LIS Basics: CP and AP LIS Design and Operations

Pathology Informatics 2011
October 4, 2011

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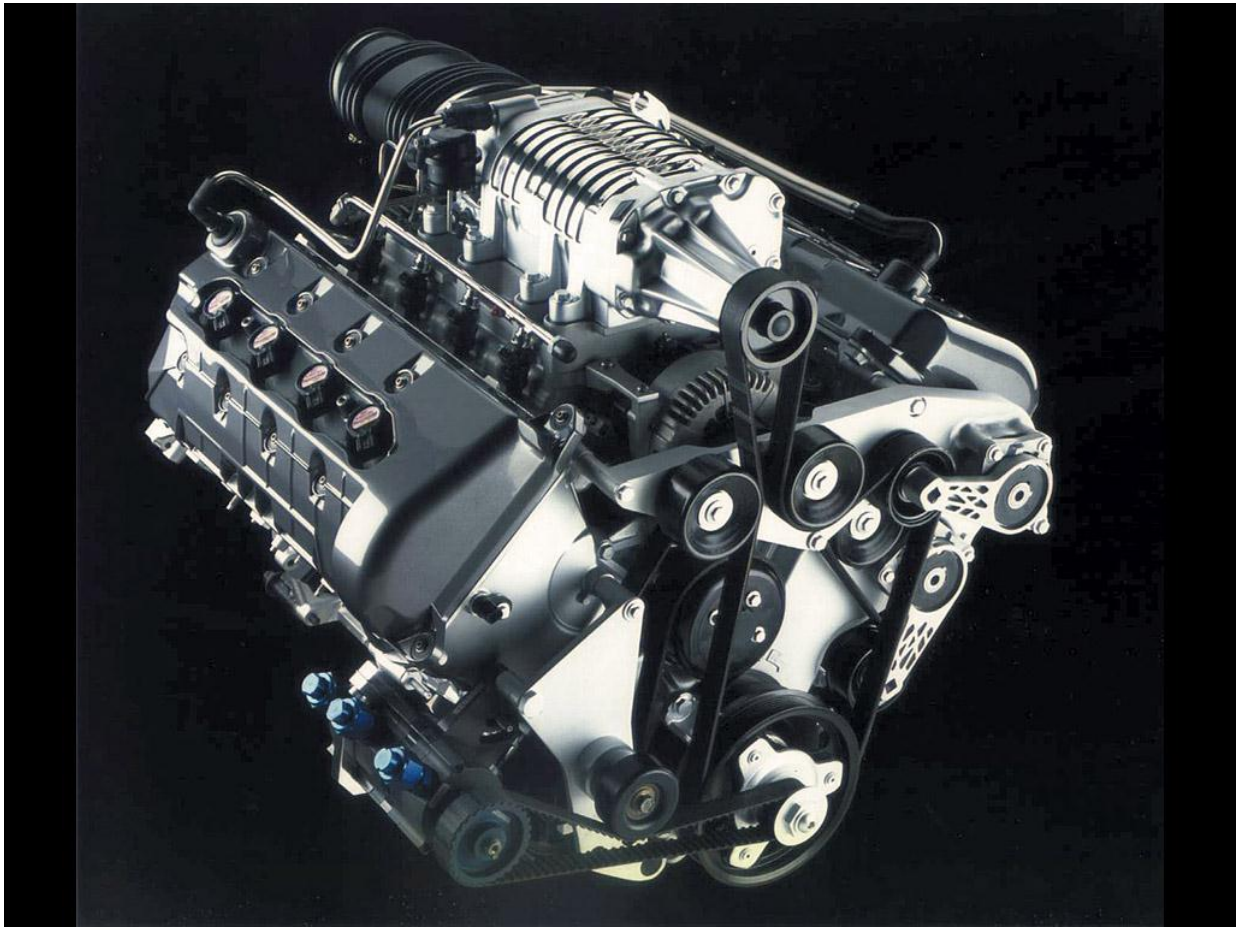
Introduction to Laboratory Information Systems (LISs) Learning Objectives

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

The LIS is the Engine of the Laboratory



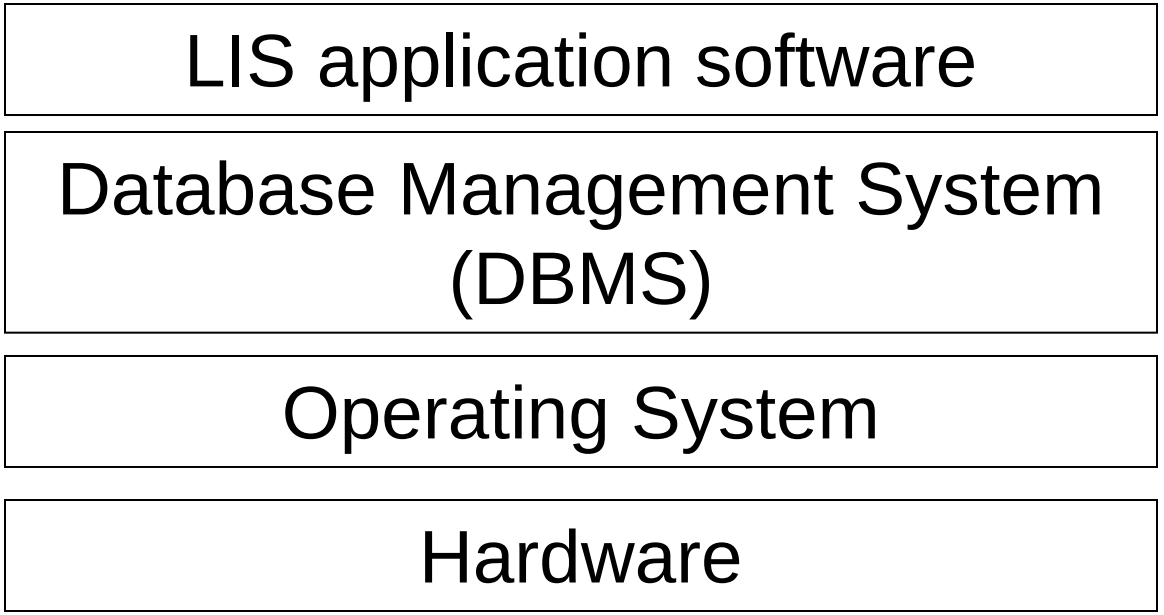
Laboratory Information System (LIS)

- Interrelated programs and hardware that provide electronic data processing and information management functions necessary for laboratory operations
- Database that establishes and maintains standard definitions and information processing procedures (Elevitch and Aller)

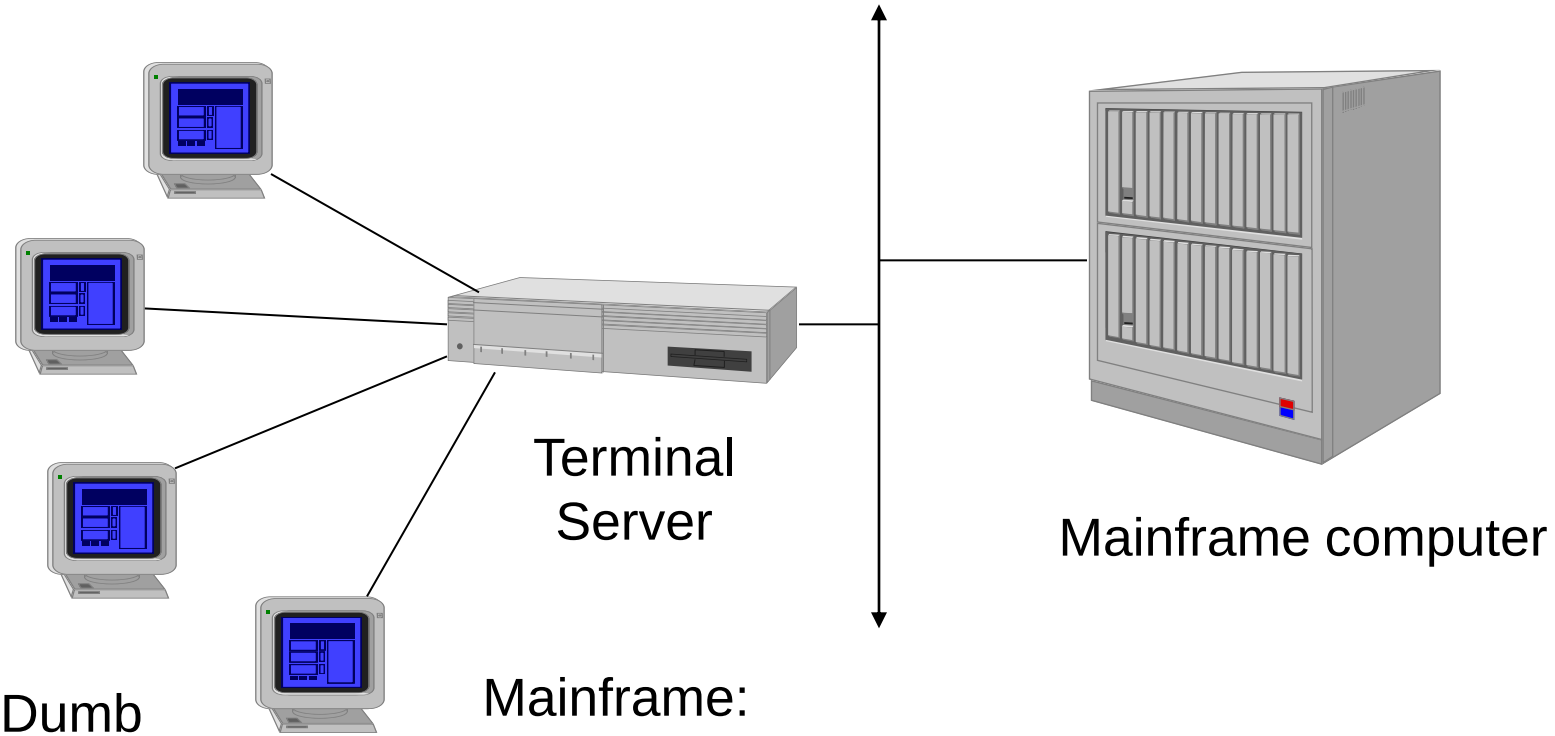
Introduction to LISs – Outline

- 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



Host-based LIS Architecture



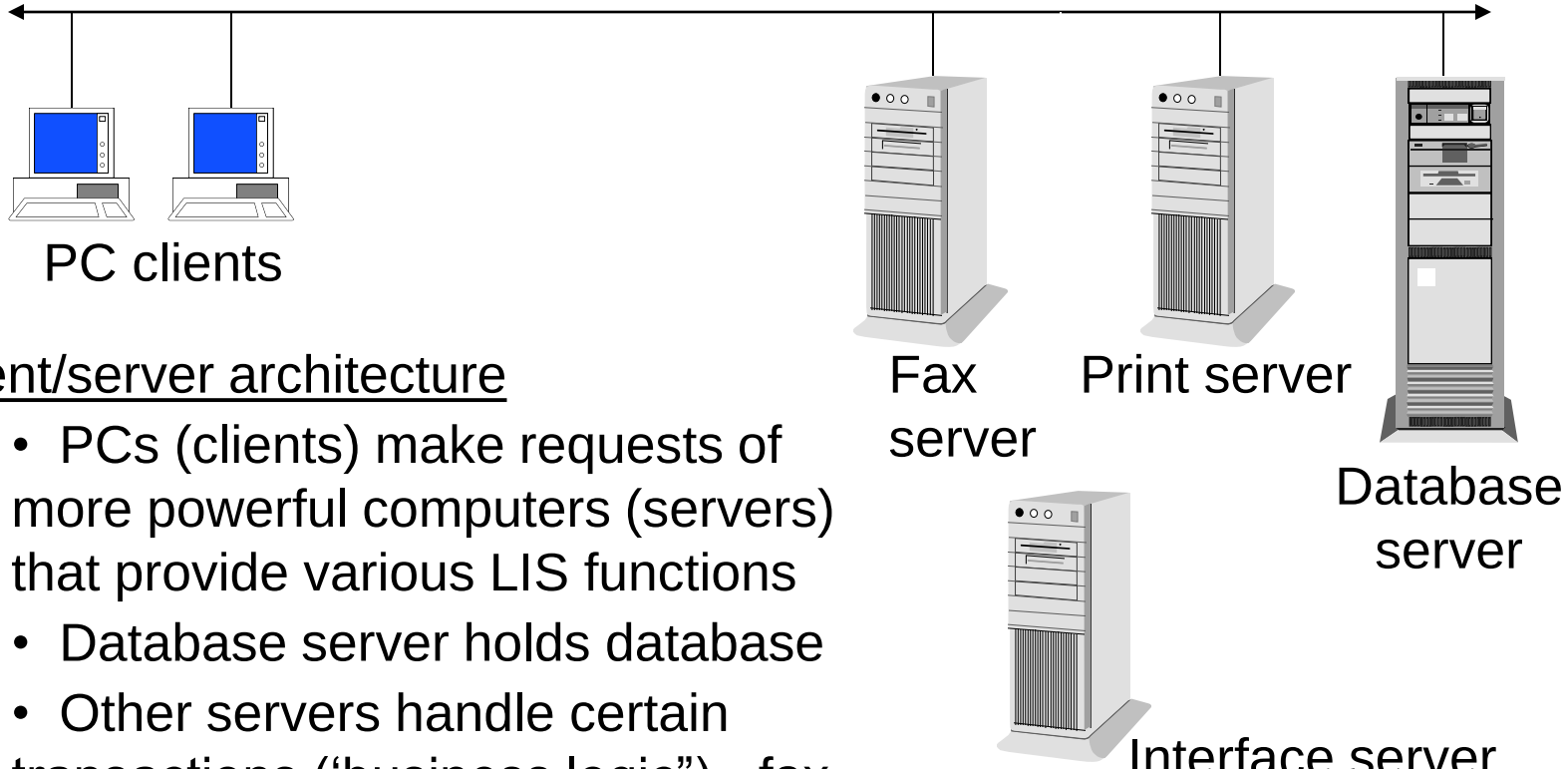
Mainframe:

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

Terminals:

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

Client/Server LIS



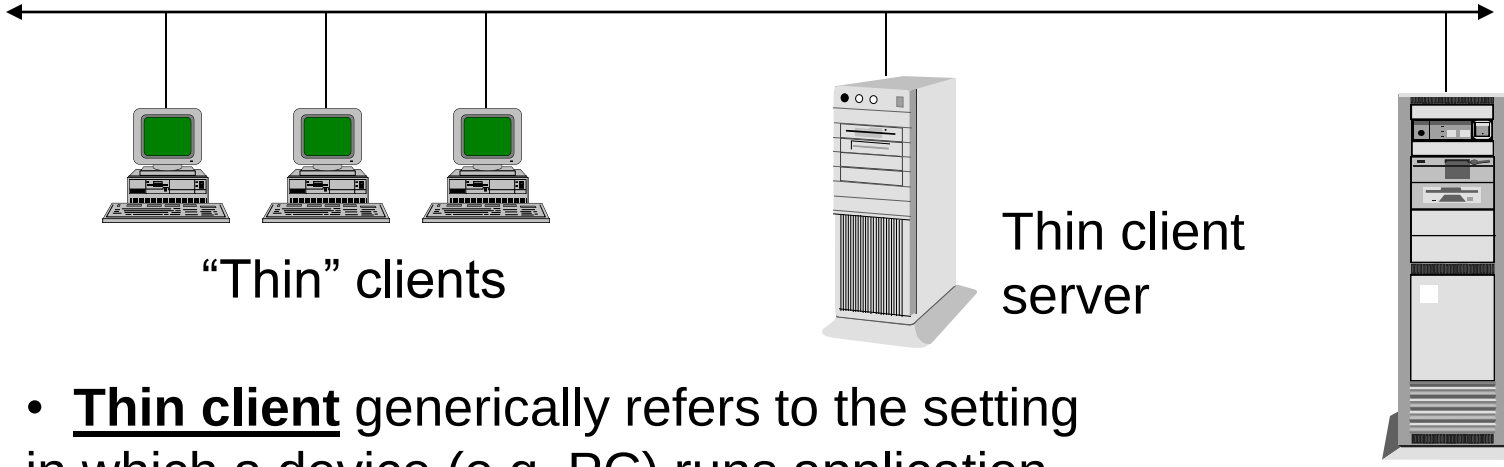
Client/server architecture

- PCs (clients) make requests of more powerful computers (servers) that provide various LIS functions
- Database server holds database
- Other servers handle certain transactions (‘business logic”) - fax, print, interface
- LIS software functions are **distributed** across all clients and servers

Mainframe vs. Client/Server

- 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** generically refers to the setting in which a device (e.g. PC) runs application software that is relatively simple and requires less computer power and resources to operate
- All application logic executes on thin client server
- Resembles host-based/mainframe model in some respects (connection through an 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
- Inability to do specialized functions on thin client workstation, e.g. imaging, voice recognition

Introduction to LISs – Outline

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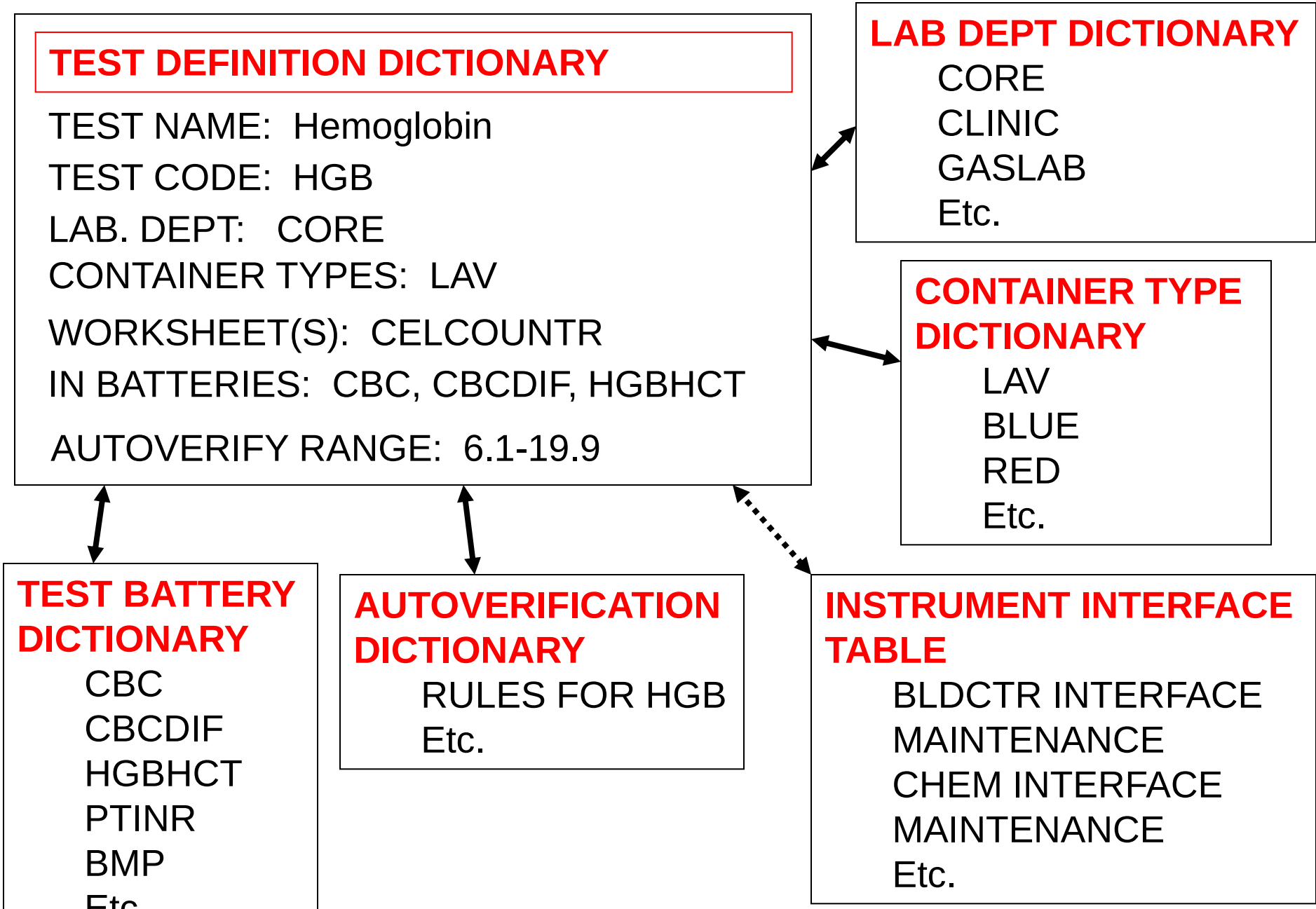
LIS Dictionaries define the framework for information processing and workflow throughout the laboratory

- Standardize and structure lab conventions and procedures
- Standardize laboratory and LIS terminology and definitions
- Ensure entry of valid data by constraining data entry choices for data fields
- Define content and format of elements that appear on reports (e.g. units of measure)
- Define rules and calculations

LIS Dictionaries – 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.

Maintenance Definitions in AP LISs

- Many dictionary types in AP LISs overlap with those in CP LISs, but…
- AP LISs must support operations and data flow that are quite different from the clinical laboratory.
- Specimen Type (or Part Type) and Special Stain dictionaries are analogous to test definitions in CP LIS.
- Example: "stomach bx" defined in Specimen Type dictionary would be tied to histology protocols (e.g. H&E x2), special stain protocols (e.g. Giemsa), billing information, SNOMED codes, and other data.

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

PART TYPE DICTIONARY (mock)	
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Protocol:	LUNG TRANSPLANT BX
Fee Code(s):	LEVEL V

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 time, attention, and planning.
- Some dictionaries must be built in sequence, since entries depend on other dictionaries.
- Dictionaries may be pre-built by vendor, but more important is defining tables in a way that meets your lab's specific needs.
- Definition changes require careful attention to ensure that all appropriate tables are updated and that the changes tested before use.

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 – orders vs. results
- Broadcast vs. query
- Unique specimen number on LIS-generated barcode specimen label links order and result data in the analyzer and the LIS.
- Other devices possibly interfaced to LIS: 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 when changes are made.

YOUR LIS is connected to many other systems
(LIS-application interfaces)

- Electronic medical record (EMR) / Clinical information system (CIS) / Hospital information system (HIS)
- 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 defines various message types, such as laboratory test orders and results, patient admission-discharge-transfer (ADT), others.
- Messages (e.g. order, result) consist of segments comprised of fields

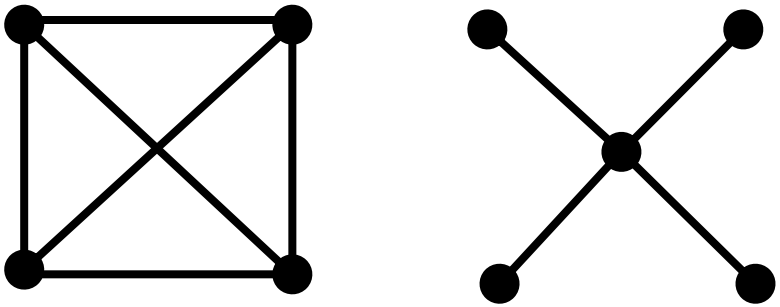
  OBX|1|NM|CK^CK|1|251
  |U/L|30-220|H|||F|||||201006082152|

HL7 helps but does not eliminate the difficulties of implementing interfaces

- System vendors develop HL7 interface specifications for their own systems; such specifications usually do not match those of other vendors/systems.
- Institutions can define custom, site-specific segments (allowable in HL7; very flexible)
- Lab test name codes definitions differ between systems, and translation tables are necessary to cross-reference different codes.
- Interface deployment requires cooperation among system vendors, laboratory, and information system support personnel
  - testing, validation, documentation

Interface Engine

- System that routes and translates messages among multiple disparate computer systems
- Reduces number of individual interfaces (point to point) needed for multiple systems
- Widespread in healthcare organizations
- Improves interface management in complex environments but is also a potential point of failure



Point-to-point | Interface engine (“hub”)

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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

- Electronic order entry into EMR/HIS
  - Test choices and data are entered in EMR
  - Orders cross HL7 interface to LIS
  - Interface design ensures that correct orders are filed in LIS based on matching or translation of test codes
- Paper requisition order entry
  - Paper accompanies specimen to laboratory
  - Orders are entered into LIS, with test choices determined by dictionaries

Specimen Collection and Labeling – CP LIS

- Inpatient – phlebotomist sweep collection
  - LIS assigns unique (accession) specimen and/or container number.
  - LIS automatically places orders on a phlebotomy collection list for the next scheduled sweep (or “AM labs”).
  - 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

- Inpatient – clinician collection
  - Clinician acquires specimen, e.g. STAT.
  - Clinician enters order in EMR (or completes paper req.).
  - EMR prints generic specimen labels at point of order entry; LIS may print labels at patient unit.
- Outpatient – phlebotomy draw station
  - Interfaced orders – phlebotomist accesses existing orders in LIS, prints labels, and collects specimen.
  - Paper orders – phlebotomist enters orders for specified tests into LIS, prints labels, and collects specimen.

Specimen Receipt and Tracking – CP LIS

- Electronic interfaced orders
  - When specimen arrives in lab, orders already exist in LIS.
  - Lab staff acknowledges specimen receipt in LIS and confirms label and orders.
- Paper-only requisitions
  - 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 batteries (or panels) of multiple individual test components, e.g. chemistry panel of Na, K, Cr, etc.
- LIS files orders for individual test components.
- LIS generates labels with bar code specimen ID
  - Primary tube
  - Aliquots for splitting samples and distribution
- Bar code labels 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 EMR 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.
- 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 dictionaries
- Results or specimen-related data from the instrument that fall outside defined criteria are held for human review

Autoverification – Possible Criteria

- Reference (normal) range
- Technical range of the assay
- Instrument-defined filing range
- Critical value range, or other “verify” range specified in dictionary
- Delta checks
- Acceptance criteria for inpatients vs. outpatients
- Criteria based on other results in same test (e.g. RBC indices)
- Instrument flags

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

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
```

Grossing and Specimen Preparation – AP LIS

- Main information outputs in LIS of “grossing” phase are:
  - Text entry in LIS “Gross Description” field
  - Designation of tissue sections in Histology module
  - Status updated, e.g. “Gross Complete”
- LIS interactions in grossing the specimen may include:
  - Specimen bar code identification
  - Speech recognition software for data entry
  - Automatic cassette labeling based on interface with cassette labelers
  - Acquisition of gross digital images into LIS

Slide Preparation and Work Distribution – AP LIS

- LIS directs slide preparation workflow – e.g. tissue sections (histology) and liquid-based preps (cytology) based on LIS rules.
  - Pre-defined protocols for levels and stains
  - Histology logs defining worklists of cases and blocks from grossing step
  - Slide labels based on data entered in histology module and protocol/stain definitions
- Special stains ordered based on LIS dictionary entries and appear on specified logs (e.g. immunohistochemistry log)

Slide Preparation and Work Distribution – AP LIS

- LIS produces “working draft”
  - Hard copy distribution to pathologist with slides
  - Paperless review in LIS
- Working draft format and content are based on template configuration in LIS
  - Clinical information
  - Gross description
  - Frozen section report (if performed)
  - Summary of previous results, based on LIS search of database

Report Generation – AP LIS

- Entry of Final Diagnosis may be facilitated in LIS by
  - Pre-defined templates, checklists, and formats
  - Coded text entry – short codes that trigger dictionary look-ups that translate into expanded text
  - Speech to text conversion capability
  - Automatic entry of billing (CPT) and diagnosis (ICD) codes based on dictionary definitions
- "Synoptic" LIS modules provide capability to enter and to store pathology report information as discrete data elements

Report Generation – AP LIS

- After entry of diagnosis, status is updated to indicate case ready for sign out, e.g. “Final complete”
- Pathologists may and edit review cases from “queue” or “worklist”
- Sign out consists of electronic signature that locks the case and represents final verification of case in database.

Post Analytic Phase Information Management

- Generation and delivery of lab results and test reports
- Correcting, amending, and updating (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-based interfaces can preserve formatting, but receiving system may not accommodate.

Corrected Results – CP LIS

- When a correction is necessary, the LIS report must clearly identify the new result as a corrected result.
- 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 …”).
- When the corrected report is transmitted to the EMR, it will replace (overlay) the previous result; original is kept in audit trail

Amendments and Addenda – AP LIS

- LISs identify amended and addended reports as such.
- Report formats should be configured so that amended or addended status is obvious to reader
- For addenda, the entire report is re-printed or re-transmitted across the interface with the new addendum identified as such
- In the EMR, the new report overlays the previous report.

Supplemental Laboratory Applications

- Provide capabilities beyond “traditional” LIS functions
- May be integrated as part of LIS or purchased from third party
- May fill gaps with functions that may not be obtainable as part of LIS

Supplemental Laboratory Applications Examples

- Middleware
- Patient bedside ID systems
- Lab Portal = Web-based results, orders
- Point-of-care testing (POCT) data management
- Document management (e.g. scanning of paper requisitions, reports)
- Specimen tracking and archiving
- Digital image integration
- Voice recognition

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 data management in all phases of testing.
- Capabilities in LISs reflect workflow differences between CP and AP.