LIS MONITORING TOOL

Organization Information

Laboratory Name	
Facility Name (if different)	
City	
Your name (assessment lead)	
Organization you are affiliated with	
Names of other members of assessment team with affiliation	
Date of assessment *(dd/mm/yyyy)*	

Laboratory Staff Involved in Completion of Questionnaire

Name	Job Title (related to LIS)	Telephone	Email address

Infrastructure

1	Do you have electrical plug points in your work area?	Yes	No	Unsure
2	Are these outlets enough to support all computers and instruments?	Yes	No	Unsure
3	Are there network points for computers?	Yes	No	Unsure
4	Are these network points enough to support all necessary PC's?	Yes	No	Unsure
5	Are all computers networked to the server?	Yes	No	Unsure
6	Do you have adequate and continuous supply of electricity?	Yes	No	Unsure
7	Are cables and wires tied up neatly?	Yes	No	Unsure
8	Are computer and server areas free of dust?	Yes	No	Unsure
9	Do you have a backup generator?	Yes	No	Unsure
9a	Is it working adequately?	Yes	No	Unsure
10	How many computers are there in your lab?	Number:		
10a	Of these how many are used for the LIS?	Number:		
10b	How many of these computers have Internet access?	Number:		
11	Is there someone in the laboratory or hospital who is in charge of maintaining the computers?	Yes	No	Unsure
12	Are they routinely available to deal with any issues?	Yes	No	Unsure
13	Are they available on site?	Yes	No	Unsure
14	How often are they available?	On call	Daily	Weekly
15	Is there a flow diagram to represent the standardized approach to maintenance and the levels of support?	Yes	No	Unsure
16	What is the turnaround time to resolving problems?			
17	Do you have designated space for the server?	Yes	No	Unsure
18	Is the server in a location that can be locked and has limited access during work hours?	Yes	No	Unsure
19	Do you have accessible fire fighting equipment?	Yes	No	Unsure
19a	Is it still valid?	Yes	No	Unsure
20	Is other equipment, such as analyzers, computers, barcode scanner, and printers, positioned in accordance with supplier instructions?	Yes	No	Unsure
21	Does the current placement promote optimal workflow?	Yes	No	Unsure

22	Do you have an adequate supply of consumables, such as paper for printing, ink cartridges, labels, etc?	Yes	No	Unsure
23	Is Internet connectivity available in the lab?	Yes	No	Unsure
23a	Is it reliable?	Yes	No	Unsure
23b	Is it high speed?	Yes	No	Unsure

Hardware

1	Is there a hardware maintenance plan? This plan includes introducing new hardware, phasing out of hardware older than a certain length of time, maintenance responsibilities, etc.	Yes	No	Unsure
2	Is there a list/inventory of hardware (server, computers, printers, scanners and peripherals) that was provided for the deployment and use of the LIS?	Yes	No	Unsure
2a	If there is a list, does it include model and serial number too for the hardware?	Yes	No	Unsure
2b	Is this list updated regularly based on turnover of hardware?	Yes	No	Unsure
2c	Is description/current specifications of the hardware included in this plan?	Yes	No	Unsure
3	Does hardware meet required/original specifications?	Yes	No	Unsure
4	Is all hardware that is required for the LIS fully functional?	Yes	No	Unsure
5	Is all hardware (computers, printers, analyzers) connected to a UPS?	Yes	No	Unsure
6	Is there a maintenance and support contract for all hardware provided for the LIS?	Yes	No	Unsure
7	Is there a list of all laboratory analyzers?	Yes	No	Unsure
7a	Does each item on the list have a unique ID?	Yes	No	Unsure

Software

1	What data on specimens received are you recording in the LIS?			
1a	Patient ID	Yes	No	Unsure
1b	Test Requested	Yes	No	Unsure
1c	Date/Time of Collection	Yes	No	Unsure
1d	Requestor	Yes	No	Unsure
1e	Acceptance/Rejection Criteria in LIS	Yes	No	Unsure
1f	Name of Receiving Staff Recorded in LIS	Yes	No	Unsure
1g	Treatment/Diagnosis	Yes	No	Unsure

2	Are you able to use the LIS to trace an aliquot back to the original source?	Yes	No	Unsure
3	Does every sample in the LIS have a unique identifier?	Yes	No	Unsure
4	Is a sample ID always linked to a patient ID?	Yes	No	Unsure
5	Can you prioritize testing in the LIS?	Yes	No	Unsure
6	Can the LIS generate a tracking form to accompany shipped samples?	Yes	No	Unsure
7	Can the laboratory determine pending or incomplete tests for a patient?	Yes	No	Unsure
8	Can the laboratory compare tests completed against tests requested?	Yes	No	Unsure
9	Does LIS record name/ID of staff performing test?	Yes	No	Unsure
10	Do the laboratory staff record results in the LIS manually or by interface?	Manual	Interface	Unsure
11	Can results in the LIS be associated with the instrument that was used, if there is more than one instrument available for the same test?	Yes	No	Unsure
12	Can the LIS track inventory - media, reagents?	Yes	No	Unsure
13	Are there agreed upon turn around times for each test?	Yes	No	Unsure
13a	If yes, are there different turn around times for routine and urgent?	Yes	No	Unsure
14	Does the LIS archive data?	Yes	No	Unsure
15	If so, can the archived data be retrieved as needed?	Yes	No	Unsure
16	How many types of tests are automated?	Number:		
17	How many analyzers are interfaceable?	Number:		
17a	Of these, how many are interfaced with the LIS?	Number:		
18	Are you able to use the LIS at every step of the specimen life cycle - registration, test results and reporting?	Yes	No	Unsure
19	Are there any manual/hand written steps involved?	Yes	No	Unsure
20	Are you able to add new tests in the LIS?	Yes	No	Unsure
21	Are you able to create a new report in the LIS?	Yes	No	Unsure
22	Are you able to add/remove a user in the LIS?	Yes	No	Unsure
23	Is there a process for sending comments to improve the LIS?	Yes	No	Unsure
24	What kind of support contract covers the software?	Yes	No	Unsure
25	Is the lab able to batch enter sample data into the LIS?	Yes	No	Unsure
26	Is there stock management functionality in the LIS?	Yes	No	Unsure

27	What are the level of users configured in the LIS?	

Documentation

1	Are the following SOPs available:		
1a	General SOP for basic receipt, testing and result reporting	Yes	No
1b	System failure procedure when LIS is non-functional	Yes	No
1c	Retention of documents	Yes	No
1d	Validation	Yes	No
1e	On-going Verification	Yes	No
1f	Support Procedure Flow Chart	Yes	No
1g	Statistics on parameter results	Yes	No
1h	Statistics on test method results	Yes	No
1i	Total tests performed per month	Yes	No
1j	QC	Yes	No
1k	Specimen rejection	Yes	No
1l	Monitoring of TAT	Yes	No
1m	Routine data back-up, verification and recovery	Yes	No
1n	Stock Management	Yes	No
1o	Sample Referrals	Yes	No
1p	Positive test results statistics	Yes	No
1q	Daily check of outstanding work per workstation	Yes	No
2	Is the LIS used for documentation control management?	Yes	No
3	Does the Lab have access to and maintain the server log?	Yes	No
4	Does the lab use the LIS to review on a monthly basis the following: (quality indicators)		
4a	Specimen Rejection	Yes	No
4b	Statistics	Yes	No
4c	Inventory Reports	Yes	No
4d	QC Data	Yes	No
4e	LJ charts	Yes	No
4f	Turnaround time	Yes	No

5	Can the lab manage data for a sample received through PT program?	Yes	No
6	Is the Master List for all documents available in the LIS?	Yes	No
6a	If yes, is this list up-to-date?	Yes	No
7	Does the LIS maintain historical data of amended reports?	Yes	No
8	Does the LIS include recording of nonconformities?	Yes	No
9	Does the LIS include recording of corrective action?	Yes	No
10	Does the LIS include recording of preventive action?	Yes	No
11	Data on specimen receipt and storage (if any)?	Yes	No
12	Recording of IQC and EQC (put with quality indicators) ?	Yes	No
13	Does the laboratory use the LIS to enter QC data, verify it, and plot it on a daily basis prior to release of patient?	Yes	No
14	Is analyzer calibration and maintenance recorded in the LIS?	Yes	No
15	Are maintenance records stored in the LIS?	Yes	No
16	Is the LIS being used to record specimen rejection?	Yes	No
17	If QC is out of range, is there documentation of corrective action?	Yes	No
18	Is there a list of roles and contact information for the LIS within the lab?	Yes	No
19	Is there contact information for implementers posted within the lab?	Yes	No
20	Is there a log of backups of the LIS?	Yes	No
21	Is there a log of verification of results?	Yes	No
22	Is there documentation of maintenance/support work carried out by LIS support staff?	Yes	No

Communication

1	Does the laboratory communicate with lab management about LIS successes, challenges and provide routine reports on operations and use of the LIS? (each lab or TWG has to define success criteria)			Yes		No	
2	If yes, what is the frequency?	Daily	Weekly	Monthly	Quarterly	Annually	Non-routine
3	Is this communication documented?			Yes		No	
4	After an assessment, do they receive a nonconformity report?			Yes		No	

Validation and Verification

LIS needs to be validated by cross checking manual reports with LIS reports.

1	Is there any process of verification of data on the request form and the data recorded in the LIS?	Yes	No
2	Is there a process of verification of results output from the analyzers and the data entered into the LIS?	Yes	No
3	Does the above verification happen before release of results or after?	Before release	After release
4	If after, how is corrective action taken?		
5	Does the tester carry out the verification of test results before authorization?	Yes	No

Data Quality Assessment

1	Laboratory section			
2	Today's date (*dd/mm/yyyy*)			
3	Time period for assessment		Start Date *(dd/mm/yyyy)*	End Date *(dd/mm/yyyy)*
4	Number of specimens in logbook		Number of specimens in LIS	
5	Duplicate records in logbook	Yes No	Duplicate records in LIS	Yes No
	COMPLETENESS			
6	For the records under observation, study the data on specimens received and note the following:	Number of records in logbook with incomplete data elements (use the list below)	Number of records in LIS with incomplete data elements (use the list below)	Number of records with entries in logbook different than LIS (use the list below)
6a	Patient ID			
6b	Test Requested			
6c	Date of Collection			
6d	Time of Collection			
6e	Requestor			

6f	Acceptance/Rejection criteria in LIS (the rejection should be for both LIS and logbook)			
6g	Name of receiving staff recorded in LIS			
7	For the records under observation, study the data on reports/results and note the following:	Number of records in logbook with incomplete data elements	Number of records in LIS with incomplete data elements	Number of records with entries in logbook different than LIS
7a	Patient Name			
7b	Patient Address			
7c	Hospital/Facility Requesting			
7d	Lab Producing Report			
7e	Name of Person Requesting			
7f	Type of Sample Received			
7g	Test Requested			
7h	Date/Time of Specimen Collection			
7i	Date/Time Specimen Receipt			
7j	Date/Time Release of Report			
7k	Normal Reference Ranges			
7l	Interpretation of Results (if applicable)			
7m	Rejected Specimen and Reason (if applicable)			
7n	Name of Person Authorizing Release			
7o	Signature of Person Owning Responsibility for Content/Who is Tester - Name			
7p	In paper-based reports, are the reports standardized? (same format)			
	INTEGRITY			
		In the logbook	In the LIS	Number of modified records in logbook different than LIS
8	For the records under observation, how many were updated/modified?			
9	Count the number of each of the following fields that was modified for the records you are observing:	Number of records that have been modified in the logbook	Number of records that have been modified in the LIS	Number of modified records in logbook different than LIS
9a	Patient ID			
9b	Test Requested			
9c	Date of Collection			

9d	Time of Collection			
9e	Requestor			
9f	Acceptance/Rejection criteria in LIS			
9g	Patient Name			
9h	Patient Address			
9i	Hospital/Facility Requesting			
9j	Lab Producing Report			
9k	Name of Person Requesting			
9l	Type of Sample Received			
9m	Test Requested			
9n	Date/Time of Specimen Collection			
9o	Date/Time Specimen Receipt			
9p	Date/Time Release of Report			
9q	Normal Reference Ranges			
9r	Interpretation of Results (if applicable)			
9s	Rejected Specimen and Reason (if applicable)			
9t	Who made the change			
9u	When was the change made			
	TIMELINESS			
			In the logbook	In the LIS
10	Are the records up-to-date?			
10a	Please record the most recent date for specimens with completed results *(dd/mm/yyyy)*			
	ACCURACY			
11	For the records under observation, count the number of records for which data between the logbook and the LIS are different			

Reports

1	Do the reports generated by the laboratory all follow a standard?	Yes	No	Unsure
2	Do the reports include the following:			
2a	Patient name	Yes	No	Unsure
2b	Patient address	Yes	No	Unsure
2c	Hospital/facility requesting	Yes	No	Unsure
2d	Lab producing report	Yes	No	Unsure
2e	Name of person requesting	Yes	No	Unsure
2f	Type of sample received	Yes	No	Unsure
2g	Test requested	Yes	No	Unsure
2h	Date/Time of specimen collection	Yes	No	Unsure
2i	Date/Time of specimen receipt	Yes	No	Unsure
2j	Date/Time release of report	Yes	No	Unsure
2k	Normal reference rages	Yes	No	Unsure
2l	Interpretation of results (if applicable)	Yes	No	Unsure
2m	Rejected specimen and reason (if applicable)	Yes	No	Unsure
2n	Name of person authorizing release	Yes	No	Unsure
2o	Signature of person owing responsibility for content	Yes	No	Unsure
2p	Critical results	Yes	No	Unsure
3	Does the LIS record tester name/ID?	Yes	No	Unsure
4	Does the LIS produce reports on technician workload by test?	Yes	No	Unsure
5	Does the LIS produce reports on tests done by defined time period?	Yes	No	Unsure
6	Can the laboratory use the LIS to track altered results?	Yes	No	Unsure
7	Can the laboratory use the LIS to track amended/corrected reports?	Yes	No	Unsure
8	Can the laboratory use the LIS to track who results are released to?	Yes	No	Unsure
9	Can the laboratory use the LIS to determine how many times a report was printed?	Yes	No	Unsure
10	Does the laboratory submit weekly reports to government agencies (e.g. MOH)?	Yes	No	Unsure
11	Are request forms standardized for all tests?	Yes	No	Unsure
12	Is there a weekly roster showing dedicated persons to authorize reports?	Yes	No	Unsure
13	Can quality indicators be retrieved from the LIS?	Yes	No	Unsure
14	Does the laboratory report results for referred samples?	Yes	No	Unsure

Data Use Assessment

1	Are you a user of data from the laboratory?					Yes			No		
2	If yes, what type of data do you use?	Lab test results by test	Lab QA/QC results	Patient results	Aggregate data on number and types of tests	Data on workload of laboratory staff	Data on laboratory supplies used and new stock required	Number of cases identified	EQA	Turn around time	EQA
3	Please indicate the ways you use these data	Verification of results, completeness of testing, cross-checking results as well as checking results against what was requested	Validation of results, verification of results	Review results for all tests requested on a patient to assess completeness. Clarify that this is about report. Authorization of results/ report	"Make decisions about patient's treatment Lab could use the data to determine statistics, determine turnaround time, to monitor quality indicators	Make decisions about re-organizing workload for staff	Order supplies/ kits. Forecast supplies based on the numbers and consumption	Make policy decisions for the laboratory	Overall performance in laboratory	Use laboratory data to demonstrate success or failure of programs - too vague/ ambiguous. Advocate for funding. Monitor success of treatment. Determine prevalence rates in surveillance studies	Make decisions about expanding laboratory clients or test menus/ testing capacity
4	Are they provided to you from the LIS?	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	
5	If no, and you wish to request these data from the LIS, can you do so yourself? Or do you have a point of contact for this request?					Extract data myself			Request from point of contact		
6	Do you receive them printed from the LIS, handwritten, or both?		Printed			Handwritten			Combination		
7	Are there any additional data available from the LIS that are not mentioned above?					Yes			No		

8	If yes, what type of data from the LIS would be most beneficial to you?							
9	Do you consider data you currently receive from the LIS to be userful when making decisions regarding data quality? Relate this to what is written on the report (e.g reference ranges on report tell you if it's out of range).			Yes			No	
10	Do you believe you can use the data you currently receive from the LIS to make decisions that impact programs and/or services (can they use data to improve lab services)?			Yes			No	
11	Do you believe you can use the data you currently receive from the LIS to demonstrate the impact of programs and/or services (is data easily accessible, analyzable, can it be aggregated)?			Yes			No	
12	In your opinion, are there any barriers that are preventing you from using the data you have listed above?			Yes			No	
13	If yes, what are these?	Insufficient data	Data not of appropriate format	Data does not answer my questions	My organization does not encourage use of LIS data	I do not know where to go/ who to ask to get what I need	I don't know enough about the LIS to have expectations in terms of data	
14	Do you have suggestions for improvements to the LIS?							
15	What is your role within the organization?	Laboratory Technician	Data entry staff	Laboratory Manager	Laboratory Director	Doctor	Nurse	Medical Director of hospital

Security

1	Patient confidentiality - security of LIS, authorized users have access	Yes	No
2	Authorized users have ability to change patient data and/or results	Yes	No
3	Are data backed up?	Yes	No

4	With what frequency area data backed up?	Daily	Weekly	Monthly	Multiple times per day
5	On what media are data backed up?	Flash drive	External hard drive	CD ROM/DVD	
6	Is backed up data in a secure location, under lock and key?	Yes	No		
7	Are archived patient results backed up or stored (paper or data storage media) in a secure location accessible only to authorized personnel?	Yes		No	
8	Is there anti virus software on the computers?	Yes		No	
9	Is the anti virus installed on individual PC's or available through the server?	Individual		Server	
10	Is the software up to date/valid?	Yes		No	
11	Is there system fault tolerance?	Yes		No	
12	Are there measures in place to assure data integrity?	Yes		No	

System Operations and Application

1	Is the Lab generating worksheets from the LIS?	Yes	No
2	Is the LIS integrated with any systems?	Yes	No
2a	If yes, what systems:		
2b	Hospital information system	Yes	No
2c	Electronic medical record	Yes	No
2d	Pharmacy system	Yes	No
2e	Stock/inventory system	Yes	No
3	Is the LIS used to refer samples to another laboratory?	Yes	No
4	Is there an audit trail to monitor processes and amendments made to data and patient results?	Yes	No
5	Have LIS operations been uninterrupted over the last 12 months?	Yes	No

Training and Competency

1	Are staff deemed competently-trained in LIS use?	Yes	No
2	Is a refresher training available for staff on the LIS and documentation maintained?	Yes	No
3	Is training available for newly hired staff and documentation maintained?	Yes	No
4	Are there methods to assess whether staff are properly trained in the LIS?	Yes	No

5	Are there different levels of users for the LIS?	Yes	No
5a	Super User	Yes	No
5b	User	Yes	No
5c	Administrator	Yes	No
5d	More	Yes	No
5e	Are the levels known to the individuals and to others?	Yes	No
6	Is the User guide for LIS available to staff?	Yes	No
7	Have the staff been provided with basic PC training skills?	Yes	No
8	Are the Super Users duties clear, available and distributed to sites?	Yes	No

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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