LIS Design and Functionality

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Walter Henricks, MD

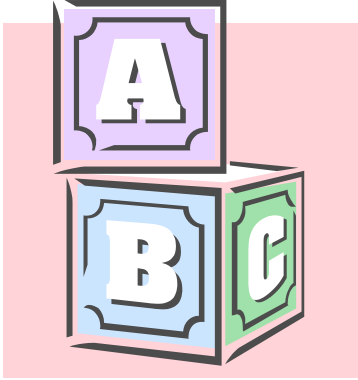
Introduction to Laboratory Information Systems (LISs) Learning Objectives

- Define terms and jargon related to LISs
- Describe central importance of dictionaries and interfaces to LIS function and laboratory operations
- Identify LIS functions as they relate to laboratory workflow in CP and AP

Introduction to LISs – Outline

- LIS architecture
- LIS dictionaries (a.k.a. maintenance tables)
- LIS functions in laboratory workflow
  - Clinical laboratory (CP)
  - Anatomic pathology (AP)

Building Blocks of Laboratory Information Systems



LIS application software

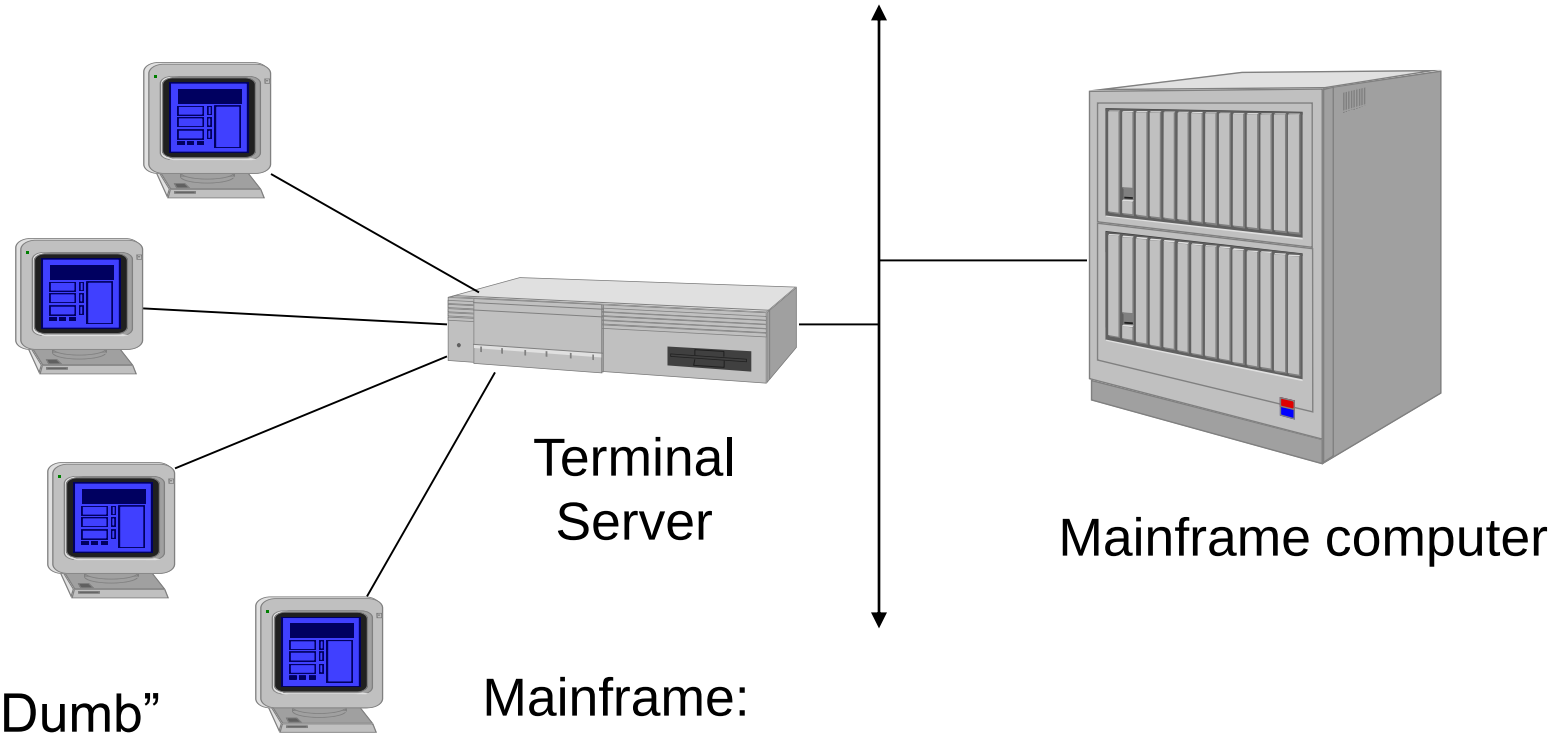
Database Management System (DBMS)

Operating System

Hardware

Peter B. Lewis Building, Case Western Reserve University. Architect: Frank Gehry

Host-based LIS Architecture



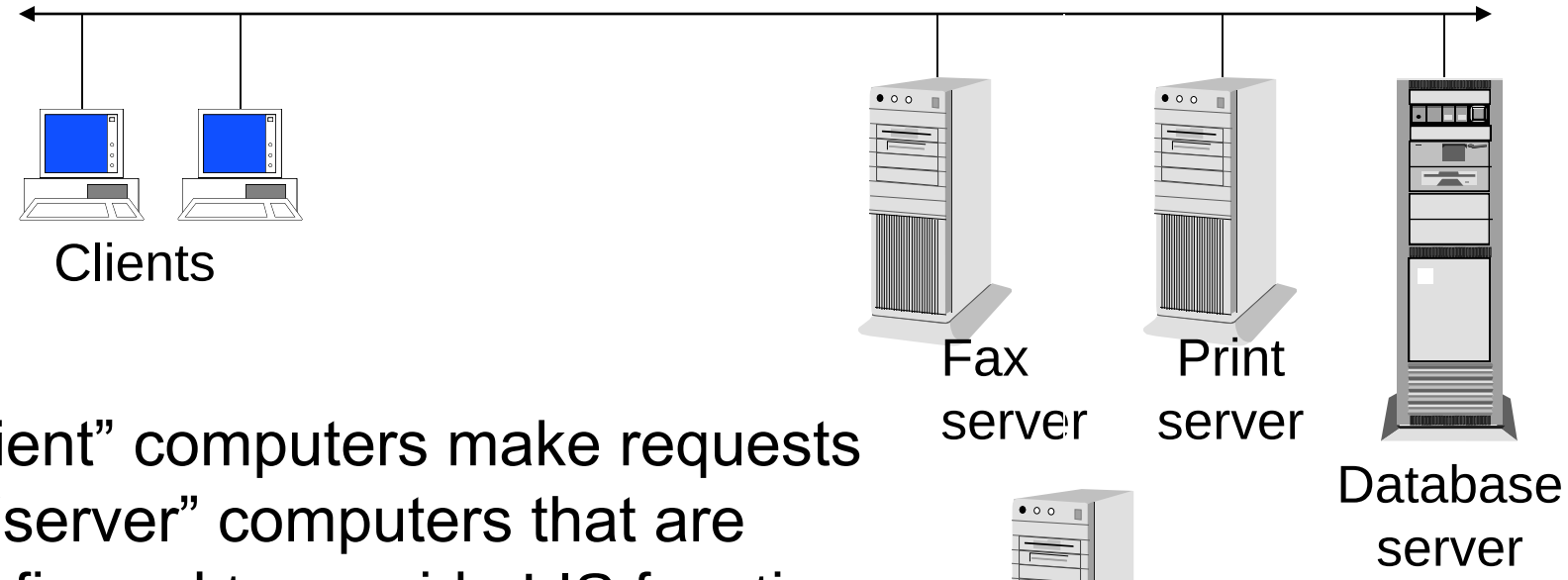
Mainframe:

- holds database and all LIS software
- manages all LIS functions and transactions

Terminals:

- data display and input only
- PCs can connect using "terminal emulation"

Client/Server LIS



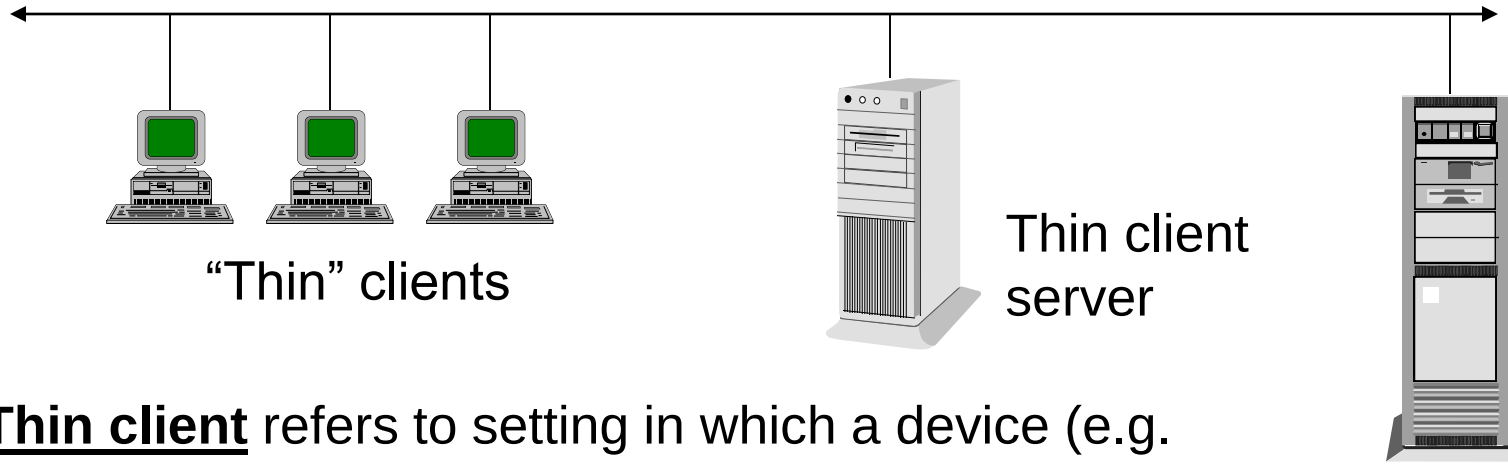
"Client" computers make requests of "server" computers that are configured to provide LIS functions

LIS software functions are **distributed** across all clients and servers

Mainframe vs. Client/Server LIS

- **Mainframe/Host-based**
  - Typically character-based user interface
  - Limited flexibility
  - Good security
  - Centralized maintenance and control
  - Single point of failure
- **Client/Server**
  - Graphical user interface
  - Greater configurability
  - Greater security risks (e.g. viruses, PC ports)
  - Decentralized and more distributed maintenance
  - Multiple points of failure, though each less catastrophic

Thin Client Architecture in LIS



- **Thin client** refers to setting in which a device (e.g. PC) runs software that is relatively simple (="thin") and requires less computer power and resources

- Application logic executes on *thin client server*

- Resembles host-based/mainframe model in some respects (connection through intermediate server)

Thin Client Computing for the LIS
How it may benefit YOUR laboratory

- Easier administration
  - Standardized application/programs controlled centrally
  - Easier to implement software updates in a complex environment
- Cross-platform (PC, Mac)
- Lower hardware requirements and costs
- Remote access
- Less network traffic

Thin Client Computing for the LIS
Why YOUR laboratory may think twice

- Hardware and license costs
- Single point of failure for all workstations connected to thin client server
- Effectiveness of vendor's implementation of thin client
- Potential inability to do specialized functions on thin client workstation, e.g. imaging, voice recognition

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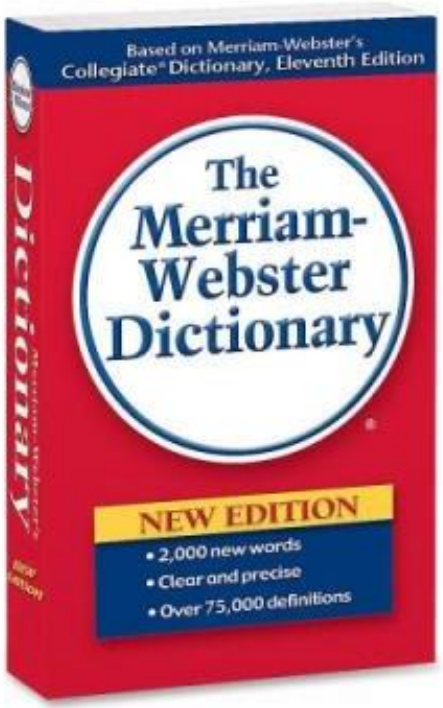
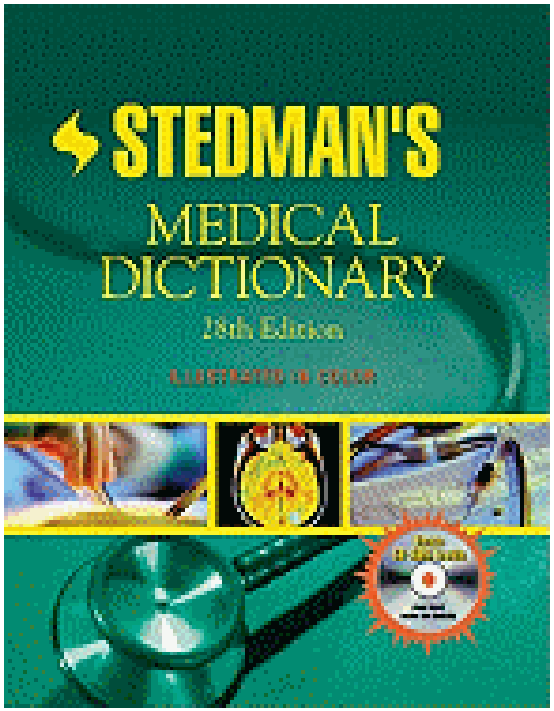
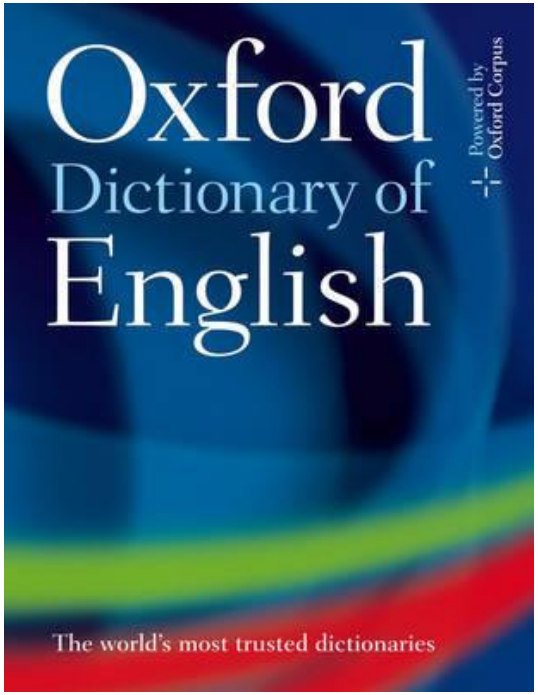
What do dictionaries contain?







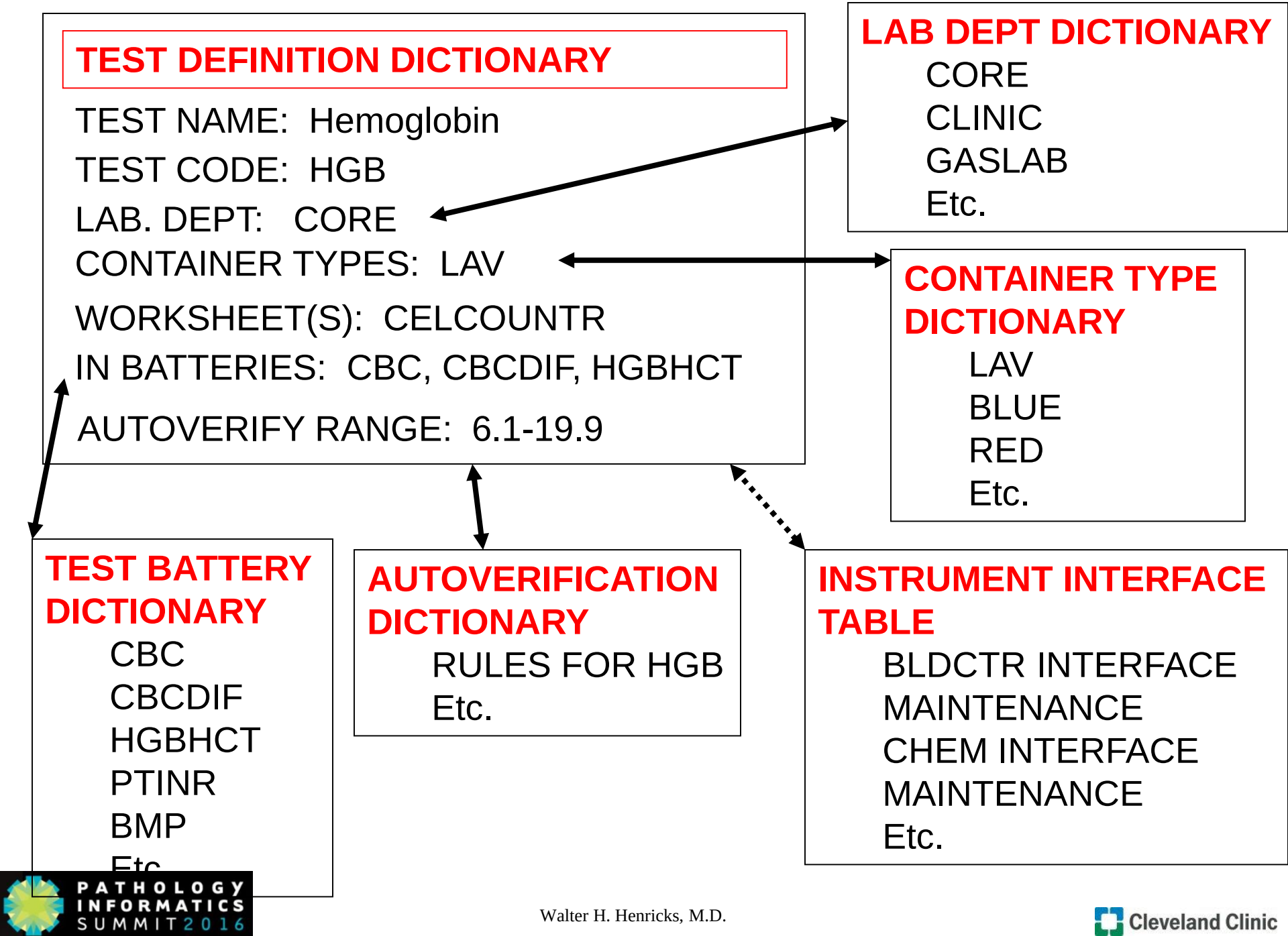
DEFINITIONS!

LIS Dictionaries *Define* Your Laboratory's Information Framework

- Standardize naming conventions and procedures
- Standardize laboratory terminology and definitions
- Constrain choices for data fields to ensure valid data entry
- Define content and format of reports (e.g. units of measure)
- Define rules and calculations

LIS Dictionaries Define *People, Places, Things*

- Test and test battery/profile definitions
- Test worksheets / worklists
- Person dictionaries (e.g., ordering physician, pathologist, technologist)
- Security/access level privileges for user types
- Patient locations
- Laboratory locations (e.g. sections, “areas”)
- Specimen types
- Histologic stain protocols (e.g. Giemsa on gastric bx)
- Analyzer/instrument interfaces
- Autoverification parameters
- Many others…


TEST DEFINITION DICTIONARY
TEST NAME: Hemoglobin
TEST CODE: HGB
LAB. DEPT: CORE
CONTAINER TYPES: LAV
WORKSHEET(S): CELCOUNTR
IN BATTERIES: CBC, CBCDIF, HGBHCT
AUTOVERIFY RANGE: 6.1-19.9
LAB DEPT DICTIONARY
CORE
CLINIC
GASLAB
Etc.
CONTAINER TYPE DICTIONARY
LAV
BLUE
RED
Etc.
TEST BATTERY DICTIONARY
CBC
CBCDIF
HGBHCT
PTINR
BMP
Etc.
AUTOVERIFICATION DICTIONARY
RULES FOR HGB
Etc.
INSTRUMENT INTERFACE TABLE
BLDCTR INTERFACE MAINTENANCE
CHEM INTERFACE MAINTENANCE
Etc.

Example AP LIS Dictionary: Specimen Part Type

PART TYPE DICTIONARY (mock)	
Entry Name:	LUNG, TXP BX
Shorthand:	TLBX
Description:	LUNG TRANSPLANT BIOPSY
Synonyms:	LUNG
	LUNG BIOPSY
	PULM
Specimen Categories:	SURGICAL ROUTINE
	SURGICAL OUTSIDE REVIEW
	SURGICAL CONSULTATION
Protocol:	LUNG TRANSPLANT BX
Fee Code(s):	LEVEL V

PROTOCOL DICT.
LUNG BX
LUNG TRANSPLANT BX
PROSTATE BX
⋮

FEE CODE DICT.
LEVEL I
⋮
LEVEL VI

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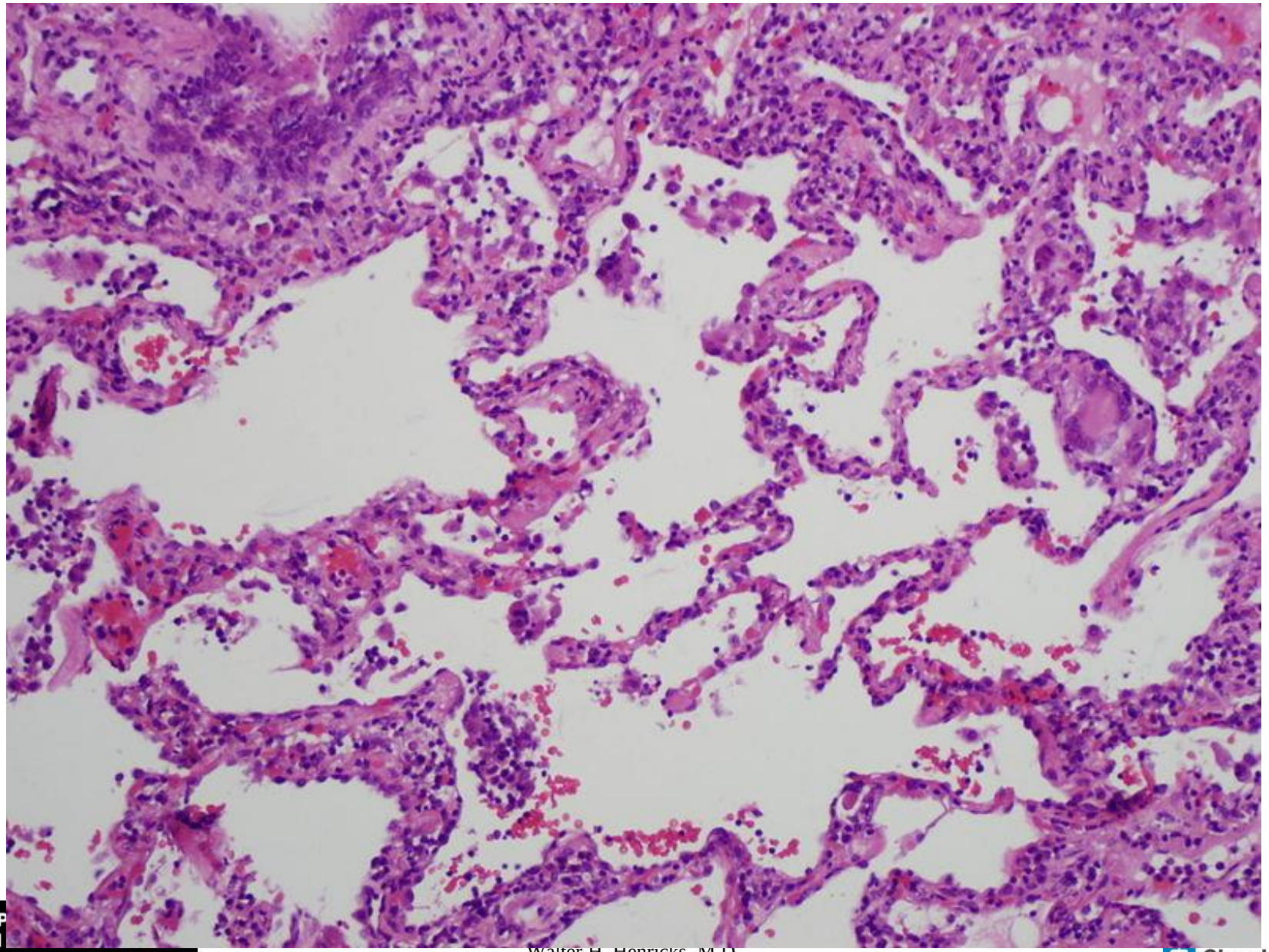
HISTO PROTOCOL DICTIONARY (mock)	
Entry Name:	LUNG TRANSPLANT BX
Shorthand:	TLBX
⋮	
Components:	H&E, INITIAL
	H&E, LEVEL
	MOVAT STAIN
	GMS STAIN

STAIN DICTIONARY (mock)	
Entry Name:	MOVAT STAIN
Shorthand:	MOVAT
⋮	
Label Print:	MOVAT
Stain Fee Code(s):	SPECIAL STAIN GRP 2

Dictionaries and maintenance tables *tailor* the LIS to YOUR laboratory

- Table definition is critical to successful LIS implementation and requires planning and user involvement.
- LIS “out of the box” may have default entries, which will most likely need to be re-defined.
- Definition changes require careful attention to prevent unintended consequences.
- Changes must be tested before being “put into production”.

Interfaces are important to life…and to laboratories



LIS Interfaces

Interface – software and connections that translate electronic messages so that otherwise incompatible systems can *exchange* data

LIS interfaces are critical to laboratory success (e.g. test order receipt, results reporting)

LIS-Instrument Interfaces

- Download = direct transfer of patient identification and test order data from LIS to instrument
- Upload = direct transfer of results back to LIS
- Uni-directional vs. Bi-directional
- Broadcast vs. query
- Unique specimen number on *LIS-generated barcode specimen label* links order and result data in the analyzer and the LIS.

- Other LIS interfaces: handheld phlebotomy devices, tissue cassette engravers, point of care testing devices

LIS-Instrument Interface Implementation

- LIS vendors have “off-the-shelf” interfaces for most common instruments (revenue source).
- Installation of a new interface is not “plug and play.”
- Interface software must be installed in LIS dictionaries.
  - Definition of data and sequence in the manner expected in the relevant worksheet(s).
  - Rigorous testing and validation prior to use and with changes.

YOUR LIS is interfaced to many other computer systems

- Electronic health record (EHR)
- Admission-Discharge-Transfer (ADT) – pt. registration
- Web portal system
- Physician office systems
- Billing
- Other LISs
- Others…

HL7 (Health Level 7) – Most Important Data Exchange Standard In Healthcare

- *HL7 defines the format (syntax, structure) but not the specific content of messages*
- HL7 tells computer systems “how to say it” to each other but not “what to say”.


ZÁKAZ TLUMOČENÍ
TRANSLATING
PROHIBITED

HL7 does not eliminate the difficulties of implementing interfaces

- HL7 interface specifications for LIS typically do not match other vendors/systems.
- Institution-specific HL7 segments often exist.
- Translation tables are necessary to cross-reference different test codes in different systems.
- **LOINC** is a standardized vocabulary of lab test names with goal of interoperability
- Interface deployment requires testing, validation, documentation

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Preanalytic Phase Information Management

- Order creation and test selection
- Specimen collection and labeling
- Specimen receipt and tracking

Order Creation and Test Selection – CP LIS

- Orders interfaced from EHR
  - Laboratory test orders are entered in EHR (based on menu choices and EHR definitions).
  - Orders cross HL7 interface to LIS.
  - Interface design ensures that correct orders are filed in LIS based on matching or translation of test codes.
- Non-interfaced test requisition order entry
  - Paper accompanies specimen to laboratory.
  - Lab staff enters orders into LIS, with test choices based on LIS dictionaries.

Specimen Collection and Labeling – CP LIS

- Inpatient – phlebotomist sweep collection
  - LIS assigns unique (accession) specimen and/or container number to each order.
  - LIS places orders on a collection list for next scheduled sweep or “AM labs”.
  - Phlebotomist may generate label dynamically at bedside using portable device.
  - Collection list or labels may guide phlebotomist as to appropriate container type to use.
  - Phlebotomist applies LIS-generated label to specimen.

Specimen Collection and Labeling – CP LIS

Outpatient – phlebotomy draw station (service ctr.):

- EHR-interfaced orders – phlebotomist/tech accesses existing orders in LIS, prints labels, and collects specimen.
  - There may be a preliminary step that involves locating patient orders in EHR and "pulling them into" LIS
- Non-interfaced orders – phlebotomist/tech enters orders for specified tests into LIS, prints labels, and collects specimen.

Specimen Receipt and Tracking – CP LIS

- EHR-interfaced orders
  - When specimen arrives in lab, orders already exist in LIS.
  - Lab staff acknowledges specimen receipt in LIS and confirms label and orders.
- Non-interfaced orders
  - Orders do not exist in LIS when specimen arrives.
  - Lab staff orders tests in LIS, prints and applies labels.
- Specimen status in LIS: “received” or “in-lab”

Specimen Receipt and Order Creation – AP LIS

- LIS assigns specimen a unique accession number ("accessioning").
- Different "number wheels" can be used to distinguish different classes of specimens
  - e.g. by location, HS-11-123, CS-11-123
- Multiple specimen parts are identified under one accession number.
- Other data from requisition are entered– e.g. physician, clinical hx
- Patient demographic data may be pre-populated in LIS from ADT interface data.

Specimen Receipt and Order Creation – AP LIS

- Two field types in LIS identify each part:
  - Part type – selected from a dictionary; categories of specimen types, e.g. colon, polyp
  - Part description – free text additional description provided with specimen, e.g. “large colon polyp at 50 cm”
- Part types may be linked in LIS to histology protocols or special stains.
- LIS may print specimen label with bar code.
- Specimen status is updated, e.g. to “Accessioned”.

Analytic Phase Information Management

- Work distribution and specimen preparation
- Test performance and analysis
- Test interpretation
- Additional testing based on initial results
- Results entry

Work Distribution – CP LIS

- Many “orderable” tests in CP consist of groups (or panels) of multiple individual test components, e.g. BMP, CMP
- LIS files orders for individual test components.
- LIS-generates bar code labels with unique specimen IDs that are key to instrument interfaces and specimen tracking.
- Test orders are *routed* to the appropriate LIS worksheets based on the worksheets assigned in the LIS test definitions.

Work Distribution and Worksheets – CP LIS

- Tests performed on interfaced instruments have LIS worksheets linked to instrument maintenance dictionaries, ensuring download to appropriate instruments
- Download to instrument may occur based on different triggers:
  - Receipt of order in LIS from EHR interface
  - Receipt of specimen in lab (as tracked in LIS)
- For batched tests, orders are routed to the appropriate LIS worksheets, which technologists access (or print) to see the list of work for that run.

Test Performance and Result Entry – CP LIS

- For interfaced instruments:
  - Instrument software reads bar code specimen number and performs the tests per downloaded orders (from LIS) linked to that specimen number.
  - Results are uploaded back to LIS, tied to specimen number
  - Interface specifications shared between LIS and instrument software ensure data transfer in expected sequence and format.
  - LIS worksheets linked to the instrument maintenance ensure that test results are filed correctly in the LIS.

Test Performance and Result Entry – CP LIS

- For tests performed on non-interfaced analyzers or manually, technologists enter results into LIS worksheets using the LIS resulting function.
- *Footnotes* or *comments* may be required to add additional information – free text vs. coded template from LIS dictionary

Rules and Additional Testing – CP LIS

- Worksheets link test or battery to any rules or calculations to be performed based on initial results, e.g. anion gap.
- Reflex Testing – automatic generation of new test order in LIS based on initial results meeting defined criteria, e.g. titration of positive ANA screen
- Autoverification – automatic final verification in the LIS of results from automated instruments without manual intervention.
- Criteria are based on algorithms defined in LIS
- Results or specimen-related data from the instrument that fall outside defined criteria are held for review.

Autoverification Table in LIS

```
TEST: HGB

Use Normal Range (<Y>/N)                        : N
Use Borderline Range (<Y>/N)                    : N
Use Technical Range (<Y>/N)                     : N
Use Verify Range (<Y>/N)                        : N
Use Delta Check (<Y>/N)                         : N
Use Instrument Filing Range (Y/<N>)             : Y      (Fail Cup)
Use Invalid (???) Range (Y/<N>)                 : N
Fail on Result Flag(s) (Y/<N>)                  : Y      Include: 4,
Fail on Pattern(s) (Y/<N>)                      : N
```

Middleware

- **Middleware**: rules-based processing provided by instrument vendor or third party that "sits between" the LIS and instrument
  - Autoverification
  - Reflexive test ordering based on result
  - Automatic dilutions, repeats, smear creation
  - Other aspects of instrument management, e.g. maintenance alerts

Grossing and Specimen Preparation – AP LIS

- Main information outputs in LIS of “grossing” phase are:
  - Text entry in LIS “Gross Description” field
  - Use of pre-defined templates for some specimen types
  - Designation of tissue sections in Histology module
  - Status updated, e.g. “Gross Complete”

Slide Preparation and Work Distribution – AP LIS

- LIS directs slide preparation workflow
  - Pre-defined protocols for levels and stains
  - Histology logs defining worklists of cases and blocks from grossing step
  - Slide labels (+/- bar codes) based on data entered in histology module and protocol/stain definitions
  - Special stains appear on specified logs (e.g. immunohistochemistry log)
- "Asset" tracking based on bar code labels and points of scanning defined

Slide Preparation and Work Distribution – AP LIS

- LIS produces “working draft” report for pathologist – paper vs. paperless
- Working draft format and content are based on template configuration in LIS, e.g.
  - Clinical information
  - Gross description
  - Frozen section report (if performed)
  - Summary of patient’s previous results, based on LIS search of database

Report Generation – AP LIS

- Entry of Final Diagnosis in LIS facilitated by:
  - Pre-defined templates, checklists, and formats
  - Speech to text conversion capability
  - Automatic entry of billing (CPT) and diagnosis (ICD) codes based on dictionary definitions
- "Synoptic" LIS modules enable entry of *discrete data elements.*
- Pathologist signs out cases with electronic signature that locks the case.

Post Analytic Phase Information Management

- Generation and delivery of lab results and test reports
- Correcting, amending, and addending reports

Report Distribution

- Hard copy report format is based on configurable template in LIS.
  - Printing – scheduled batches, on demand
  - Faxing – automated if fax numbers in dictionary
- For electronic reporting, reports pass from the LIS to receiving system via an interface
- *The format and display of interfaced reports is dictated by the screen design in the receiving system.*
- PDF and RTF interfaces preserve formatting; receiving system must accommodate.

Corrected Results – CP LIS

- LIS report must clearly identify the corrected result as corrected.
- Corrected result must also include the original result.
- Corrected result typically also includes documentation of the person correcting the result and a record of any communications (e.g. “corrected result called to …”).
- Corrected report typically replaces (overlays) previous result in EHR; original kept in audit trail.

Amendments and Addenda – AP LIS

- Report formats should be configured so that amended or addended status is obvious.
- Entire report is re-printed or re-transmitted across the interface with the new addendum identified as such
- In the EHR, the new report overlays the previous report.

Microbiology – LIS Considerations

- Specimen sources
  - e.g. blood, urine, tissue, fluid
- Specimen description and clinical data
  - e.g. Abdominal abscess; transplant patient
- Organism dictionaries
  - *Think **SNOMED-CT** here too!*
- Preliminary reports, sequential updates
- Antibiotic susceptibility testing and reporting
- Epidemiological and public health reporting

Microbiology Challenges in LIS-EHR Integration

- Congruent fields and definitions for specimen sources and specimen descriptions in LIS and EHR
- Clear distinguishing of preliminary and final reports
- Flagging “abnormal” microbiology results
  - What results should be flagged? – normal flora?
- Results of slow growing cultures
  - e.g. positive at 2 weeks – scroll back to order date?
- Formats of susceptibility results and codes

Blood Bank/Transfusion Medicine LIS Considerations

- Blood component identification
- Component status – e.g. allocated, issued
- Antibody work ups
- Special needs – e.g. irradiation, CMV neg, etc.
- Donor center functions
- Transfusion reactions
- Apheresis
- FDA approval; validation; inspections

Blood Bank/Transfusion Medicine Challenges in LIS-EHR Integration

- Patient historical information needed at time of transfusion need
  - ABO/Rh types
  - Availability of current Type and Screen sample
  - Clinically significant alloantibodies
  - Any other factor that will affect availability of blood
- Integration with bedside positive patient identification/transfusion manager process
- Closed loop information regarding component unit disposition, e.g. transfused, discarded, etc.

Molecular Genetic Pathology
LIS Considerations

- Multi-step protocols and procedures
- Modular protocols, e.g. DNA extraction
- Data transfer from non-interfaced analytical platforms
- Integration with bioinformatics platforms
- Complex result data
- Interpretive reporting
- Integration with CP and AP systems

LIS Fundamentals – Summary

- LIS dictionaries define the framework for information processing and workflow.
- Worksheets and logs define the data and specimen flow in the laboratory.
- LIS is central to laboratory operations throughout all phases of testing.
- Capabilities in LISs reflect workflow differences between CP and AP.