How Harvest Supports Molecular & Toxicology Testing

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Orchard Software Symposium
June 17-18, 2015
Learning Objectives

• At the conclusion of this session, the participant will:
  – Understand how Harvest LIS can support molecular testing
  – Understand how Harvest LIS can support toxicology testing
Batch Processing

• How can you leverage patient-centric LIS to manage batch processing?
MDx Testing – It’s Not One Size Fits All

• PCR (polymerase chain reaction)
• FISH (fluorescence in situ hybridization) and its cousin CISH (chromogenic in situ hybridization)
• IHC (special staining in the pathology lab)
• DA microarray
• DNA sequencing
How Harvest LIS Can Help

- Use **Load Lists** to create batches and plate maps
- **Text Shortcuts** to log master mix information
- Configure **Statuses** to map your workflow
- **WIP Pivot View** for ease of result review
- Add **Linked Images** to your report
- **Interface** up to the capability of your analyzers
- Data is **discrete** and **mineable**
Creating a Load List

• Add “Load List by Order Choice” to your Work Centers toolbar

• Click on “Instruments” at the top of your home screen
• Tests can be selected individually or in batch
• Tests can be filtered by status
Move Testing Onto Your List

![Image of software interface]

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Preview Tab to View Plate Map
• Graphical representation of your Load List
• Create templates for your plates
• Harvest LIS will add samples to the plate map in the orientation you configure
More Options on the Load List Window

- Use comments section to record Master Mix information
- Create Load List ID
- Load Lists can be:
  - Exported
  - Printed
  - Recalled
  - Saved
Master Mix Text Shortcut

• Type your text shortcut into the comment box

• Record pertinent information for Master Mix
Text Shortcut With Variables

[Image of a computer screen showing a software interface for a load list by order choice with variables and shortcut values]

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• Master Mix
  – Eliminate paper logs
  – Information is stored and saved electronically
  – Information associated with batch
Text Shortcut Setup

- File
  - Table Setup
- Text Shortcuts
Text Shortcut Setup

- Click **New** button
- Assign
  - Shortcut keys
  - Shortcut group
  - Shortcut text
Text Shortcut Setup

• Click **Test** button to try out your new shortcut

• Remember **/help** if you forget
Load List Processing Summary

• Use Harvest LIS tools to create “form entry” for Molecular
• Reduce binder overpopulation
• Help Molecular departments use Harvest LIS to assemble information
Use Statuses to Organize Workflow

- Examples:
  - Molecular
  - Flow Cytometry
  - PCR
  - Amplification
  - Extraction
WIP Pivot View

• At-a-glance view of:
  – Testing performed
  – Comparison of results
  – Complete vs. not complete
WIP Pivot View: Why?

• Side-by-side comparison of test results
  – Comparison of results for evaluation
  – Duplicate runs

• Spreadsheet look and feel
Molecular Report Using AP Module

- **Add images to report**
- **All data is discrete and mineable**
- **Use rules to differentiate abnormal result findings**

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**Final Molecular Pathology Report**

**Specimen Type:** Formalin-fixed, paraffin-embedded, 4μm

**Indication for Study:** Bladder cancer

**FISH Panels:**
- Commeneq 2, 3, 4, 5, 7, 9, 11, 12, 13, 17, 18, 21, 22
- Extra copies of 3p, 5q, and 17q

**Interphase Nuclei Scored:** 200

**Results:**

**POSITIVE for the 3q, 5q, and 17q copies. Normal for the 9p21 probe.**

**FISH Interpretation:**

Molecular detection of abnormality for chromosomes 3, 5, 7, 11, and the loss of 9p21 was performed by fluorescence in situ hybridization (FISH) using the Vyysis LSI dual-color interphase fluorescence in situ hybridization (FISH) probe set. The probe set was designed to detect abnormalities of these chromosomes and the loss of 9p21.

Suppression of the 3q, 5q, and 17q copies is observed, indicating the presence of an abnormality.

**Patient Result:**

**FISH POSITIVE (BLOWOUT)**

(Additional comments: a gain of these chromosomes is seen in 4 out of 5 cases, and a decrease in the loss of 9p21 is seen in 7 out of 8 cases)

**Comment:**

The assay is designed to detect abnormalities in chromosomes 3, 5, 7, 11, 12, and 17, as well as loss of 9p21. The performance of this test has been validated by the laboratory. The results are intended for use in clinical practice.

**Pathologist:**

Kare Lund, M.D., Pathologist

**Sample:** 106-62-21

**Review:**

Reviewed by: [Signature]

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Let’s Move from Molecular to Toxicology

• Similar workflow management
• Batch processes
• Ever-increasing number of molecular toxicology tests
Let’s Talk Toxicology

- New Harvest LIS v10 Medications Table
- Load lists for manual plate map setup
- Rules, rules, rules to manage orders, results, and reporting
- Data mining using our ad hoc report writer
New Medications Table

- Contains a current list of all medications in the Harvest LIS database.
- Allows users to edit, add, inactivate, and add notes to the medications list.
Medications Table Setup

• File
  – Table Setup
    • Medications
• In addition to manually entering medications and aliases, there is an option to **import** these items.

• **Custom list** can be imported or…

• The Medications table can import the 26.5MB **National Drug Code (NDC)** file available from FDA.gov that has 86,746 entries.
Import Alias File

- Open the file explorer.
- Navigate to the directory containing the alias files.
- Select the file to import.
- In the import window, choose the option to import medication aliases.
- Click 'OK' to proceed.

Alert: Medication Aliases: 2646 records were imported; 15 were rejected.
Medications Table Setup

- Medications can be assigned:
  - Name
  - Class
  - Alias
  - Marked as “Common”
  - Linked to a lab test
Medication Class Setup

- Each medication can be assigned to a **Class**
- Classes can be added as needed using the + button.
- Drop-down to set Class

![Medication Class Setup](image_url)
Mark Medication as Common

- Mark the **Common** checkbox
- If marked, the medication will appear on the Common tab when adding medication information to an order
Assigning An Alias

• Click the **Aliases** button to open the Aliases window
Medication Alias Setup

Each Medication can be assigned none, one, or many Aliases.
• Aliases can be brand name, common name, street name, code numbers, or anything else used to refer to the medication.

• Alias is a searchable attribute when adding medication to patient orders.
• Click the **Tests** button to display a read-only list of the lab test(s) that the medication is linked to.

• Linking of medications to lab tests takes place in the **Lab Tests table**.
Linking a Lab Test

- File
  - Table Setup
- Lab Tests
Linking a Lab Test

- Select the appropriate lab test
- Click the Medications button to link
• Orders can be entered manually

OR

• Orders can be received electronically
  • Ability to send and receive a patient’s current medications in HL7 messages
OPS has a button for adding medications to the order.
Adding Medications to an Order

- If a test with a tied medication is ordered and the user does not use the button to enter meds, the system can be set to prompt.
- “Search” field will look up medication by name or any assigned alias.
Adding Medications to an Order

- **Previous tab** is always present
- Tab that appears by default can be defined by ACO
- Displays all meds that have been ordered for this patient based on a **range of time**
- Defaults to one year, but can be changed via ACO or by altering the number in the text box
Adding Medications to an Order

- The **All tab** displays every known active medication based on alias.

- This means there can be many duplicate medications in this list, but under a different alias.

- Once one alias is selected, any other aliases are grayed out as they are the same medication.

- The selected medications list will display the medication name and beside it show the alias the user selected in parentheses.

- Medication name stored on the order will be by the table entry name, not alias.
Adding Medications to an Order

• All tabs after Previous and All are dynamically built based on user-defined medication classes

• Each tab is named based on the linked classes to active medications

• If all medications containing a given class are inactive, the class will not be listed as one of the tabs

• All medications within each of these tabs are based on the associated class

• The option to add additional favorite or client-specific tabs is expected to be added in a later build
Kit Screen Testing

"Where’s the washroom? I need to detoxify."

© Mike Baldwin / Comstock
More Order Entry Options

- **Use clinical info questions** to capture test kit screening results performed at the physician’s office
- **Click on the Clinical Info button** to enter results
Clinical Information Questions

- Answers can be set as required or optional
- Information can be added to the patient results
- Clinical information can be received electronically via HL7
Clinical Information Setup

- File
  - Table Setup
    - Clinical Info
Clinical Info Question Setup

- Info can be tied to a test
- Default answers can be defined
- Answer types can be:
  - Free-form text
  - Multiselect
  - Numerical
  - Pre-defined
• Configure **Statuses** to organize workflow
• Examples:
  – Tox screening
  – Tox confirmatory
  – Tox molecular
  – Supervisory review
Review Results

- Use thresholds to interpret numerical data as < or >
- Use rules to interpret data as consistent or inconsistent with current medications

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Let’s Take a Look

- This patient is currently taking Hydrocodone
- Our “expected positive” is Hydrocodone
- We have no inconsistent results...yet
**What’s the “Truth”**

**Drug: Hydrocodone**

**Metabolites: Hydromorphone, dihydrocodeine**

<table>
<thead>
<tr>
<th>Hydrocodone</th>
<th>Hydromorphone</th>
<th>Dihydrocodeine</th>
<th>Outcome</th>
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### Result Evaluation Rule Triggers

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Sample ID</th>
<th>Test</th>
<th>&lt; &gt;</th>
<th>Result</th>
<th>Test Result</th>
<th>Units</th>
<th>Ranges</th>
<th>Origin</th>
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<tbody>
<tr>
<td>Saunders, Tom</td>
<td>K0325141510</td>
<td>Medications</td>
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Result Evaluation Rule Setup

• File
  – Table Setup
• Rules - Result Evaluation
Define Your Conditions
Define Your Actions
Reflex Confirmatory Testing Via Rule

- Methamphetamine result is inconsistent
- Result evaluation rule triggers D-L isomer testing to reference lab

<table>
<thead>
<tr>
<th>Patient Name</th>
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</table>
# Auto-generate Reference Lab Requisition

## Laboratory Requisition

### Order Sent To:
**Quest Diagnostics**  
7774 West Main St.  
Camel, IN 460330009

### Order Information:
- **Sample ID:** R1001535044  
- **Collection Date:** 3/5/2015  
- **ABN Status:** Not applicable  
- **Fasting No.:**  
- **Enc.:**

### Guarantor:

### Patient Information:
- **Name:** Saunders, Ford  
- **Patient ID:**  
- **Sex:** M  
- **DOB:** 9/26/1969  
- **SSN:**  
- **Phone:** (209) 155-4872  
- **Address:** 6450 Maple St.  
- **Bloomington, IN 474010000

### Comments:

### Ordered Items:

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<th>Rout Code</th>
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| 00143    | Metanephrines  
           | Urine Cup  
           | 41        | Insurance  
           | QUEST RF20G |

### Authorized Signature:  
**Printed on:** May 9, 2015  
**Page:** 1

### Authorization Date:
Define Rule Condition
Define Rule Action
More Rule Fun—Specimen Validity

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More Rule Fun—Specimen Validity

- Trigger pop-up instructions
- Move result to “tox review” status

```
Toxicology Comprehensive (X14-00092): Specimen is Invalid, Cancel all testing and document provider notification in patient report.
```
Define Condition
Define Actions

![Diagram of Define Actions interface with specific settings highlighted.](image)

**Orchard Software Symposium – June 17-18, 2015 – Orlando, Florida**
Don’t Forget Load Lists

- Same functionality as for molecular
- Great for *manual* setup of plate map
- We interface up to the capability of the analyzer
  - Liquid handlers typically do not interface well with our plate map
What About QC?

- Great for capturing EIA screening testing
What About QC?

• Mass Spec Analyzer
  – Chromatographs cannot transmit to LIS
  – LIS can capture numerical data and serve as a secondary repository
Data Mining

- Access Result Browser via your Work Centers toolbar
- Click “Laboratory” at the top of your home screen
Browser Setup

- Select **tests**
- Apply a **date range**
- Select **optional columns**
- Set **schedule** and **output options**
Consistent vs. Inconsistent Results
Filter Inconsistent Results by Provider

![Screenshot of a software interface showing a table with patient data and results. The data includes fields for Patient Name, DOB, Test, Text Result, Collection Date, and Provider. The interface is used to filter and display results consistent with medication intake.](image-url)
Graph Data by Test
We Don’t Hold Your Data Hostage

Export

Email

Print
Learning Objectives Review

- Understand how Harvest LIS can support molecular testing
- Understand how Harvest LIS can support toxicology testing
# Upcoming Training Classes

## 2015 Training Classes

<table>
<thead>
<tr>
<th>Course Name</th>
<th>Start Date</th>
<th>End Date</th>
<th>Course Close Date</th>
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<td>8/3/2015</td>
<td>8/7/2015</td>
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Day 2 P.A.C.E.® Program Information

- **P.A.C.E.® Provider Number:** 526
- **Program Number:** 526-902-15
- **Program Title:** Day 2 Orchard Symposium 2015
- **Speakers:** Nancy Stoker, Dr. Michael Glant, Ginger Wooster, David Bracewell, Beth Eder, Ben Bush, John Wallihan, Jacob Eickhoff, Wendy Forgey, Ryan Howard
- **Contact Hours:** 4
Questions?

Thank you!