Partnership Success Story

Data Innovations® partners with Rex Healthcare™ to develop an automated solution that combines the HPV result with PAP interpretation on a consolidated report

UNC REX HEALTHCARE

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Data Innovations LLC recently partnered with Rex Healthcare℠, a member of UNC Health Care®, to develop an automated solution to populate the Human Papillomavirus (HPV) result along with the PAP interpretation on a single consolidated report. This solution is independent of the testing department (clinical vs. anatomic) or the LIS system the HPV testing is documented in.

This automated solution adapts to any laboratory and replaces existing labor intensive, manual methods; thus, enhancing workflow efficiencies and reducing the potential for manually entered errors and providing consistent adherence to recommended diagnostic protocols.

Collaboration

Data Innovations partnered with Rex Healthcare to create a reliable, repeatable solution for an error-prone process which was prevalent amongst their customer base, by automating the placement of the HPV result onto the PAP smear interpretation for a single consolidated report. The solution had to be agnostic to the clinical and anatomic LIS systems present, as well as where the HPV testing was being performed, clinical (molecular) vs anatomic (molecular/cytology) department.

Rex Healthcare Facts:

- Type: Private, acute care, not-for-profit hospital and a member of UNC Health Care
- Beds: 665
- 2,000 PAPs and 1,100 HPVs/Month
- LIS: Cerner CoPath® (AP) and Cerner Millennium™ (CP)
- Region: Raleigh, North Carolina

Current State Process

Rex Healthcare wanted to automate their current manual process of adding the HPV result, which is performed in the clinical molecular lab, to the PAP interpretation in the anatomic pathology LIS. Rex performs approximately 2,000 PAPs/month and 1,100 HPVs/month with roughly 100 of those reflexively added if an Atypical Squamous Cells of Undetermined Significance (ASCUS) interpretation is reported. The molecular lab utilized the Panther® Systems from Hologic to perform the testing for the HPV and Cerner Millennium™ as their Clinical LIS. Cerner CoPath® is their Anatomic Pathology LIS.

Rex's initial workflow, as shown in Figure 1, was to have the PAP submitted to Cytology. Depending on the order submitted by the clinician, the HPV is reflexed if an ASCUS interpretation is reported. For specimens which have the HPV at the time of clinician order, the PAP is performed in the Clinical side of the laboratory for accessioning in Cerner Millennium and for analysis. Once the HPV is completed, a copy of the results would print in Cytology. The HPV results were then provided to the Cytologist reading the PAP smear for manual matching to the patient requisition. Once the PAP interpretation was complete, sometimes days after the HPV result was complete, the Cytologist would manually enter the HPV result into the PAP interpretation for a single integrated report for the ordering clinician.

For those specimens needing a reflex HPV test if the PAP test had an ASCUS interpretation, the workflow was different. Often it would take a few days to process and interpret the PAP smear. If the specimen presented with an ASCUS interpretation, the HPV would be ordered at that time. The original specimen would be located, an aliquot obtained and sent to the Molecular lab for processing and analysis as noted above. Once testing was completed the result would be sent to Cytology for manual matching and manually entered into the PAP report before the result was finalized for the ordering clinician.

This manually intensive process was inefficient and potentially error-prone. The manual process created an opportunity for transcription errors while entering the HPV result and/or matching the result to the correct patient's PAP requisition or interpretation. Inaccurate results could potentially lead to mis-diagnosis or mistreatment. In addition, relying on human intervention to consistently reflex HPV test if the PAP test had an ASCUS interpretation provided opportunity for incomplete testing.

Automating the Process

In order to automate the process, the current and future state processes were mapped to understand the scope of the project and to ensure the end goal of automating the manual process of matching the HPV result with the correct PAP smear was achieved. Rex Hospital, Cerner, Hologic and Data Innovations collaborated on designing, testing and implementing this new workflow.

To replace the manual process at Rex Hospital the following changes were needed:

- *Cerner – Cerner enabled the Rex Hospital Cytology department to create a 'procedure' in the patient record within CoPath to accept the HPV result which was performed in the Molecular lab as part of the Clinical Pathology Department. This 'procedure' allowed for the HPV result for the patient to automatically file into Cerner CoPath (and also Cerner Millennium) once the testing was completed.*
- *Data Innovations* – Data Innovations (DI) utilized its laboratory middleware product, Instrument Manager™ (IM), to automate many parts of the future state

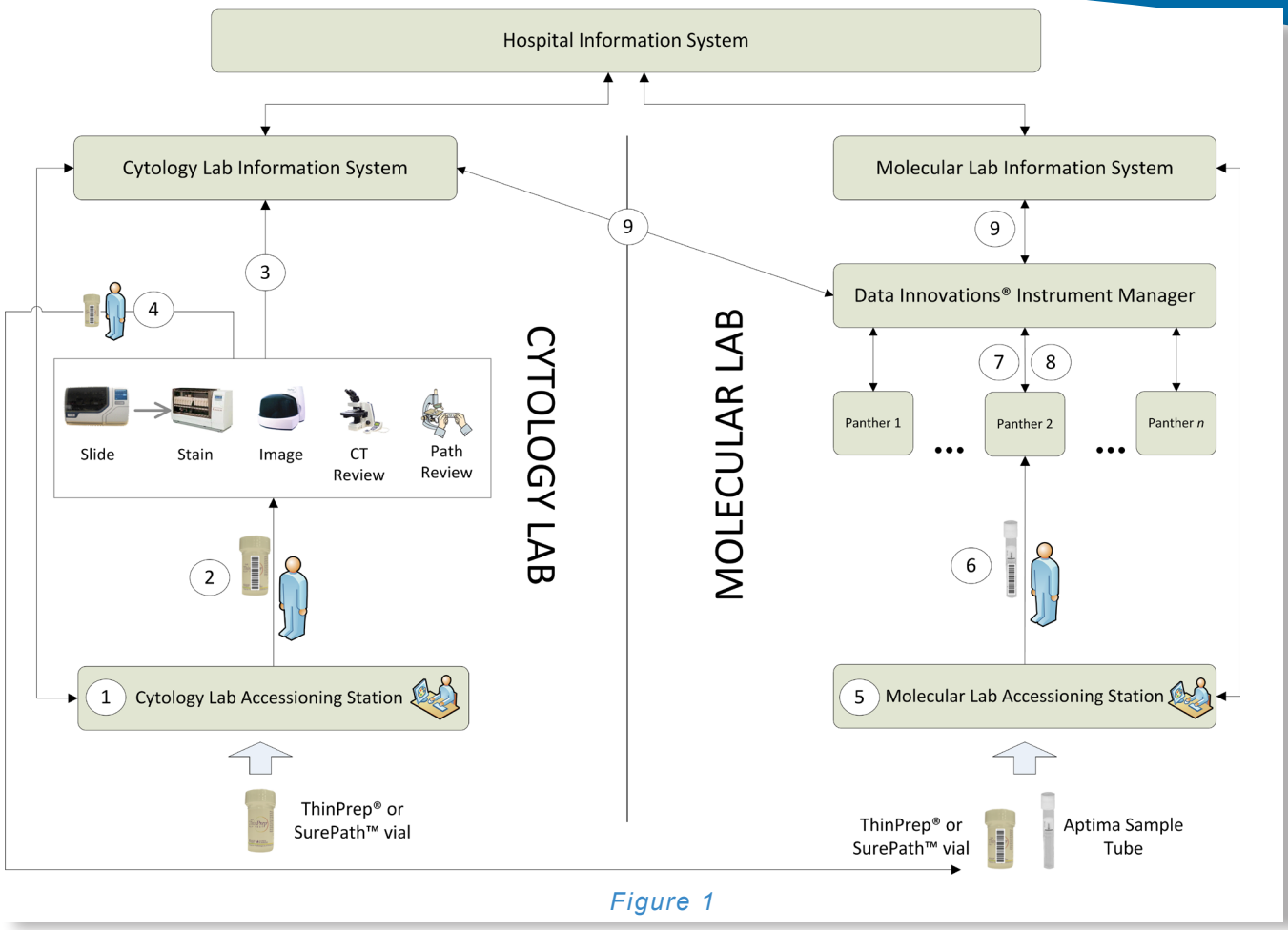

Figure 1

The Data Innovations Instrument Manager allows the Hologic Panthers to be connected to the Molecular Information System and Cytology Information System concurrently. This allows information from the Panthers to always be sent to the Molecular Information System and selectively sent to the Cytology Information System based on user defined criteria.

Steps	Description
01)	*A vial is accessioned in cytology and data is entered into the cytology LIS (Cerner CoPath) and a new bar code is generated for the vial.*
02)	*The cytology process begins.*
03)	*The cytology process completes and results are manually entered in the cytology LIS system.*
04)	*During the Cytology process, an aliquot is created and the aliquot tube is sent to the molecular lab. The timing and criteria varies when the aliquot is sent and there are variations on when the aliquot is taken and transferred to the tube. The details in criteria and timing is outside the scope of this document.*
05)	*In the molecular lab, the vial/tube is accessioned and data is submitted to the Molecular LIS (Cerner Millennium) and a new bar code is generated and placed on the molecular tube.*
06)	*A technician takes a set of specimen tubes and loads them on a Panther that has the appropriate reagents for the tests to be performed.*
07)	*Once loaded, the Panther reads the bar code and performs a host-query to the middleware (Instrument Manager) to determine what tests should be performed on this specimen.*
08)	*The Panther runs the appropriate tests and reports the results to the middleware.*
09)	*The middleware always sends all molecular results to the molecular LIS (Cerner Millennium) and only sends the HPV results to the cytology LIS (Cerner CoPath).*
10)	*The cytology doctor can now review all PAP and HPV results in one report/view.*

workflow. DI had existing bidirectional interfaces for the Hologic Panther and Cerner Millennium in which to communicate orders and results. There was an existing DI interface for Cerner CoPath in Anatomic Pathology which required enhancements to be able to autofile the HPV result into CoPath once the patient and specimen matching occurred.

DI added unique functionality to the Cerner CoPath interface integration in order to positively identify the patient's requested tests, the PAP smear and HPV result. When a HPV is ordered, Cerner Millennium creates a unique accession number for the patient sample. When a PAP smear procedure is requested in Cerner CoPath, it is assigned a unique case number. The challenge was to match the disparate accession and case numbers to the correct patient.

This matching was achieved using the positive patient identification criterion which is contained within the DI driver for CoPath. Depending on the customer's specific needs, matching criteria can occur on many different identifiers, to include patient name, date of birth, MRN and/or visit number. Based on the selected matching criteria, once the HPV is completed the Panther will send the result to IM to perform the matching. When a positive match occurs, IM will send the HPV result to CoPath and will file it into the HPV procedure designated for the patient; providing a completely automated process as designed as part of Rex Hospital's future state workflow.

Outcome

The result of this collaboration enabled a successful and completely automated future state workflow for inserting HPV results into the PAP results. After a few months of utilizing the new workflow, Rex Hospital reported the following:

- *Reduced Manual Error Rate*

  Upon implementing the automated process, two internal clinical and cytology workflow issues were identified and additional process improvements made.

  The first improvement identified was the process for verification of the HPV results in Molecular. The results for the HPV testing were being released in batches without review. The batch release process was discontinued as it presented the opportunity to perform repeat testing based on pre-established criteria when needed prior to verifying the result. This process was improved by deselecting the release of those results from batch processing of the HPV results on the Panther Systems.

  The second process improvement occurred when the HPV testing was completed so quickly there was no procedure ordered in Cerner CoPath for the result of the HPV to automatically populate within the integrated report with the PAP interpretation. This required a review of the individual workflows in each lab to ensure the order of the HPV 'procedure' in CoPath existed prior to providing the aliquot to Molecular for the HPV testing.

- *Positive Cytology workflow changes and impact*

  The Senior Technologist in Cytology stated this new workflow had a positive impact on the laboratory. The initial impact was the efficiency and proper utilization of a cytotechnologist's time as they no longer have to manage and manually match the printed copy of the HPV results to the appropriate patient's PAP requisition. Additionally, it was easy to add the procedure for the HPV into CoPath with the simple click of a button. Another positive impact was the PAP interpretation was not able to be verified or signed-out until the HPV result was present (i.e. when a HPV was ordered if ASCUS detected). Most importantly were the improved outcomes with the automated workflow as cytotechnologists were no longer having to hand-enter the HPV results. Due to the matching criteria and capabilities within the DI interface for CoPath, the opportunity for a transcription error or incorrect patient/result matching to occur was eliminated.

- *Pathologist's viewpoint of the automated solution*

  Overall, the Pathologists workflow did not change with this solution as the system now automatically generates a request for HPV testing if a diagnosis of ASCUS is made. This automated trigger alerts Cytology of the need for an aliquot of the original sample to be sent to the Molecular lab for HPV testing. Additionally, this process works well since the system also precludes sign out of the case until the HPV results are completed. Lastly, the automated workflow is definitely a major advancement and it would be welcomed by peers and beneficial for laboratories to consider this workflow for efficiency and reduction in manual errors.

- *Impact to the Ordering Clinician*

  The impact to the ordering clinician was essentially unchanged. As previously provided in the manual process, the automated resulting of the HPV with the PAP smear interpretation still occurred but was presented in a slightly different format.

Conclusion

A combination of Laboratory Information System (LIS) and middleware working synergistically can create future state workflows and outcomes that are both automated and enhance the efficiencies of your laboratory and staff. Most importantly provide better diagnostic services and more positive outcomes which is everyone's objective.

This particular example proves the power that information technology solutions provides while being agnostic of the vendors. As laboratories continue to envision innovative solutions for the various workflows, the continual staffing shortage while striving for improved patient care delivery, collaboration with key vendors may alleviate those issues.

** Special thanks to DuWayne Engman, LIS, and Pam Godwin, Cytology Senior Technologist, at Rex Healthcare for their dedication in making this project successful! **

About Data Innovations

Founded in 1989, Data Innovations (DI) is the world's largest, most successful clinical and blood laboratory middleware company. With a focus solely on laboratory data management, DI offers the most complete middleware system in the market to manage laboratory operations, including pre-analytical, analytical, and post-analytical sample processing and non-clinical tasks such as equipment maintenance and specimen archiving.

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