The University of Iowa | State Hygienic Laboratory

CLIA CORNER

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In This Issue...

- **Review of the Post-Analytic Quality System and Sample Audit Checklist**

We have finally come to the conclusion of our discussion about the four quality systems and the quality assessment (QA) policies and activities all non-waived laboratories must have in place. We discussed the general laboratory system in the 2020 3rd Quarter issue, the pre-analytic system in the 2020 4th Quarter issue, and the analytic system in the 2021 2nd Quarter and 2021 3rd quarter issues. In this issue, we'll conclude with an overview of the post-analytic system.

Four QA Systems:

General Pre-Analytic Analytic **Post– Analytic**

The post– analytic quality system focuses on reporting patient test results and the test report in which they are contained. Below, sections of the post-analytic system are reviewed and include QA probes on which to focus.

Test Report: Result Transmission

☑ The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (interfaced or entered manually) to the final report destination, in a timely manner

☑ The test report information must be maintained as part of the patient's chart or medical record and must be readily available

QA Probes:

→ Periodically verify transcribed or electronically transmitted results for accuracy both within the laboratory's laboratory information system (LIS)/ electronic health record (EHR) and at the report's final destination

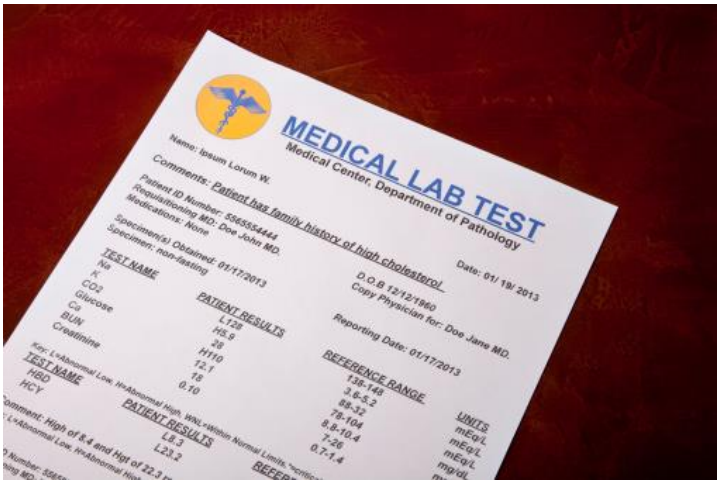
→ Verify the reports received at a final destination other than the laboratory (i.e. nursing home or physician's clinic) have the same data sent by the laboratory

→ Verify system security of facsimile and/or LIS and EHR interfaces used to transmit results from the laboratory to the authorized individual's location or electronic system

Test Report: Required Components

☑ The final test report must indicate the following:

- For positive identification: the patient's name and identification or a unique patient identifier and identification number
- Name and address of the performing laboratory
- Test report date
- Test performed
- Specimen source, when appropriate
- Test result and, if applicable, the units of measurement or interpretation, or both
- Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability



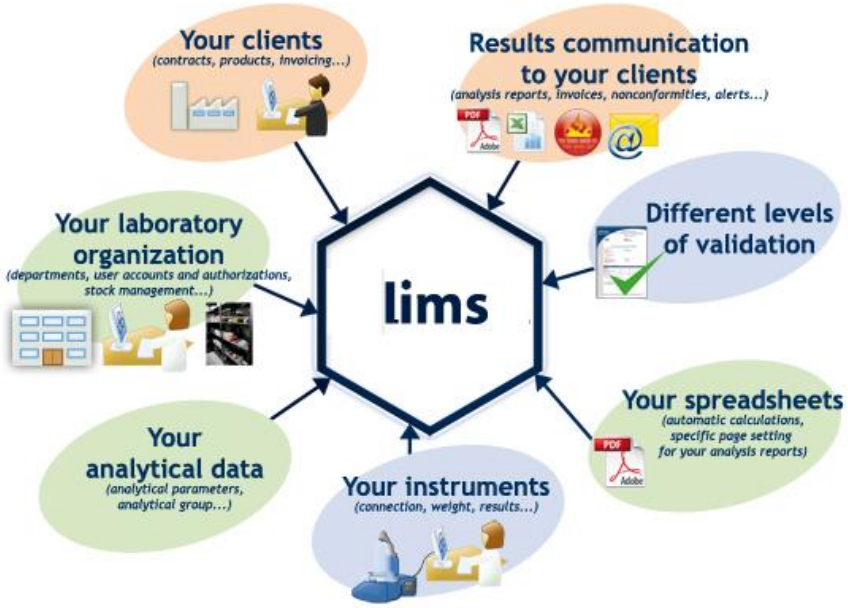
QA Probes:

→ Periodically audit test reports for completeness and accuracy, including manual entries into the LIS and/or EHR

→ Verify the accuracy of calculated data

→ Verify the accuracy of each test report component when a new test or test method is introduced

→ Verify that the test report identifies the performing location for each test result if testing is performed at multiple locations



Test Report: Availability of Information

☑ The laboratory must make available to authorized individuals pertinent reference intervals or normal values

☑ The laboratory must, upon request, make available to clients a list of test methods used by the laboratory

☑ Information that may affect the interpretation of test results must be provided upon request

☑ Pertinent updates of testing information must be provided to clients whenever changes occur that affect test results or interpretation of test results

QA Probes:

→ Periodically audit information given to clients to ensure it is current, including a list of test methods used, interpretation of test results, and reference intervals/normal values

→ Verify clients are notified when there are changes in the laboratory's test menu

Test Report: Notification and Release of Test Results

☑ Test results must be released only to authorized individuals and, if applicable, individuals responsible for using the test results and the laboratory that initially requested the test

☑ The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values

☑ When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing

☑ Upon request by the patient (or the patient's personal representative), the laboratory may provide patients and their personal representatives, as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient

QA Probes:

→ Review and evaluate the procedures for notification and release of test results, including:

- The laboratory's definition of an "authorized individual"
- Process for reporting results ordered verbally
- Criteria for identifying and reporting imminently life-threatening conditions, or panic or alert values, including who may receive the results over the phone (e.g. nurse vs. provider) and documentation of who reported the results, the date, time, test results, and person to whom the rest results were given
- Process for verification and release of test results through the LIS/HER
- Criteria for the laboratory's authentication process for release of completed laboratory reports to patients and/or their personal representatives

→ Monitor and evaluate turn-around times

→ Review and evaluate alternative testing and reporting methods used by the laboratory when the LIS, EHR, or test system is down and delay in reporting patient test results may negatively impact patient care

Test Report: Referral Testing

☑ The referring laboratory must not revise results or information directly related to the interpretation of the results provided by the testing laboratory

☑ The referring laboratory may permit testing laboratories to send test results directly to the authorized individual who initially requested the testing. The referring laboratory must retain or be able to produce the exact duplicate of the testing laboratory's report

Test Report: Referral Testing, continued...

☑ The authorized individual who orders the test must be notified by the referring laboratory of the name and address of each laboratory location where testing was performed

QA Probes:

→ **Monitor and evaluate the system for tracking patient specimens sent to reference laboratories to ensure the referral laboratory sends results in a timely manner**

→ **Request reference laboratory CLIA certificate(s) to ensure they are valid and current**

Test Report: Retention and Retrieval

☑ All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility

☑ Test report information maintained as part of the patient's char tor medical record must be readily available to the laboratory

QA Probes:

→ **Review policies for retention and retrieval of test reports and ensure they are retained and retrievable for the minimum time for all regulatory agencies**

→ **Evaluate and monitor the laboratory's back-up system for electronic records and systems**

Test Report: Corrected Reports

☑ When errors in reported patient test results are detected, the laboratory must promptly notify and issue a corrected report to the authorized individual ordering the test and, if applicable, the individual using the test results

☑ The laboratory must maintain duplicates of the original report, as well as the corrected report

QA Probes:

→ **Ensure the laboratory has an effective mechanism to notify authorized individuals of corrected results in a prompt manner**

→ **Ensure the laboratory can differentiate between incorrect original reports and corrected reports**

→ **Ensure corrected reports clearly indicate both the corrected result(s) and the fact that the report is corrected**

→ **Evaluate the laboratory's system for maintaining copies of original and corrected reports**

An effective QA program is the key to ensuring accurate and reliable test results.

An example of a Post– Analytic System QA audit tool can be found on the following pages. This example has been created by the Iowa CLIA State Agency as an aid in the laboratory QA process and is not an official form created by the Centers for Medicare & Medicaid Services.

If you would like to be added to the CLIA Corner newsletter, email us at:

Kristine-Rotzoll@uiowa.edu or Melinda-Bochmann@uiowa.edu

Quality Assessment Audit: Post- Analytic Laboratory System				
Result Transmission		**Yes**	**No**	**N/A**
Record review: Choose 5 random patient test results manually entered into the laboratory information system (LIS) and review them for completeness and transcription accuracy				
	Patient 1:			
	Patient 2:			
	Patient 3:			
	Patient 4:			
	Patient 5:			
For each instrument interfaced to the LIS/EHR, do test results and pertinent patient information flow accurately and reliably? **Document corrective action below, if needed:**				
Reports sent through the LIS are received at off-site locations with accurate patient information and test results **Document corrective action below, if needed:**				
Transmissions sent by fax, LIS, or other electronic systems are sent securely **Document corrective action below, if needed:**				
Required Components		**Yes**	**No**	**N/A**
Review final test reports for each test system. Do they include all of the following: 2 patient identifiers; name and address of performing laboratory; test report date; test performed; specimen source, as appropriate; test results and, as applicable, units of measure or interpretation; information regarding unacceptable specimens **Document corrective action below, if needed:**				
All calculations performed by the instrument and/or LIS are accurate **Document corrective action below, if needed:**				
Test reports identify the performing location for each test result when testing is performed at multiple locations **Document corrective action below, if needed:**				
Availability of Information		**Yes**	**No**	**N/A**
Do clients have the most current information from the laboratory including a list of testing currently available, test methods used, interpretation of test results, and reference intervals/normal values? **Document corrective action below, if needed:**				
Notification and Release of Test Results		**Yes**	**No**	**N/A**
The laboratory has a policy to define an “authorized individual” **Document corrective action below, if needed:**				

Quality Assessment Audit: Post- Analytic Laboratory System

Notification and Release of Test Results, continued...		Yes	No	N/A
The laboratory has a policy that includes criteria for identifying and reporting imminently life-threatening conditions or critical values, including who may receive the results over the phone and documentation of who reported the results, date, time, test results, and person to whom results were given **Document corrective action below, if needed:**				
Record review: Choose 5 patient test reports with critical/panic values and ensure they were reported and documentation is complete and accurate according to the laboratory's policy				
	Patient 1:			
	Patient 2:			
	Patient 3:			
	Patient 4:			
	Patient 5:			
Patient testing turn-around times fall within the laboratory's established criteria **Document corrective action below, if needed:**				
The laboratory has a system in place for alternative testing and/or reporting methods when the LIS, EHR, or test systems fail and delay in reporting patient test results may negatively impact patient care **Document corrective action below, if needed:**				
Referral Testing		**Yes**	**No**	**N/A**
The laboratory's tracking system is adequate for ensuring patient specimens are sent to and results received from referral laboratories in a timely manner **Document corrective action below, if needed:**				
Retention and Retrieval		**Yes**	**No**	**N/A**
Test reports and patient testing records are readily available to the laboratory, even when there has been a change in electronic systems **Document corrective action below, if needed:**				
The laboratory has an adequate and secure back-up system for electronic records and systems **Document corrective action below, if needed:**				
Corrected Reports		**Yes**	**No**	**N/A**
The laboratory has an effective method for notifying providers of corrected reports in a timely manner **Document corrective action below, if needed:**				
The laboratory can differentiate between the original and corrected reports **Document corrective action below, if needed:**				
The corrected report clearly indicates the corrected result and that the report is corrected **Document corrective action below, if needed:**				
The laboratory retains copies of both the original and corrected test reports **Document corrective action below, if needed:**				