

# **AUTOMATION OF FLOW CYTOMETRIC ANTIBODY SCREENING AND REPORTING**

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## **INTRODUCTION**

One Lambda Flow PRA™ beads are a highly sensitive and specific means to determine the presence of IgG anti-HLA antibodies in patient sera and is the method we employ for monthly antibody screening of our growing kidney transplant candidate list. We have incorporated software interfaces to accommodate the management of large volume test data generated by the One Lambda FlowPRA™ screening assays. SystemLink's lab management software, HistoTrac™, facilitates the data management using an interface during the testing process with the Becton-Dickinson flow cytometer analysis software, CellQuest™, and then using the PRA upload function to create a PRA results file for upload to the United Network for Organ Sharing (UNOS) online database, UNet<sup>SM</sup>.

## **MATERIALS AND METHODS**

The HistoTrac™ batch and labeling modules allow for the accessioning, test ordering, and sample label creation for large numbers of samples. Multiple order rules can be specified in the database, which generates a list of patients that meet defined criteria such as transplant program or patient status. Sample tube labels containing the patient name, sample date, and sample identification number can be printed to the designated label printer during the accessioning step.

Once a batch is created with tests assigned, a worklist for the flow cytometer is set up. The HistoTrac/CellQuest Interface creates a tab-delimited file formatted for the WorklistManager software for acquisition by the AutoLoader™ on the FACSCalibur™ flow cytometer. The WorklistManager has up to six columns available for sample data where columns are populated by designated fields from the HistoTrac™ database. At minimum, the columns must include the sample number and test names (FlowPRAI and FlowPRAII) in order to link the results with the sample in HistoTrac™ following analysis. The remaining columns can include other fields such as patient name and sample date. Although the FlowPRAI and FlowPRAII must be assigned as two individual tests in HistoTrac™, the interface merges the two tests for the worklist since they are run as a single assay. The assay and panel names must be identical to those defined on the flow cytometer for the file to be imported into the WorklistManager.

Following acquisition, batch analysis of the data is performed with CellQuest™ and the PRA values generated from the analysis are exported to a tab-delimited file. This file is converted to a Microsoft Excel file for import into HistoTrac™. The sample number and test names are the only fields required during batch analysis to create the import file. Following import, a message displays the number of results available for import and the number of tests updated, not updated, or found but not 'Assigned',

allowing the user to make any changes and repeat the import if necessary. After results are properly imported, the PRA values will appear, rounded to the nearest integer, from the Results Menu, ready for the usual test review and sign off process.

Once signed out, the PRA data are exported from HistoTrac™ for upload into UNet<sup>SM</sup>. The export file is created in HistoTrac™ and contains current Class I PRA data for UNOS-listed patients in the format required by UNet<sup>SM</sup> for import.

## **RESULTS**

A test batch was created to demonstrate the usability of the system. The batch accessioning/ordering function was used to assign a FlowPRAI and FlowPRAII test to five patients. The order rule was executed and the five patients were selected for sample accessioning and test ordering. For each sample, the appropriate date, type, sample count, and ordering physician were selected (figure 1). Sample tube labels containing the patient name, sample date, and sample identification number were printed.

Once samples were added to the test batch, a file for the WorklistManager was created. The HistoTrac/CellQuest interface allowed for the sorting of samples by any field selected and created the tab-delimited file that was imported into the WorklistManager (figure 2).

A batch analysis of the data was performed with CellQuest™ following acquisition of the samples by the FACSCalibur™. The PRA values generated from the analysis were exported into a tab-delimited file and then converted to a Microsoft Excel file. Test results were imported into HistoTrac™ using the HistoTrac/CellQuest interface. Following import, a message verified that 10 results were available for import and 10 tests were updated (figure 3). Following review, a UNOS upload file containing current Class I PRA results was created for the test patients (figure 4). Class II PRA results can be entered into UNet<sup>SM</sup> manually when considered necessary.

## **SUMMARY**

Samples were accessioned on patients in the HistoTrac™ database. Tests were ordered and assigned to a batch. The batch was exported to the CellQuest™ software. Following completion and analysis of the FlowPRA I and II tests, results were returned to HistoTrac™, ready for review and sign off. Periodically, PRA results are exported from HistoTrac™ for upload to UNet<sup>SM</sup>. Since the interfaces occur at multiple stages, it is possible to make changes or additions throughout the process.

## **CONCLUSION**

Streamlining data management using the HistoTrac/CellQuest interface and the HistoTrac™ to UNet<sup>SM</sup> file export feature has significantly reduced the time required for data entry and reduced the potential for transcription errors.

HistoTrac - Samples - Batch Accessioning

File Tools Utilities Help

Batch Accession Samples

Edit Help

Patients to Accession Samples On

PRA 9/16/2003 Clot 1

Select/Deselect All

Populate Populate Populate Populate Populate

Patient	DOB	Log Book	Sample Date	Sample Type	Sample Count	Ordering Physician	Sample #
Heart, Harry	12/05/1966	PRA	09/14/2003	Clot	1	Carson	PRA07558
Kidney, Kelly	11/06/1971	PRA	09/13/2003	Clot	1	Mielke	PRA07559
Lung, Larry	08/06/1952	PRA	09/16/2003	Clot	1	Icenogle	PRA07560
Liver, Linda	05/31/1956	PRA	09/12/2003	Clot	1	Obermiller	PRA07561
Pancreas, Polly	05/18/1945	PRA	09/14/2003	Clot	1	Benedetti	PRA07562

Tests To Order

FLOWPRAI, FLOWPRAII

Select Tests to Order

Accession (and Order)

Close

Figure 1. Screen shot of the batch accessioning/ordering screen. The desired sample log book, sample date, sample type, sample count, and ordering physician can be selected for each patient sample as a group or individually.

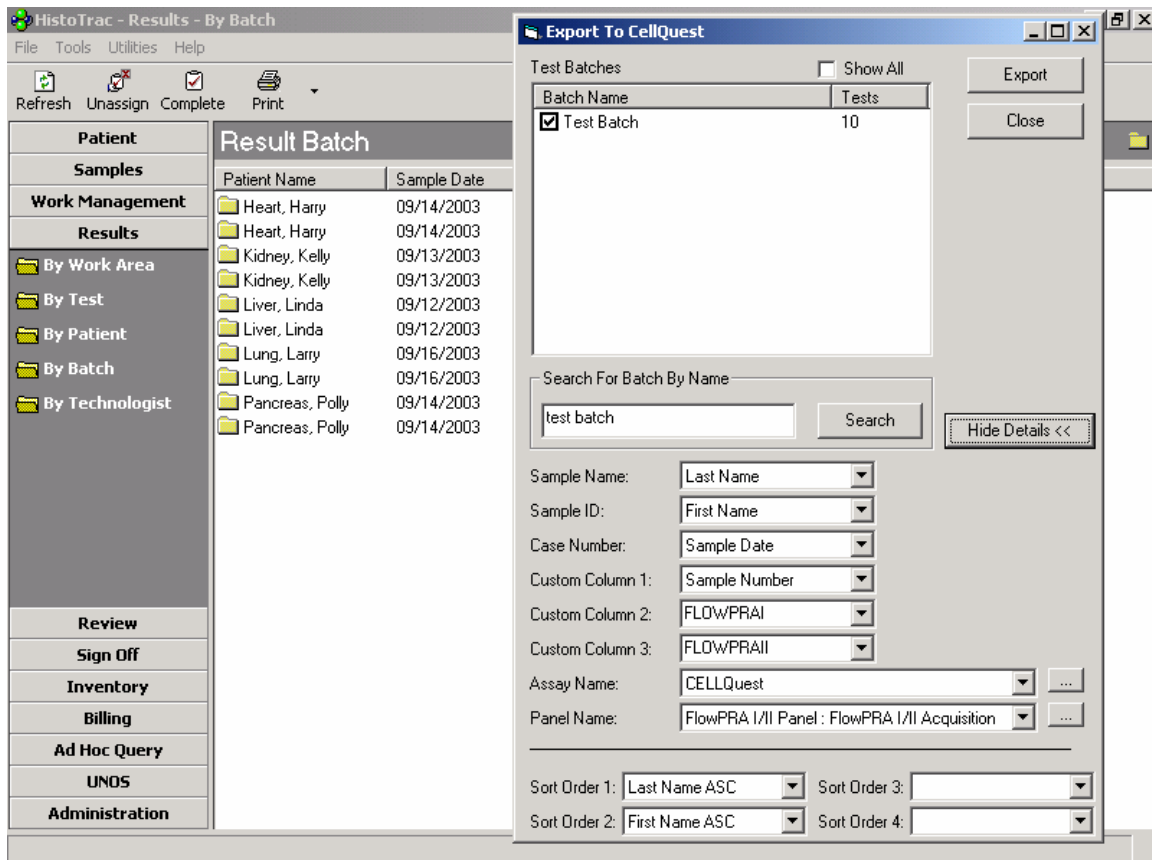


Figure 2. Screen shot of the export to CellQuest™ from HistoTrac™. The appropriate batch is selected by searching or from the list of active test batches. The column names in CellQuest™ (Sample Name, Sample ID, etc.) are populated by the selected fields from HistoTrac (Last Name, First Name, etc.). The Assay Name and Panel Name as defined in the Worklist Manager must be included in the export file.

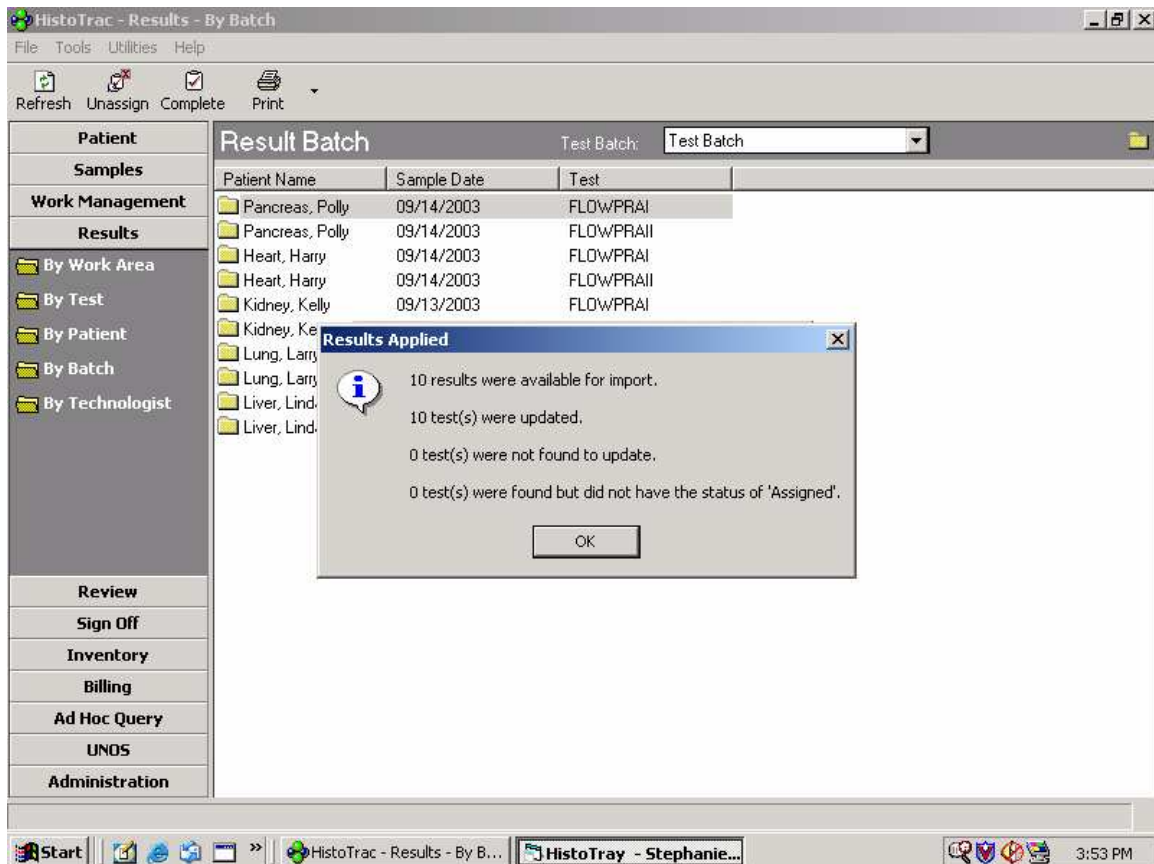


Figure 3. The results of the import from CellQuest™ are displayed.

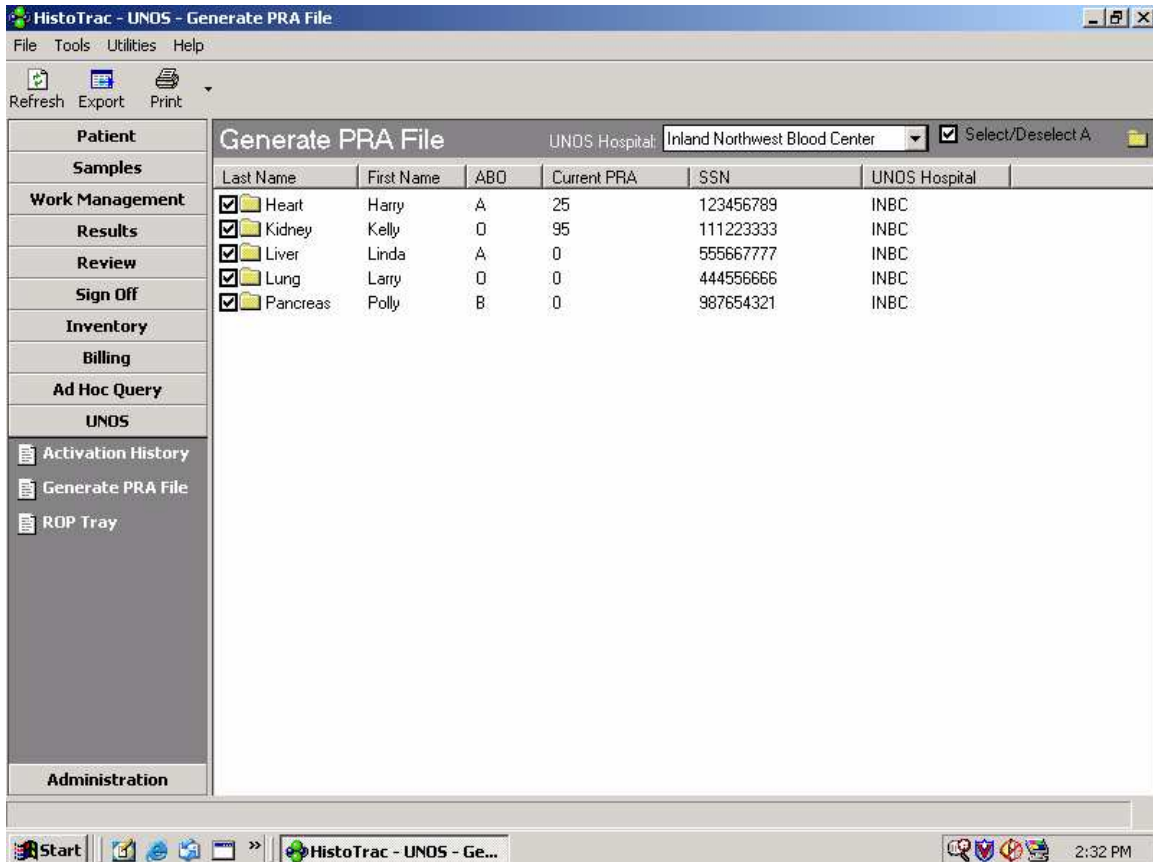


Figure 4. The UNOS upload function allows the user to select patients for the export of current Class I PRA results by selecting from a list of patients from a specified UNOS Transplant Program.