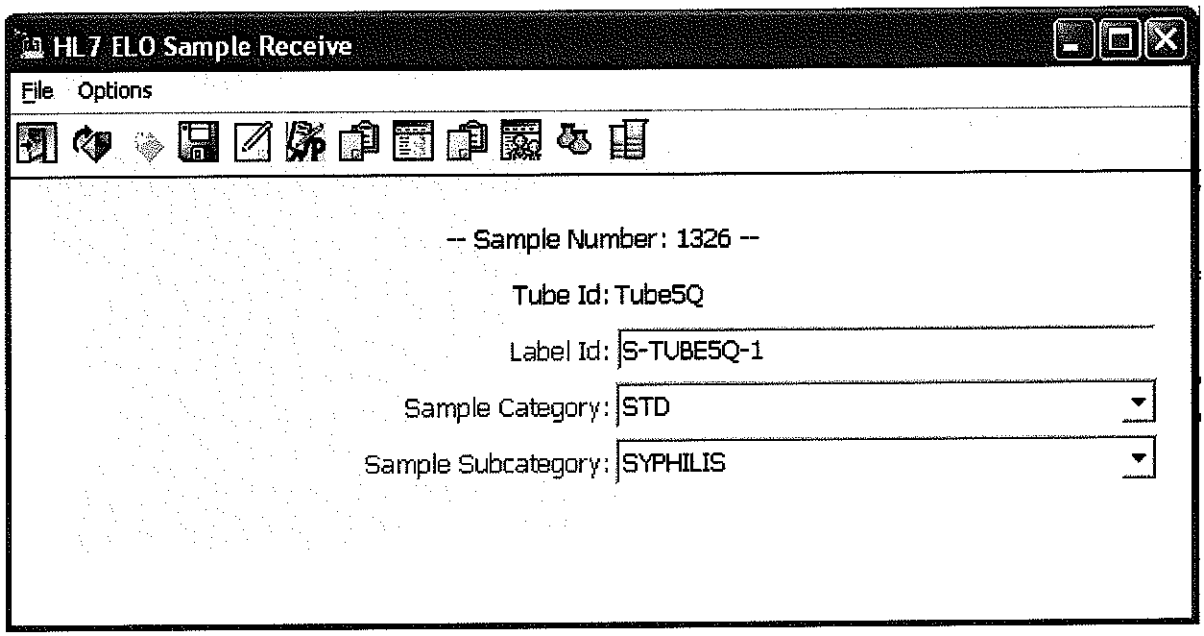
If a partial match occurs the order is queued for manual processing. A user has to view the error and determine if the order should continue to be processed or be rejected.

Below is a screen capture of the logged sample. The left pane displays the sample (1326), test (SYPHILIS), the result (Syphilis), and child test (SYPHILIS_RPR). The right pane displays sample field information when the sample is highlighted, test field information when the test is highlighted, and result field information when a result is highlighted. This status of the sample is Un-received indicating the specimen has not been delivered to the lab.



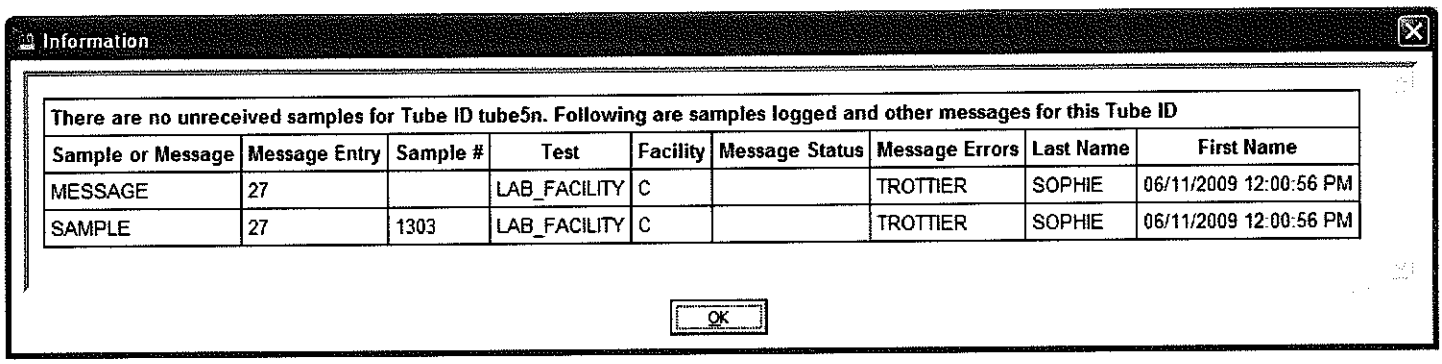
Receive Sample

The third step is called "Receive Sample" and is when the sample has been delivered. The dialog window below is display as part of receiving a specimen. The fields capture the unique label id (external identifier), sample category (lab section), sample subcategory (test type).

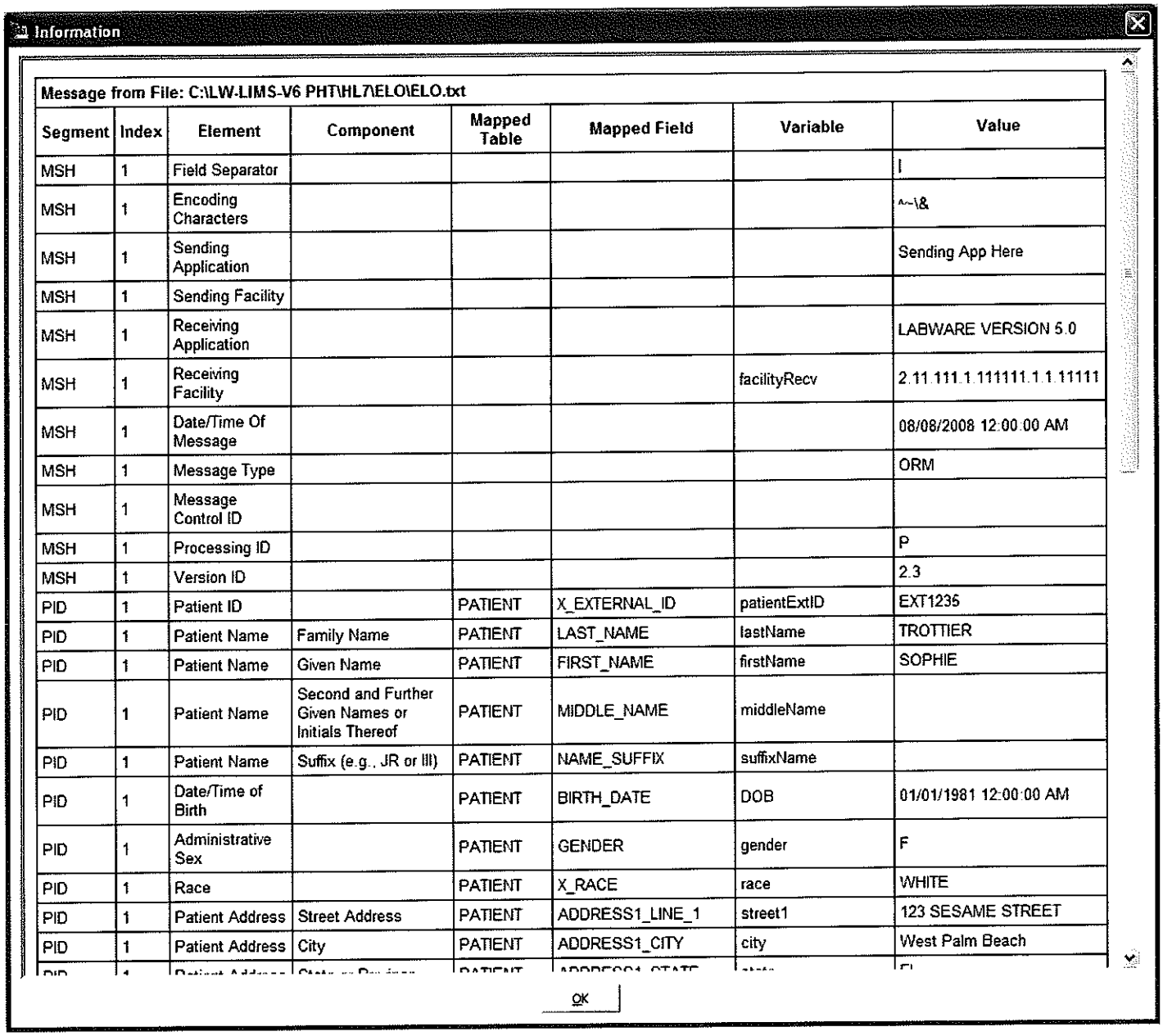


When received, the sample status changes from "Unreceived" to "Incomplete".

There is extensive error checking throughout the process. For example, below is an error message when trying to receive "tube5n". The message indicates the sample does exist, but it has already been received.



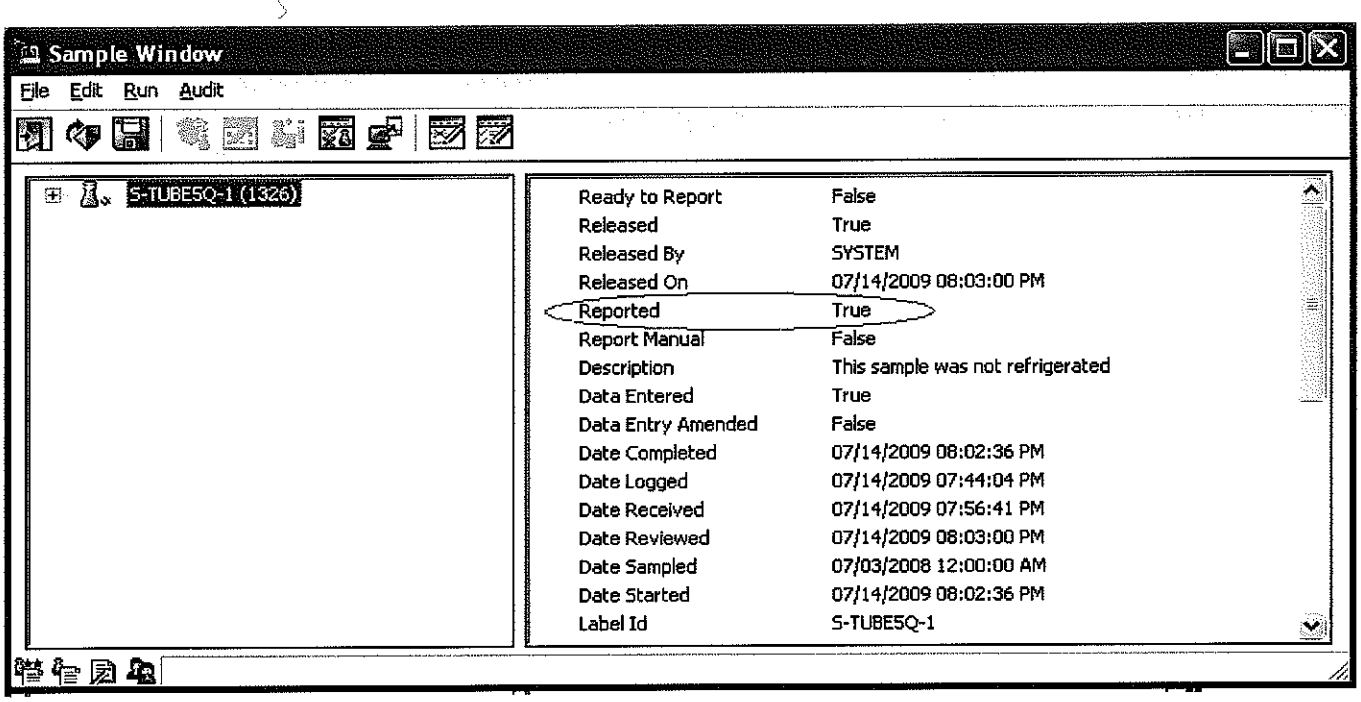
The following window displays the content of an order (ELO) and the mapping to the LabWare EDSS database. The display is used as a trouble shooting tool to verify the content of the HL7 message and its mapping to LabWare EDSS database fields are correct.



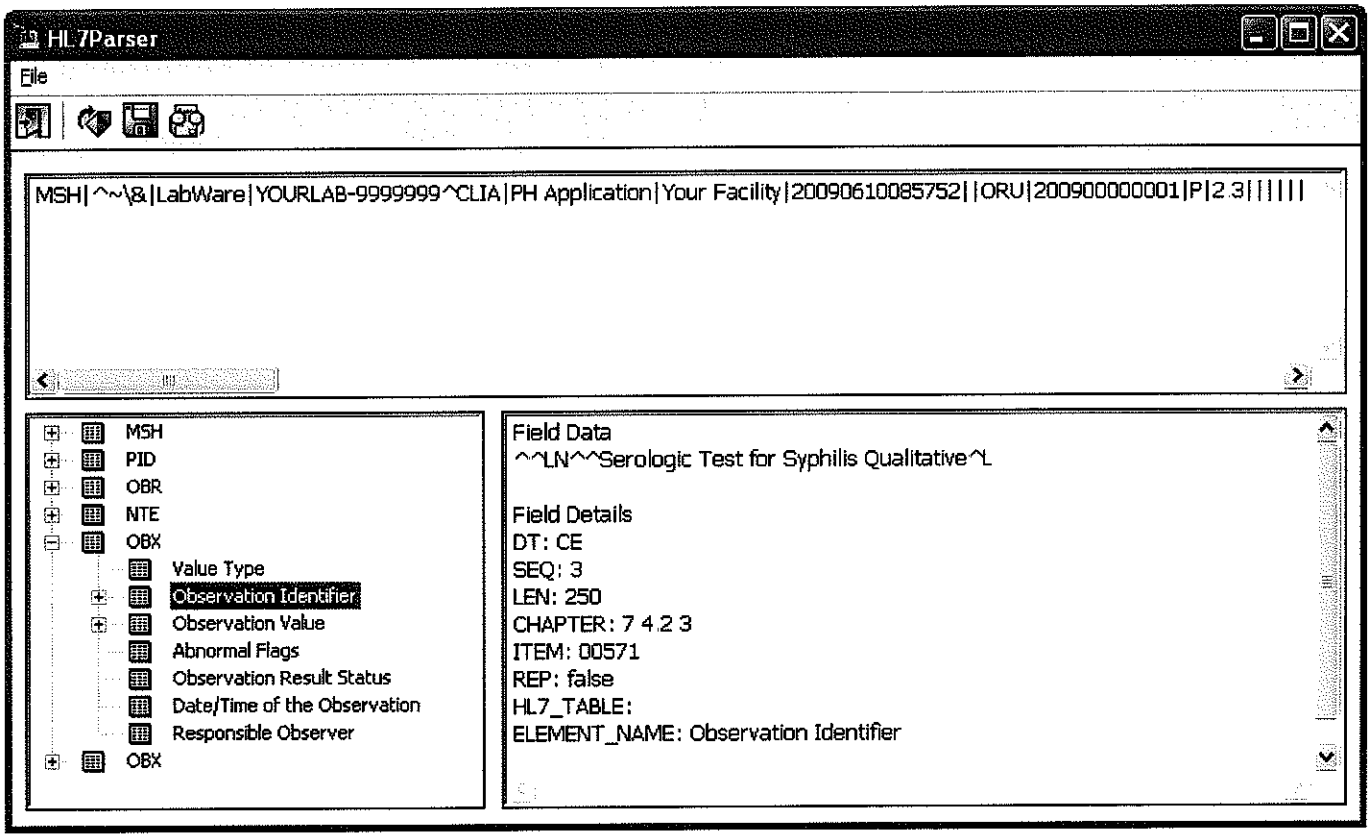
Segment	Index	Element	Component	Mapped Table	Mapped Field	Variable	Value
MSH	1	Field Separator					|
MSH	1	Encoding Characters					^~\&
MSH	1	Sending Application					Sending App Here
MSH	1	Sending Facility					
MSH	1	Receiving Application					LABWARE VERSION 5.0
MSH	1	Receiving Facility				facilityRecv	2.11.111.1.111111.1.1.11111
MSH	1	Date/Time Of Message					08/08/2008 12:00:00 AM
MSH	1	Message Type					ORM
MSH	1	Message Control ID					
MSH	1	Processing ID					P
MSH	1	Version ID					2.3
PID	1	Patient ID		PATIENT	X_EXTERNAL_ID	patientExtID	EXT1235
PID	1	Patient Name	Family Name	PATIENT	LAST_NAME	lastName	TROTTIER
PID	1	Patient Name	Given Name	PATIENT	FIRST_NAME	firstName	SOPHIE
PID	1	Patient Name	Second and Further Given Names or Initials Thereof	PATIENT	MIDDLE_NAME	middleName	
PID	1	Patient Name	Suffix (e.g., JR or III)	PATIENT	NAME_SUFFIX	suffixName	
PID	1	Date/Time of Birth		PATIENT	BIRTH_DATE	DOB	01/01/1981 12:00:00 AM
PID	1	Administrative Sex		PATIENT	GENDER	gender	F
PID	1	Race		PATIENT	X_RACE	race	WHITE
PID	1	Patient Address	Street Address	PATIENT	ADDRESS1_LINE_1	street1	123 SESAME STREET
PID	1	Patient Address	City	PATIENT	ADDRESS1_CITY	city	West Palm Beach

Sending Results

Only after the Final Report has been generated and the sample reported flag is set to True are the results ready to be sent via the HL7 interface.



Below is the HL7 message parser. The parser is a tool to display an HL7 message and parse the message for viewing. The top pane displays the HL7 message. The bottom left pane displays the HL7 message segments and their element names. The bottom right pane displays the values associated with the element names.



The **File** menu on the HL7 parser interface provides the user with the following functions.

Open	Open an HL7 message
Parse	Parse the content of the HL7 message
Save	Save the HL7 message
Exit	Exit the HL7 parser

5.5 LabWare EDSS Architecture

LabWare EDSS Components

Software Components provided by LabWare

Application Folder	The application folder contains the executables and any other files that are needed for execution of the EDSS application. This folder is typically installed on a file server and marked as read-only.
Working Folder	The working folder contains files of a temporary nature. Each EDSS application server process needs its own working folder.
Database	The database contains not only the specimen/test/result data but also the configuration data. LabWare EDSS supports ODBC-compliant database products. The database product is selected and provided by the customer, and it is typically installed on a dedicated database server.
Web Application Server	The Web application server is J2EE-based software that provides a web user interface to EDSS. It manages connections to HTTP web clients (browsers), to the EDSS application, and to the database. It is typically installed on a dedicated or shared web server.

Third Party Software

Operating System	The EDSS application runs on the Microsoft Windows operating system. This means that Microsoft Windows must be installed on any server that runs the EDSS application. If the application files are installed on a file server, the file server may run any operating system, as long as the applications files are accessible to Microsoft Windows computers. As far as the database server is concerned, the customer may choose any operating system that is supported by the supplier of the database engine. The most common operating systems are Unix for Oracle databases and Windows for SQL Server databases.
ODBC Driver	In order to enable the connection between the EDSS application and the database, an ODBC Version 3 driver needs to be installed on each computer that runs the EDSS application. LabWare recommends that such a driver be obtained from the supplier of the database engine.
Database Engine	LabWare supports the use of multi-user database engines that can be accessed via an ODBC driver. The most common database engines in use across our customer base are Oracle and SQL Server. Examples of other databases are Informix, DB2, and Sybase. LabWare encourages the use of Microsoft Access for development purposes but does not support its use in a production environment.
HTML Browser	All deployment options require an HTML browser such as Microsoft Internet Explorer or Firefox. When the web deployment option is used, the entire EDSS application is accessed using a browser.
J2EE Environment	The Web application server is J2EE-based software. It requires the presence of a J2EE runtime environment such as Tomcat, Orion or WebSphere.

Third Party Software for which LabWare provides an interface

LabWare provides various interfaces to third party software products. Use of these interfaces is optional. Each interface, if used, requires certain third party software to be installed on the same computer on which EDSS is installed, as specified below. For web deployment, the software needs to be installed on the EDSS Application Server.

Crystal Reports	LabWare encourages the use of Crystal Reports for generating reports. The Crystal Reports runtime files must be installed on any computer that will generate such reports. LabWare recommends the use of Crystal Reports Professional for designing such reports.
Adobe Acrobat	LabWare provides tools for creating electronic analytical worksheets and for saving reports in Portable Document Format (PDF). The full Adobe Acrobat product needs to be installed on any computer that will be used for creating or modifying such worksheets and/or for saving PDF reports. The Adobe Acrobat Reader product is sufficient for those computers that will have read-only access to worksheets and reports.
Electronic Mail	LabWare provides tools for sending email messages from EDSS. LabWare supports the MAPI and VIM interfaces and also provides an interface to the Lotus Notes product. The Lotus Notes client or an email client that implements the MAPI or VIM interface must be installed on any computer from which email messages will be sent.
Microsoft Office	LabWare provides tools for creating reports using Microsoft Word and/or Microsoft Excel. Microsoft Office must be installed on any computer that will generate such reports.

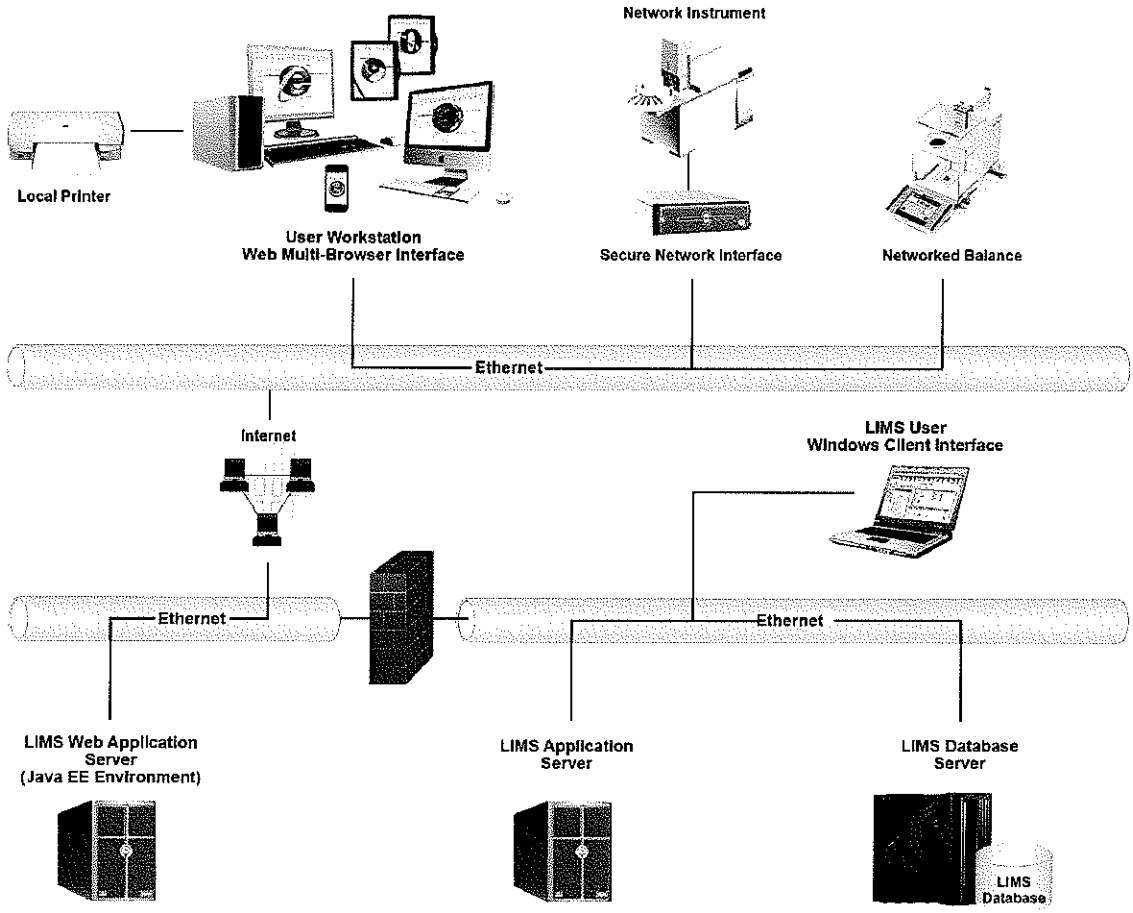
Hardware Components

LabWare does not provide hardware. All hardware components must be obtained from a third party vendor.

Workstation	A workstation is a computer that is used by a user to access the EDSS application.
File Server	The file server is a computer on which the EDSS Application Folder is installed. The only requirement for this computer is that files must be accessible to Microsoft Windows computers by mapping a drive letter or by using UNC file paths.
Database Server	The database server is a computer on which an ODBC-compliant database product is installed.
Web Application Server	The web server is a computer on which the EDSS JAVA code is installed.
EDSS Application Server	The application server is a computer that runs LabWare EDSS for the purpose of satisfying requests from a Web Application Server.

Web Deployment Using the Web Application Server – Network Diagram

The diagram below shows a web implementation of LabWare EDSS that uses the LabWare Web Application Server.



The EDSS Application Server and the Database Server reside within the corporate firewall. All communications with users via the internet are handled by the J2EE Web application server which is located outside the firewall. Users access the application via any HTML web browser that supports JavaScript. Reports and labels can be printed from using such devices, as well.

Web Deployment – Hardware/Software Cross-Reference Table

	Workstation	Database Server	Web Application Server	EDSS Application Server
Software Provided by LabWare				
Application Folder				☐
Working Folder				☐
Database		☐		
Web Interface				☐
Third Party Software				
Microsoft Windows				☐
ODBC Driver				☐
Database Engine		☐		
HTML Browser	☐			
Interfaced Third Party Software				
Crystal Reports				☐
Adobe Acrobat				☐
Electronic Mail API				☐
Microsoft Office				☐
Where software executes				
Runs EDSS				☐
Runs Interfaced Software				☐
Runs Database Engine		☐		
Runs J2EE Web Interface			☐	

5.6 Delaware Article

A Message from the President

Tech Matters: Changing the Lab World

APHL and CDC have launched a program—the Public Health Laboratory Interoperability Project (PHLIP)—that promises to change the way we do business. Just as laboratory information management systems (LIMS) have revolutionized operations on the state-scale, PHLIP aims to link us nationally and give us fluid electronic dialogue among all labs and CDC. (See page three to learn more.) The possibilities are incredible. If we examine the way former technological advances have changed our world, PHLIP becomes even more exciting.

The effect of a good LIMS is perhaps the best herald to the benefits PHLIP may reap. Delaware's new LIMS has been a *huge* advance. We thought it would save us personnel time and effort—and it does—but it has improved the *quality* of our work immeasurably. There is no more duplicative data entry with copying and perhaps miscopying information. Data go directly from the instrument, to LIMS, to the report. Submitters enter specimen information directly into LIMS. As soon as tests are completed, results are available to the submitter. This service is provided to other state agencies, clinic-based health centers and soon to hospital laboratories. All of our quality data are right there in LIMS, automatically. We don't lose specimens in the courier van: we know it's on its way, and if we don't get it, we go look for it. All of our SOPs are online and are much easier to update—which, of course, helps us meet CLIA requirements. Our inventory management has improved. It has streamlined our lab operations.

The initial success we have enjoyed with the LIMS has encouraged us to spend a lot of money to get our newborn screening system onto the Web. We will be able to store each child's data, track the specimen from the hospital to the lab and tie it all together with the birth certificate, hospital identification and immunizations. We are *not* going to lose that blood spot! Having the test results available online for doctors will eliminate delays in getting treatment to a baby. This real-time reporting of results can make a huge difference in the quality of a child's life.

With LIMS, it has become easier to direct public health activities and treatment options toward clusters of positive results. All reportable disease results go automatically to our Epidemiology Office for follow-up. I often need to know: *How many of that test have we performed? How many results were positive? Where did they come from?* The data are available. It took me moments this year to check which of the state's influenza sentinel physicians were actually submitting specimens. Only two of the ten physicians had sent us anything at all; it was clearly time to get on the phone to find out what was going on.

Now imagine all of this on a national scale.

These advances all have a price—literally. It's expensive. The Delaware lab used bioterrorism grant money to implement a LIMS, as others have done. As we rely more and more on APHL, not only to assist us with our technological advances but also to provide us with more technology-based services and support, we must ask how the association can absorb the financial impact. APHL's Finance Committee has begun to discuss a number of issues, including the fact that key member programs are not fully funded by CDC (leading to a projected deficit) and that the current strategic plan calls for greater investment in public policy, communications, technology and workforce development, areas that are not historically funded through the cooperative agreement. The committee is beginning to explore financial options, which include the possibility of a dues increase. This discussion is in its infancy, and we welcome feedback and ideas from the rest of the membership.

As scientists, we should embrace the electronic age completely. A few years from now, people will wonder how we ever managed without instant, electronic data transmission with CDC. Tackling these expensive propositions with our public health budgets is daunting at best, but a can-do spirit has reaped immense benefit for us all in recent years. Teamwork, creativity and dedication often manage to trump the financial bottom line. Fortunately, those are all resources that APHL has tenfold.

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