Why Your LIS Matters

The Anatomic Pathology lab is under pressure!
    CMS.gov is reducing reimbursements – **lower revenue**
    Increasing **lab expenses**
    Increasing **regulations**

The LIS in your lab should:
    Enable workflow efficiency & make **money**
    Ensure **compliance**
    Improve **patient care**

Labs need to be digitally optimized or risk going out of business!

This paper will discuss the LIS requirements & features that you need for lab Nirvana!

What is an LIS? Or is it LIMS?

"Software is eating the world."

Marc Andreessen, general partner at Andreessen Horowitz, [The Wall Street Journal](), August 20, 2011

An **LIS** (Laboratory Information System) or **LIMS** (Laboratory Information Management System) definition:

A software system to help you manage your work in the lab

Is it LIS or LIMS? Which do I need? A breakdown of the definition:

LIS	LIMS
Patient centric model for lab to perform tests and workflows	Related to the research and pure sample testing
Hold the patient data related to what's being tested	Sample centric tests and workflows with data and results

Answer: it *depends…*

    Historically a LIMS is for research …but…
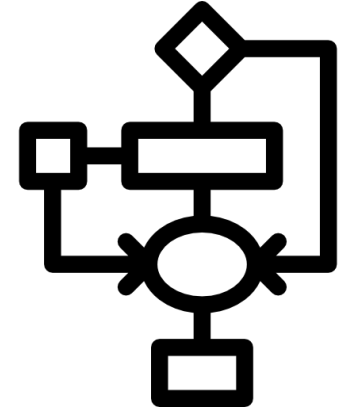
    Both manage your work

    Both have data reporting functions

    LIS is generally accepted as the patient-centric focus of work in your lab

In this presentation

    Use the LIS definition

    A clinical (patient) model for the topics in the presentation

LIS Basic Functions

Identify & **document** the work being done on the specimen:

      Identify material, work, specimen, etc. in the lab

      Who did the work on the specimen

      What did the lab personnel do on the specimen

      Where in the workflow steps of the lab the work was done

      When did the lab personnel do the work – a time stamp & log entry indicating work performed

Keeps your **Patient ⇔ Specimen** integrity intact

      Swap specimens on a patient accession == **potential misprocessing or misdiagnosis**

      Swap specimens between patient accessions == **potential lawsuit**

Manage your work and workload in the lab

      Enable work to be done – e.g. create a slide at microtomy, gross a piece of tissue

      Direct the work/specimen to the next required workflow step in the lab

      Help measure your WIP (Work In Progress) and lab throughput

Provide a framework for improved patient care and compliancy
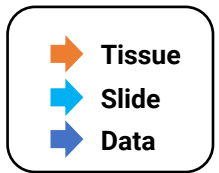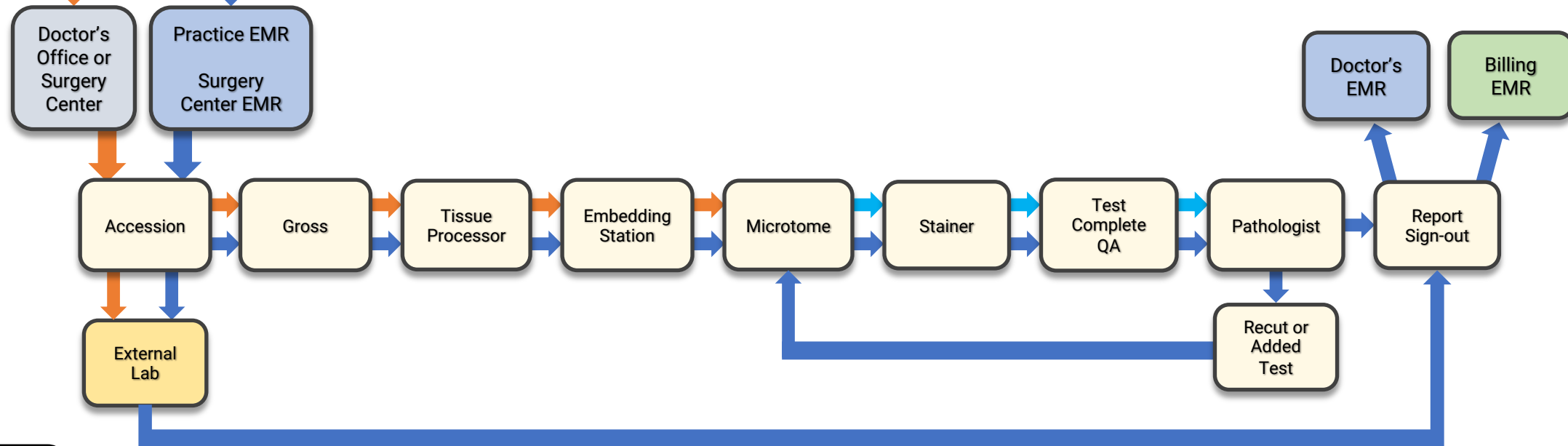
Enable the lab work to be more efficient

Enable your lab to make more money

Lab-based LIS Features

A well-designed LIS should make it easy for use, entry of data

A User Interface (UI) that has focused information

Provides a user experience (UX) for the work at hand
- Web browser based, easy to read, easy to use software
- Minimal typing & mouse clicks to accomplish the work
- Drop-down menu for the relevant data to select
- Directed macros to eliminate manual typing – gross descriptions, specimen diagnosis
- Workflow automation for applying tests, CPTs, ICDs
- Ability to route work in your lab workflow based on rules

A cloud-based LIS should be optimized for low latency, internet traffic operation

LIS should have data recovery and disaster recovery/backup capabilities
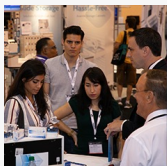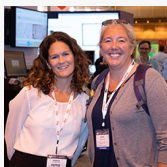- Ask your LIS vendor about:
  - Web application stack performance – from submission to web client reception
  - Web traffic framework - load balancer, job scheduler (if utilized), and web server optimization
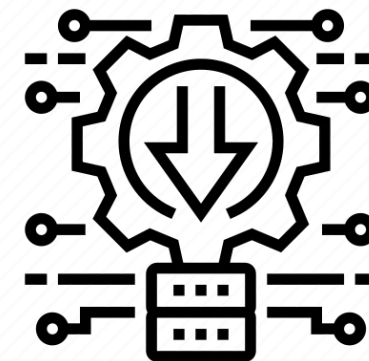 - Database engine performance, clustering or mirroring capabilities (large-scale installations)
  - Disaster recovery & backup schedules
  - Redundancy – server fall-over, network fall-over, geographical site fall-over

Digital Automation & Integration

The LIS should be digitally connected:
- Get specimen information from an EMR (Electronic Medical Record)
  - patient demographics, patient insurance
  - type and anatomy location of specimen(s)
- Identify the specimens – print labels, cassettes, slides, slide labels
- Utilize barcodes for specimen identification and workflow tracking
- Route the specimen/work through the workflow
- Connect to lab machines to auto-program & receive test information
- Show patient data, current requisition and past history at various workflow points
- Provide a method for a pathologist to create a diagnosis report
- Generate billing information of all work done
- Send lab output (final diagnosis report, billing information) to another system or EMR
- Optionally send final diagnosis report to other entities - physician, office, etc.
- Report the operational output & lab metrics – personnel productivity, workload over time, etc.

The LIS should eliminate all paperwork in your lab!

LIS Regulatory Compliance

An LIS should help you with regulatory compliance

 CLIA, CAP, FDA – 21CFR part 11, part 58, GLP, GMP, HIPAA

 Provide documentation of work done in the lab

 CAP audits go much easier with an LIS that documents your workflow!

HIPAA Stage 1 uses the term EHR (Electronic Health Records)

 Your LIS must adhere to Stage 1 requirements

 Embedded in Stage 1 are HIPAA privacy and security requirements for PHI

 PHI (Patient Health Information) includes all aspects of patient information, records, etc.

Meaningful Use Stage 1 LIS requirements

 Access controls – sign-on password, encryption

 Audit controls – logging of activity, access, functions or operation

 Integrity controls – ensure PHI cannot be improperly altered or destroyed

 Transmission security – network data is not exposed (encrypted), no authorized access

HIPAA Meaningful Use Stages
Stage 1: data capture and sharing of information
Stage 2: advanced clinical processes
Stage 3: improve outcomes

LIS Must Adhere to HIPAA Stage 1 Rules

HIPAA Stage 1
- Access controls
- Audit controls
- Integrity controls
- Transmission security

Access controls

Access controls

User access must be password protected and secure

Some key points your IT people should audit the LIS vendor:

LIS should be incorporating known one-way hashing algorithms – bcrypt, Argon2, scr

Multi-Factor Authentication (MFA) highly recommended – especially in cloud-based s

Single-Sign On (SSO) authentication through LDAP or Exchange integration
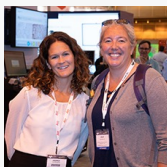
Audit controls

Logging of all user activity logins

LIS: Logging of all user activity on the work being done

Example: Histotech A. Lifeson cut accession YYZ-2112 specimen A block 1 and created slides with tests H&E, Hpylori, recorded date and time

LIS Must Adhere to HIPAA Stage 1 Rules

Integrity controls

 LIS manages routing of workflow so slide with IHC test AB/PAS goes to correct stainer

 Stored final diagnosis reports cannot be altered or deleted

 Removal of specimens, created test slides in the workflow recorded (e.g., deleted from workflow and LIS records who, when, and what was removed)

 Encryption of data at rest

Transmission security

 The LIS should encrypt all network traffic

 Website utilizes valid SSL certificate, SSL tunnel

 Additional dedicated VPN from lab network to the cloud-based or server farm LIS tenant

**Important: integrity & access controls also translates to operational functions!**

 User of the LIS should only see cases that are relevant to office or lab

  In a multi-office system, nurses/office administration only sees patient cases in LIS originating from that office

 The LIS user permissions scheme should permit/restrict functions or operations of the LIS

  Example: lab worker has accession privileges only – cannot do grossing or microtomy workflow steps!
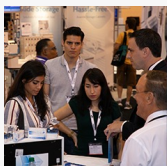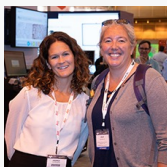
Specimen Identification

CAP Guidelines GEN.40503

    specifies documentation of specimen chain of custody requirement

How are you identifying your specimens?

Where are you printing labels, cassettes, slides or slide labels?

    Correct guideline: print each identifier (label, cassette, slide, etc) at time of requirement/use

    Batch printing all specimen identification items at beginning of workflow **SHOULD BE AVOIDED!**

    Example: at Accession, print all the cassettes and slides for the cases that arrive in the lab

        This is outdated method: old school, poor software design, lack of equipment (PCs, printers) in the lab, etc.

        The failure: swapping of specimens between two patients named "J. Garcia"

            One specimen had cancer, the other did not

            Failed CAP inspection, lab hit with lawsuit

            Result: lab lost license & could not process specimens for two years

    Print your cassettes at the Gross workflow, specific specimen

    Print your slides & slide labels at the microtomy workflow step, specific specimen

    The LIS should allow re-printing of cassettes, slides, slide labels, etc.

        A slide can be dropped on the floor before it's processed

        Printers fail at the worst possible moments!

LIS Integration
Beginning of the Lab Workflow

Consider the beginning of the specimen journey to your lab:
- The LIS should connect to the EMR to induct all data digitally:
    - All patient demographics – name, DOB, address, insurance
    - Requisition of the procedure and inventory of specimens to be sent
    - Information of each specimen
    - Accomplished through HL7 (ADT or ORM messages) or secure APIs
- The LIS should track specimens from **origin to your lab**
    - CAP GEN.40503 chain of custody requirements – documenting the SOP but also the work done
    - Courier tracking or shipping from remote sources to your lab
- When specimens arrive in your lab
    - Identify when they arrived, who accepted them
    - Verify that all specimens from the source (e.g. all bags) were received
    - Verify that all specimens from the patient (e.g. specimens in the bag) were received
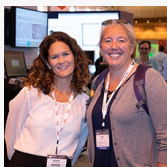   - Induct them into the accession process of your lab

LIS should have the flexibility to accession any type item
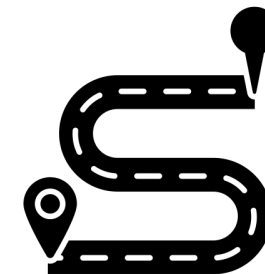- Specimen in block form – to be processed in your lab
- Consult slides from another lab
- Digital slide images

LIS Integration
End of the Lab Workflow

The output of your lab – usually a diagnosis report & billing
- The LIS should connect to the EMR to export all data digitally:
  - Diagnosis reports – preliminary, final, amended, addended reports
  - Billing information – need to get paid for the work done (technical, professional, global)
  - HL7 interface (ORU and DFT messages) or secure APIs

Capability for sending technical work to external lab
- Specimen blocks to be sent for final technical completion
- Slides sent for professional component (e.g. pathologist reading) or evaluation

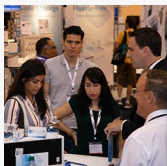Capability for external reports to be imported into the accession
- Example:
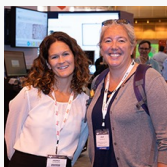 - A "send-out" case that the lab can't process due to insurance limitations
  - A consult report from another lab
- External report gets attached digitally to the accession case in LIS
- LIS sends the report to EMR which updates patient file

LIS for Lab Managers

Provide lab managers insights on lab operations
- Metrics of the lab personnel for performance
- Examples:
    - total specimens grossed by tech over time
    - Total blocks cut by tech over time

Additional Lab metrics that help the quality and workflow of the lab
- QA reports for controls
- Turn-around-time (TAT) average of cases processed
- Pathologist sign-out workload over time
- Physician case count submitted over time
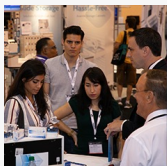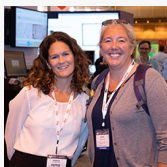- Incident reports processed over time
- Case volume over time
- Tests processed by lab over time
- Gross worklist
- Test worklist
- Work In Progress (WIP) of the lab
- Dashboard to show progress of the lab

LIS for Pathologists

The LIS should be integrated between the Pathologist and the Lab
- Pathologists view the slide quality as a reflection of the lab capabilities
- Pathologists add reflexive tests to a specimen
  - Needs to be communicated into lab workflow for re-processing

LIS UI for the Pathologist workflow step should provide
- Patient demographics
- All patient diagnosis report history
- Digital requisition for the case
- Information about the specimen
  - Accession by, Gross by, embedded by tech(s) information for the specimen, cut by tech(s) for each slide
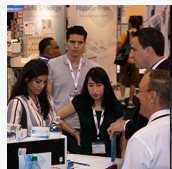 - Specimen type, anatomy, any specimen comments from the procedure, gross description
- Pathologist diagnosis features
  - Allows pathologist to diagnose a serious or cancer flag to the specimen
  - Shows all ICD and CPT codes, enables pathologist to edit all items as needed
  - Provide a preliminary & final diagnosis report preview

LIS for Pathologists

Digital Pathology is now the requirement for labs
>   Digital representation of the slide
>   Enable remote viewing – offsite from lab

AI algorithms in the viewer
>   Digitally augment inspection & diagnosis
>   Utilize multiple AI algorithms as needed
>   Provide detailed analysis – cancer cell count, size, etc.

Bi-directional information between DP Viewer and LIS
>   Start the case in the LIS to launch viewer and show slides of the case
>   Cellular measurements, annotate regions, snapshot region pictures
>   LIS receives information (measurements, pictures) from Viewer into diagnosis report
>   LIS used to sign out report, finish case
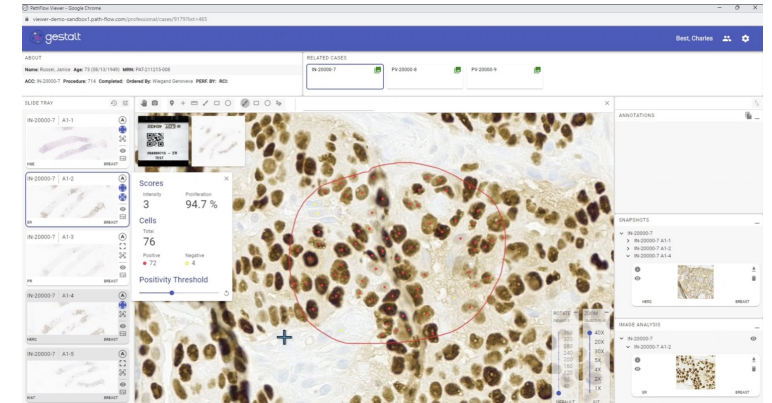
LIS For Revenue Generation

Optimize the lab workflow, make more money

Example using CMS.gov 2023 reimbursement guidelines

    Assumptions:

        A pathologist reads cases 231 days per year

        Assume one specimen per case, the specimen has H&E test applied

        Global 88305 H&E on the specimen reimbursement = $76.53 per-case signed out

    Calculating the reimbursement revenue per-day signed out:

    50 cases a day: $883,921.50

    75 cases a day: $1,325,882.25

    100 cases a day: $1,767,843.00

Optimizing the lab workload greatly impacts revenue in the lab!

Final Thoughts

The LIS is the workhorse and backbone of your lab

The LIS should be fully digitally integrated into the entire workflow of your lab

Is the LIS serving your needs or are you bending to its requirements?

Audit your LIS capabilities

     Digital integration, performance, and compliancy

Presentation deck & white papers also available:

    https://www.cerebrumcorp.com/white-papers

Thanks for attending!

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Daniel M. Jondle, M.D.
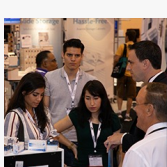Managing Partner
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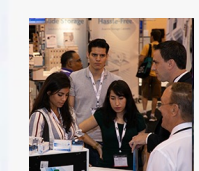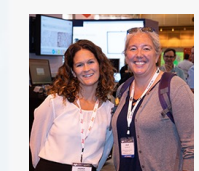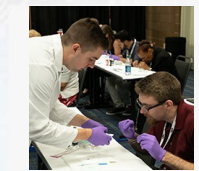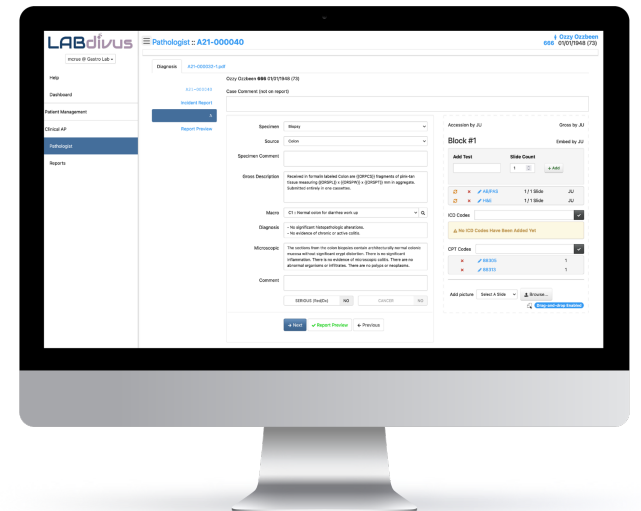klahti@arizonadigestivehealth.com

LIS Workflow Checklist

The following slides can be utilized as a checklist to audit each workflow step in your lab to an LIS requirement

The checklist items are recommendations to help your lab

- Get efficient
- Keep patient ⇔ specimen integrity
- Digitally automate your workflow

LIS Accessioning

Tracking of specimen reception via courier, shipping

All information into the lab is digital
- Patient demographics, insurance
- Digital requisitions
- Ability to take paper requisitions, scan them digitally into the LIS

Printing of specimen jar labels (if not done at specimen origin)

Ability to edit/add additional information
- ICD codes from physician
- Clinical comments or indications
- Case comments from requisition
- Identification of a "Stat" immediate need case

Streamline adding of specimens if done manually
- Drop-down menus for the case type, specimen type, specimen anatomy, collect & receive dates
- Identification of office, physician, referring physician
- Auto-create specimens for the large specimen cases
    - Example: urology prostate cases are usually 12, 16 or modified 12 (with horns)
                    automatically create all specimens and map specimen letters to associated prostate locations

Initial assignment of tests to be applied to the specimen
- Every specimen gets an H&E – variability of number of slides per H&E test?
- Anatomy location determines automatic test assignment
    - Example: stomach specimen gets assigned additional AB/PAS, Warthin Starry tests

LIS Grossing

Easy entry of grossing information
>Drop-down gross macros
>>Gross macro definition can be edited for the site by manager
>>Gross macro selected, populated to specimen can be modified per-specimen by gross tech
>Easy entry for specimen gross details – piece count, length, width, thickness, etc.
>Specimen gross details get incorporated into the gross macro description automatically
>Derm lab specialty: ability to select inking type, color, inking sequence

Printing of cassettes here
>LIS capabilities for multi-hopper, multi-color requirements
>Example: gastric uppers get blue cassette, all other specimens get white cassettes

LIS provides viewing of digital requisition to gross tech

Auto assignment to tissue processor

Ability to add tests to specimen by grossing tech

Ability to incorporate digital images (SPOT imaging, external imager)

Ability to provide an incident report on the specimen for lab manager follow-up
>Example: grossing tech found no tissue in the jar or found a surgical staple in the tissue

Routing of specimen to a "Material Jail" for further inspection by lab manager
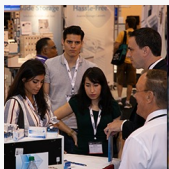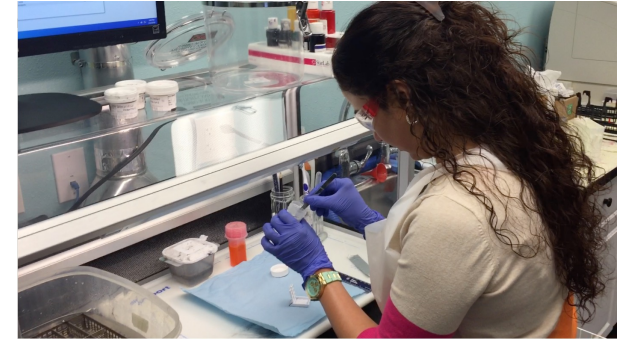
LIS Tissue Processor Tracking

Track the loading, runtime and unloading of the tissue processor

Tissue processors are getting smarter

Items to manage

- Identify lab machine, serial number, date installed, service contract
- Track runtime operation
- Track number of runs over time
- Track alcohol consumption, replacement
- Track uptime, service time requirements
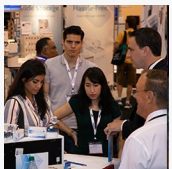
LIS Embedding

Track who and when did the embedding of the tissue

> CAP and CLIA compliance requirement

> Quality assurance measurement of lab personnel work

Scanning the barcode on the cassette enables the tracking function

> Requires a PC & barcode scanner at the embedding station

> Easy operation, small capital expense

LIS Microtomy in the Lab

Scanning of barcode on the cassette initiates the operations
> LIS should retrieve, populate the specimen block information on the screen
> Automatically print associated slides or labels for all tests on specimen

Histotech can optionally add more tests
> Automatically print associated slides, slide labels

Histotech can add control material to a specimen block/slide/test item

Ability to create a complete control slide

Identification of pathologist-ordered re-cuts, re-tests
> Show new reflexive testing additions to the microtomy list in a sortable format
> These blocks aren't usually on the new-incoming tray
> Blocks most likely located in the "to-be-filed" inventory location of lab

Facilitate easy re-print of slides, slide labels

Enable a tech to quickly search or sort for a specific block awaiting processing

Enable tech to easily complete the block and get the next block

LIS Stainer Tracking

Track the loading, runtime and unloading of the stainer

Some stainers are getting smarter
- IHC stainers require LIS to program the slide ID information
- Slide ID identifies specific slide to a specific test
- Some stainers will provide processing status and completion status

Control slides
- LIS should manage control slides, patient slides that were grouped with control slide
- QA of control slide should affect slide batch (e.g. pass or fail entire batch)

Stainer items to manage
- Identify lab machine, serial number, date installed, service contract
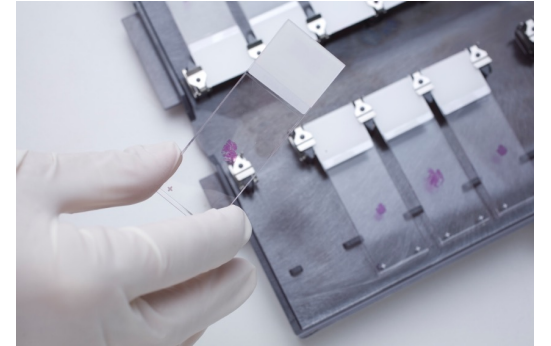- Track runtime operation
- Track number of runs over time
- Track reagent consumption, replacement
- Track uptime, service time requirements

Specific stainer items
- Track manufacturer, lot code, manufacturing date and expiration date of reagent

LIS Pathologist Requirements

Diagnosis macros to populate the diagnosis selected
    Editable fields for the diagnosis, microscopic and specimen diagnosis comment sections

Allows populated diagnosis (from macro) to be edited per-specimen

Shows information about the patient
    Patient demographics including age & insurance
    Specialty - identify under 40 yrs of age for some case types
    Patient digital requisition
    Patient previous diagnosis report history

Shows information about the specimen
    Accession by, Gross by, embedded by tech(s) information for the specimen
    Cut by tech(s) for each slide
    Specimen type, anatomy, any specimen comments from the procedure, gross description

Pathologist diagnosis features
    Allows pathologist to diagnose a serious or cancer flag to the specimen
    Enables reflexive testing addition
    Shows all ICD and CPT codes, enables pathologist to edit all items as needed
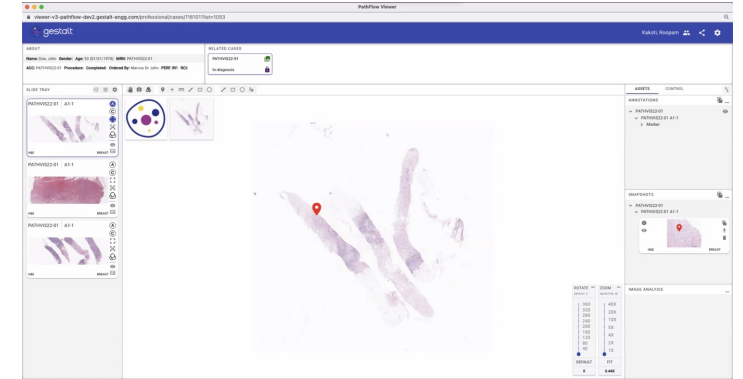   Enable preliminary or final diagnosis report preview & final signout

Show cases that are awaiting tests and signed out

Provide "waiting queue" with expiration time (e.g. 15 minutes)
    eliminates the "oops, didn't mean to sign it out" problem

LIS Digital Pathology

Implement digital scanning operations within your workflow

- Manage original sides, digitally-scanned images
- Maintain historical archive of original and annotated sides, accessibility in workflow

Bi-directional digital pathology interface

- Enhance the Pathologist cockpit!
- Data transfer between DP viewer and LIS in the diagnosis workflow
- LIS integration with Viewer initiation and LIS sign-out and case management
- Image, cancer count, specimen measurements, other info from DP Viewer into LIS
- Utilize AI algorithms for detection, measurement and augmented information

LIS Lab Metrics

Reporting functions for lab management

    Report patient cancer diagnoses to state agencies

    Lab personnel performance at various workflow steps – examples:

        total specimens grossed by tech over time

        Total blocks cut by tech over time

    QA reports for controls

    Turn-around-time (TAT) average of cases processed

    Pathologist signout workload over time

    Physician case count submitted over time

    Incident reports processed over time

    Case volume over time

    Tests processed by lab over time

    CPT volume & processed over time

    Case ICDs processed over time

    Sent-out cases turn-around time, external case count over time

    Asset usage, workstation usage

    Gross worklist, test worklist, Work In Progress (WIP) of the lab

LIS Connectivity metrics

    EMR imported & exported reports log

    HL7 or API connectivity logs

    Faxed or secure-email logs

    LIS error logs

LIS Revenue Cycle Management

Revenue of the lab, measured by, over time:

    Lab cases signed out

    CPTs assigned per case

    CPT reimbursement price, per insurance contract

    ICDs assigned per case

Expenses

    Personnel – tracked hourly or salary

    Consumables

        Printer ribbons, labels, slides, cassettes, xyelene, alcohol, gloves, paraffin, etc.

    Assets

        Lab hardware, PCs, refrigerators, etc.

    Fixed costs

        Utilities, rent, site insurance, telecom costs, network costs, LIS costs, storage, etc.

LIS Compliance & Security

Compliance that your LIS may require in your lab

    CAP compliance for your lab

    CLIA compliance

    IQ, OQ, PQ for FDA 21 CFR part 11 and part 58

    GLP, GMP certifications

    Certifications – Fed-RAMP, State-RAMP, others

Help documentation, training

Support

    phone, on-line support board, web chat, etc.

HIPAA Stage 1 security requirements

    Access controls

    Audit controls

    Integrity controls

    Transmission security

Additional security requirements - cloud & on-premise solutions

    Website encryption and transmission

    User access and authentication, login password requirements and MFA

    User permissions within the LIS for job roles – HIPAA compliancy

    Security penetration testing (pentesting)

    Encrypted storage – active or at rest
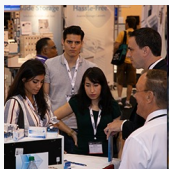
References

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