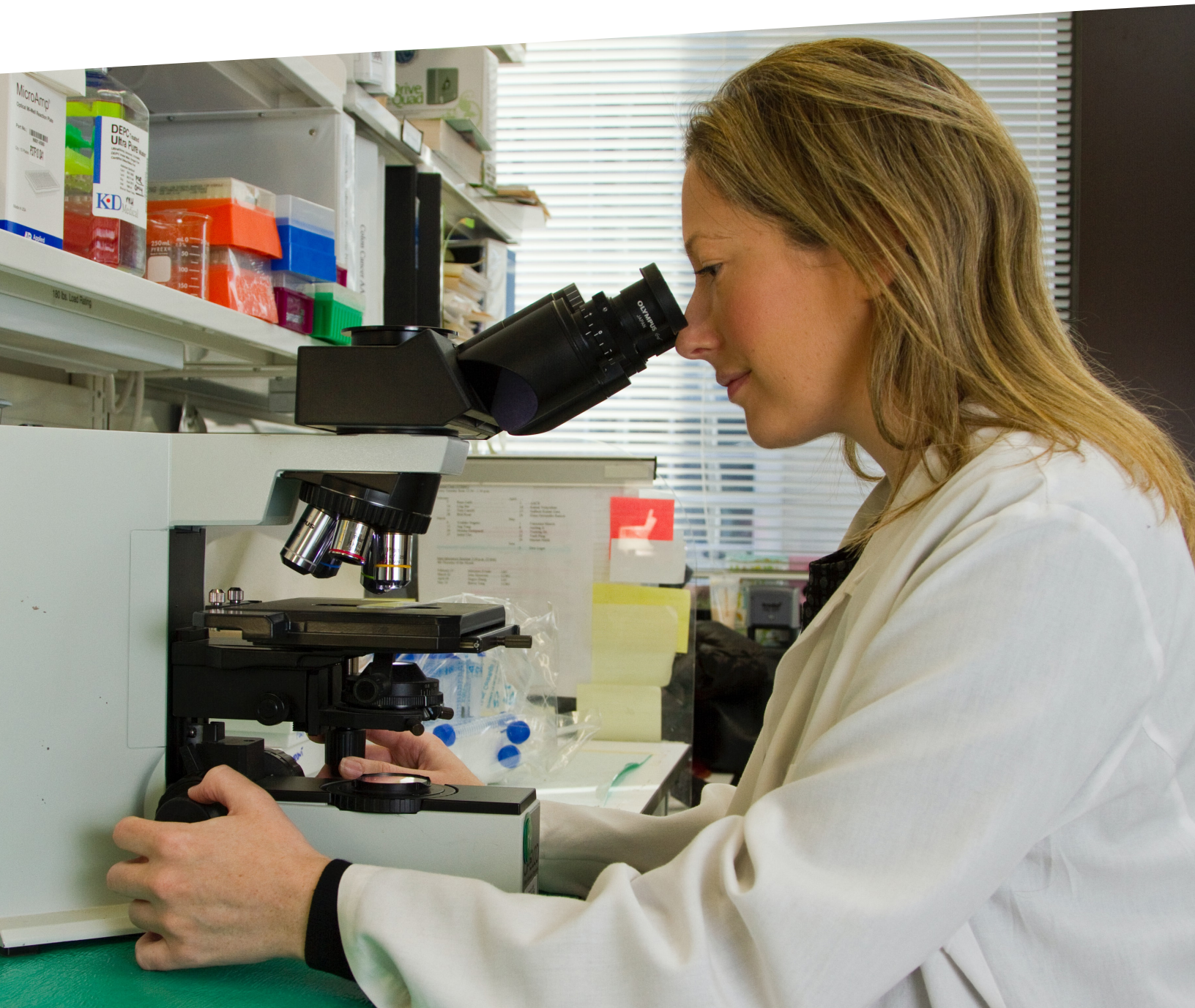




Optimizing Your Anatomic Pathology Laboratory Workflow



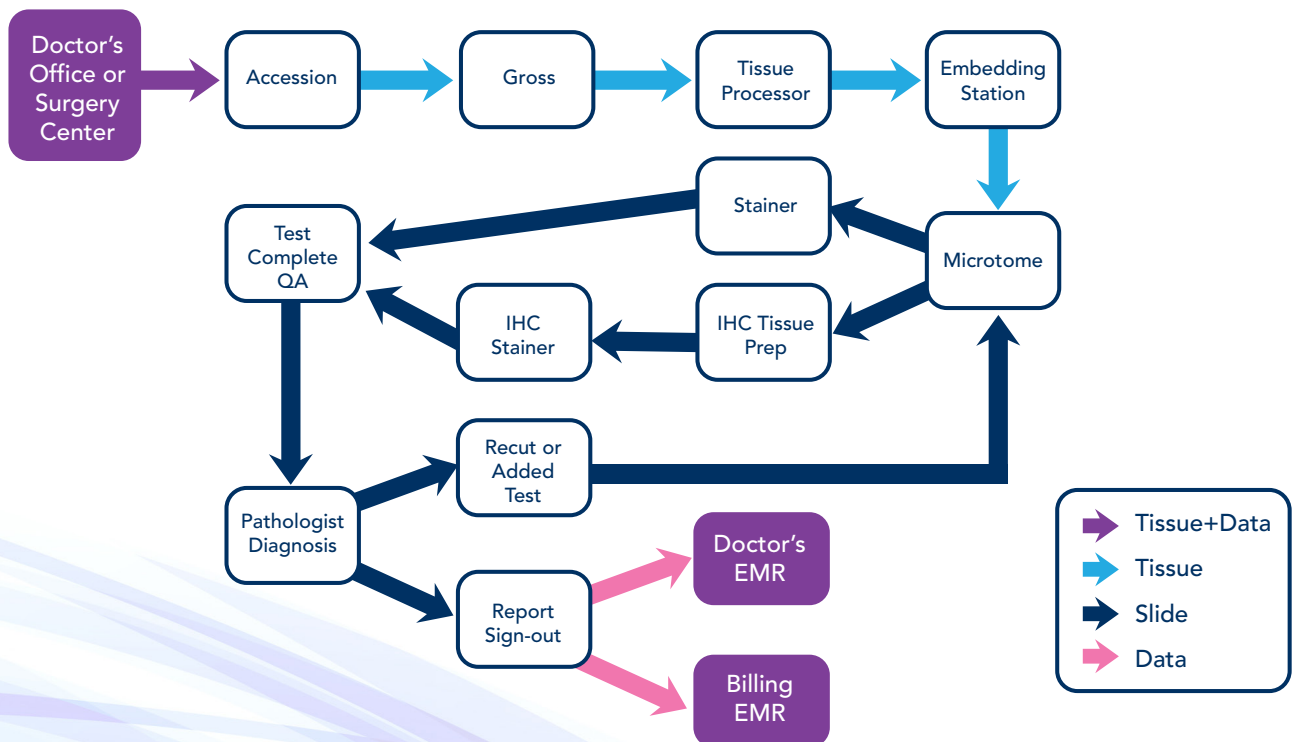
CONTENTS

Workflow Automation	2
Accession	3
Accessioning with EMRs ...	3
Accession and Insurance ...	3
Accessioning and Tests	4
Automated Controls	6
Diagnosis Work Assignment....	6
Final Diagnosis and Billing	7
Reports	7
Billing	8
Conclusions	9

WORKFLOW AUTOMATION

Optimizing the management of Anatomic Pathology (AP) laboratory workflow can have a significant impact on your overall lab performance and profitability. Many labs are still not fully digitally automated in processing patient specimens from accession to report sign-out. Digital automation in your lab using a LIMS (Laboratory Information Management System) will improve your overall laboratory testing workflow quality and recover revenue in light of the decreasing CMS reimbursement CPT payout schedules. Using a LIMS can also help with your CAP inspection and CLIA certification. If you're using a LIMS, is it doing all that it can to help with your entire workflow process? Completely digitally automating the data paths and workflow steps for tissue processing will decrease your turn-around time, add to the bottom-line of your lab revenue as well as minimize the human error issues and keep your lab certified.

Figure 1: Workflow of an Anatomic Pathology Laboratory Performing Both the Technical and Professional Components



A typical Anatomic Pathology lab workflow is defined in Figure 1 with boxes outlining the work being accomplished by the techs, pathologists or machines in the lab. Let's take a look at a few of the areas where inefficiencies commonly exist for AP labs where digital automation can greatly improve throughput and quality.

ACCESSION

For labs that are not using a LIMS to manage cases, tracking the patient using pen, paper, excel or logbooks and creating an accession number for the case by hand is a typical routine. This time-consuming practice is a primary workflow step to automate by using a LIMS in your lab. Some labs use a LIMS but are still manually hand-entering patient demographic information into the LIMS which can introduce human errors for patient-specimen integrity. Digital integration with an EMR will help your workflow, improve your patient-specimen integrity and may potentially eliminate one or more full-time employees workload depending upon the size of your lab.

Accessioning with EMRs

When evaluating LIMS options, it is important to choose LIMS software packages that will integrate with your EMR (Electronic Medical Record) systems through an HL7, FHIR or API interface. An interface should retrieve patient demographics from EMRs or other systems and other important information such as patient insurance information, patient requisitions and specimen collection information from the procedure that was done in the office, surgery or endoscopy center. There are multiple benefits in gathering patient demographics plus additional patient attributes:

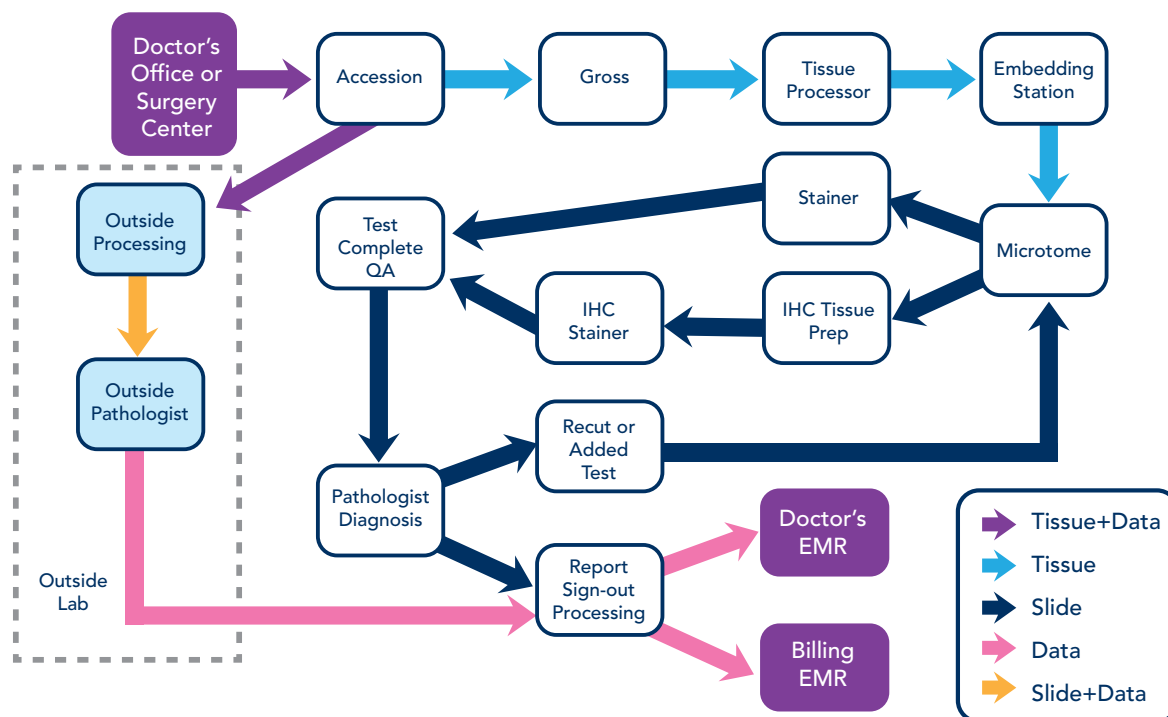
1. Specimens are labeled at the time of biopsy, extraction or resection, ensuring all PHI and anatomy codes are labeled correctly on the specimen jars.
2. Lab techs do not do manual entry of patient demographics & specimen data, saving significant amount of time and ensuring patient name and medical record information correctness. This automation not only decreases clerical work hours but also ensures correctness of PHI.
3. Lab techs can verify that the number of incoming patient samples from the digital requisition match the number received, ensuring correct delivery to the lab by the courier and prompt receipt.
4. Provides the lab an inventory list to be processed in the LIMS. This is a useful tool for helping the lab plan adequate personnel and resources for the work day.
5. Tracking the delivery of the patient specimens from the office or surgery location to the lab will highlight events such as lost specimens or failed courier deliveries, allowing corrective actions to be immediately initiated.
6. Insurance information can be utilized to help guide the accession future workflow steps and appropriate billing process.

Automating these steps can go a long way to eliminating laborious efforts in your lab while providing prompt processing of patient specimens and ensuring patient sample integrity.

Accession and Insurance

Several workflow decisions need to be addressed at the accession process, among these is the ability to process the specimens in the lab based on the patient's insurance. Physicians may accept patients and procedures as part of the physician insurance agreement, but the lab may not be able to process the patient's specimens if they do not have a contract with the patient's insurance provider. In this situation, the lab receives the patient samples and assigns an accession number for internal tracking purposes but sends the non-contracted insurance case work out to another sub-contracting laboratory with the insurance agreement for full processing and diagnosis. This workflow is shown in the purple path from Accession to the Outside Lab on figure 2.

**Figure 2: Workflow of an Anatomic Pathology Laboratory
Outsourcing Some Technical and Professional Components**

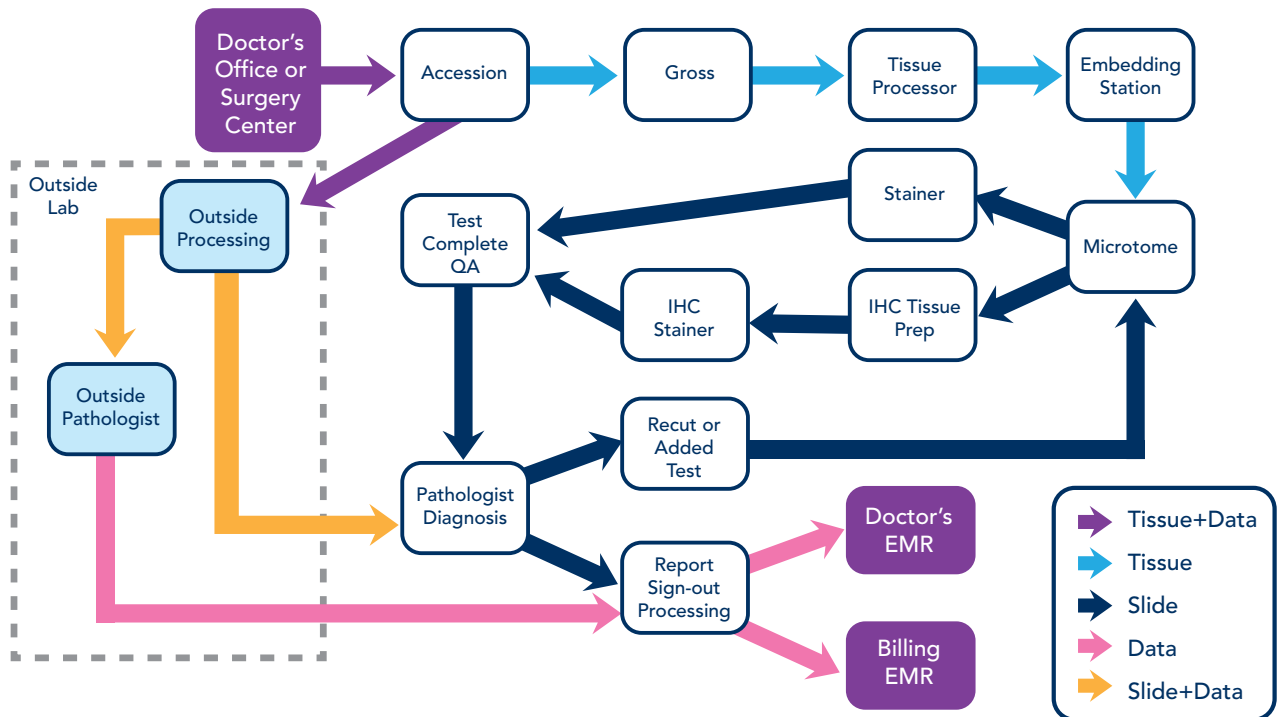


In this Outside Lab (OL) workflow example, the case is processed by the sub-contracted OL and a report generated by the OL is provided back to the originating lab. Accessioning the case first then sending out the case to the OL allows the lab to monitor and track the case for any delays. Automating the reception of this diagnosis report enables the lab to close out the outstanding accession. Additionally, a fully automated system could further automate the reception by the lab LIMS of the report and send it back to the physician EMR, closing the outstanding case. This ensures a closed-loop system of fully tracking the patient accession OL workflow, eliminating manual effort of receiving a report (secure email, fax, paper, etc.) and transferring it manually into a LIMS and then ultimately to a physician EMR.

Accessioning and Tests

Sometimes receipt of patient specimens and correct insurance still doesn't mean that the lab can perform the test or assay. In these cases, the patient specimen can be processed and some tests can be performed. However, some labs lack the advanced IHC test capabilities or specific tests, such as FISH testing of urine, or may not be able to perform the additional tests because of insurance reimbursement requirements. In these cases, the lab sends a partial case to the Outside Lab for additional processing workflow as shown in Figure 3 by the purple path.

Figure 3: Workflow Outsourcing Some of the Technical And Professional Component with Different Lab Entry Points



In this example, the purple tissue and data path flows into the Outside Lab blue box where the technical component of the OL processes the tissue. The Outside Lab workflow has two paths:

1. The technical component illustrated by the yellow path, where the OL lab performs the tests or assays and the slides are brought back into the lab for the inside Pathologist diagnosis and final report.
2. A combination of the yellow and pink paths where the OL completes the technical and professional components of processing the case and returns a final diagnosis report & billing information to the lab via the pink path.

For either of these paths, automating the send-out of cases to an Outside Lab and reception of the slides or the final report will increase the lab productivity and allow for easier tracking and case management. When choosing a LIMS solution, it is important to evaluate if the LIMS can allow an OL workflow based on test requirements in addition to helping track the OL work being done to ensure that the patient and your physician gets a timely diagnosis report. Automating the send-out and tracking of OL specimen processing eliminates a large amount of manual and time consuming accession management, further eliminating human error, increasing lab productivity and ultimately revenue of your lab.

AUTOMATED CONTROLS

Every lab needs to do controls for their stains, especially with the increased pressure to maintain a lab's license. How easy is it in your LIMS to retrieve and prove this tracking? This is important documentation element of your lab workflow. Ensuring that your accessions are tracked against the stain controls is paramount to specimen processing quality and regulatory audits from agencies such as CAP and CLIA. Your LIMS should manage your controls and include critical steps through the process including when the control was done, result indication (positive or negative), success or failure of the control result and accession with tests that are related to the control run.

In the H&E test case, controls are usually run once a day to ensure that the reagents are working correctly and the stainer instrument is processing correctly. But what if it fails? The accession slides with the H&E test that was run with the H&E control need to be rerun. A good LIMS should record all of the failing H&E test slides, notify the lab manager which accession slides need to be re-stained and not allow any slides that were not re-stained with a passing control to be used by the Pathologist for diagnosis.

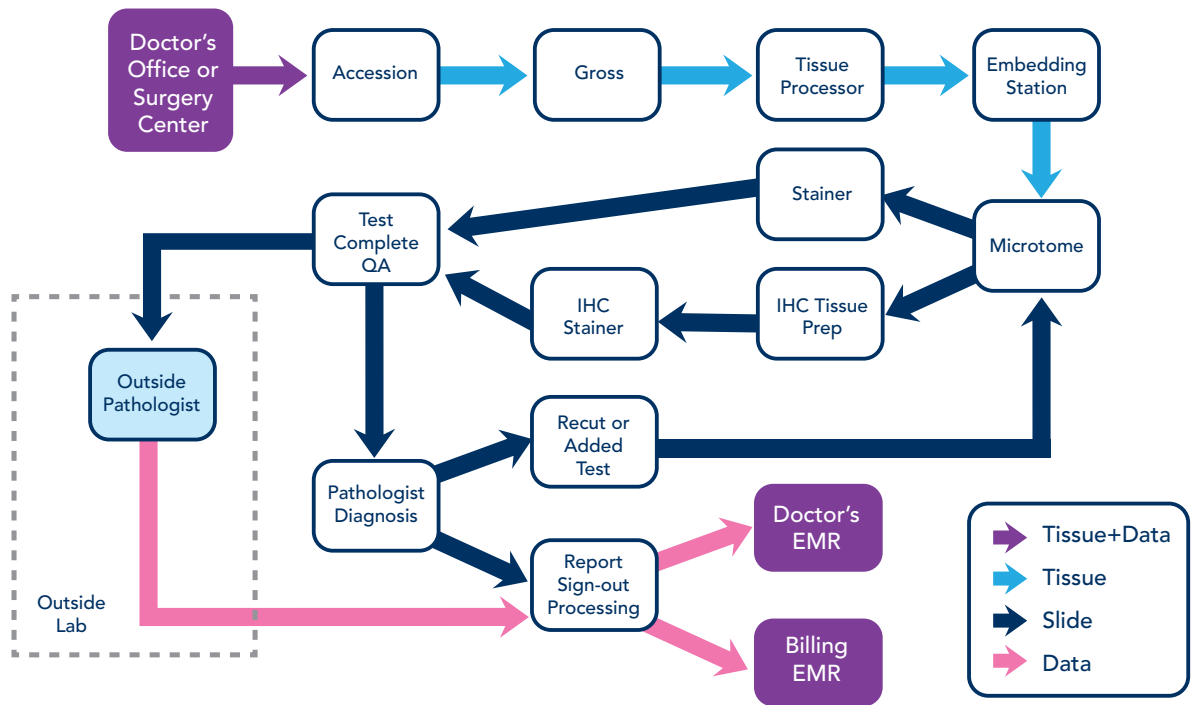
For IHC, the tests are sometimes batched per-run on the stainer with a control. If a control stain fails, the entire batch fails and should be scrapped. Does your LIMS allow for scrapping or deleting of the slides? Does your LIMS automatically scrap the slides? Your LIMS should not only scrap the slides but also handle the failing event and send the accessions with failing test back to the microtome workflow step to re-cut for that particular failing test. Having the workflow steps of scrapping material and returning the accession and subsequent failing test back to the microtome workflow step automatically ensures that failing slides are not incorrectly used by the pathologist for diagnosis and eliminates hand-tracking of failed slides. LIMS automation applied in this situation also eliminates the lab techs from manually creating separate steps in the workflow which can further introduce human errors.

Finally, does your LIMS provide you a searchable method of reporting your controls and associated accessions for regulatory purposes? The ability to easily look up a control that was linked to an accession slide with a specific test helps with regulatory auditing during lab inspections.

DIAGNOSIS WORK ASSIGNMENT

If your lab has multiple pathologists or utilizes sub-contracted or off-site pathologists, does your workflow and LIMS support case assignment as well as case reassignment? Your lab workload can vary depending upon seasonal patient population, pathologist absences or viral outbreaks. Some cases may need external consultation. The ability to assign or re-assign the diagnosis work to pathologists inside your lab as well to an Outside Lab is essential in keeping your lab efficient and processing at peak potential.

Figure 4: Workflow Outsourcing The Professional Component



As shown in Figure 4, your lab may need to send cases to an Outside Lab for additional pathologist resourcing or to other pathologists for independent consults. In some geographies, AP labs see an increased case load based on seasonal visitors. Utilizing OL pathologists helps keep lab Turn-Around Time (TAT) within acceptable levels when workload increases beyond the capabilities of the inside lab pathologists. A LIMS and workflow capable of sending stained slides to an OL pathologist and digitally tracking the cases keeps your lab on top of the work sent out. Receiving final diagnosis reports and billing information digitally from the OL eliminates manual clerical effort, saving copious amounts of time dealing with scanning, faxes, manual report importation and/or sending the reports out to the various physician receiving EMRs. Automating this workflow step can save your lab techs time, eliminate lost or delayed cases and ensure timely billing gets accomplished.

FINAL DIAGNOSIS AND BILLING

Clinical AP labs generally export two pieces of information: a final diagnosis report and billing information. Both are the most important output pieces of the lab and are crucial to the final process for both patient and lab.

Reports

How quickly can your pathologists sign out a case report? How many seconds or minutes do they spend interacting with the current system, per specimen? Can they sign out cases quickly on their own or do they need to use expensive transcriptionists? A good LIMS only requires a couple of seconds of interaction time per specimen - clicking buttons to close windows, clicking links to edit

or view data, scrolling text all adds up to valuable time which eats into the pathologist's work day. Does your LIMS provide digital requisitions of the surgical operation or do the pathologists have to hunt and flip through paperwork provided? A LIMS with an integrated requisition view that pops up when the case is entered (preferably by scanning a specimen slide) streamlines this process and eliminates the unnecessary, extraneous paperwork load.

When your pathologists are done diagnosing a case and generate the final diagnosis report, where does it go? Does your LIMS interface with the physician EMRs or other systems to transmit the report into the patient EMR folder and notify the physician it's complete? An ideal LIMS solution should be HL7 or FHIR savvy and be able to automatically send accession reports to your physician EMRs electronically after pathologist sign-out. Most EMRs are able to take a PDF or HL7-designated information set containing the accession diagnosis report as an import option. If this step isn't automated, your lab techs are most likely wasting time sending reports manually through faxing, scanning or email. Automation of your end product (the final report) delivery coupled with the ability to intake Outside Lab reports from your OL Pathologists and re-send them to your physician's EMRs will dramatically increase your efficiency and eliminate manual, time-wasting effort. An ideal LIMS solution should also be able to securely enable the reports or status of accessions available to your physicians or customers outside the lab. The LIMS should allow introspection of Work-In-Progress accession status and search for older reports. This useful capability eliminates call times wasted by your customers, physician assistants or office assistants asking for case status or an old report.

Billing

Billing is usually a difficult and tedious affair. Your lab needs to get paid for what it does, but how do you make this process more efficient and save you money? If your lab outsources billing, you can improve efficiency with your lab and your outside billing partner by automating the digital transfer of reports and billing data. A good LIMS system should be able to send out a billing report for each case that includes the patient insurance information, ICD and CPT billing codes. This will allow an outside billing company to accurately accomplish the billing process. Setting up an automated and encrypted digital link of your outgoing billing reports to your off-site billing agency greatly reduces your manual effort and increases the billing process throughput.

If you're billing in-house, automating the billing (professional and/or technical components) from your LIMS into your billing system will drastically cut down on the human workload and potential error. Many billing systems accept HL7 data format for their billing using the PV1 and FT1 codes. How your LIMS organizes these financial billing transactions in the HL7 message sent to your billing system can greatly enhance your chances of successful billing receipt from the endpoint insurance or Medicaid/Medicare entities. Usually, billing systems can take multiple FT1 entries per accession/case transaction in the HL7 message, allowing the receiving billing system to receive "preformatted" billing entries. Intelligently sorting the ICD codes within the FT1 billing message can help eliminate programmed billing rejection from the clearing house or insurance companies. These steps can eliminate a large amount of overhead by your billing staff to manually reformat the final billing report for the endpoint insurance clearing house and/or governmental agencies for reimbursement. In many cases, we found that a few changes in the LIMS billing HL7 message

formatting eliminated tedious hand-editing, reduced potential rejected billing by the clearing house, reduced operational staffing and enabled prompt reimbursement from the insurance companies.

Conclusions

Adding more automation in your laboratory workflow can cut down your manual work and reduce your potential for human-introduced errors. Fixing these areas isn't always easy and may require LIMS changes and IT-savvy work to enable these workflow improving modifications. If your LIMS is capable, many of these workflow automation steps can be automated to increase your workflow capabilities and eliminate errors. Workflow digital automation can significantly reduce your full-time employee requirements and significantly enhance the revenue stream of your lab.

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