The University of Iowa | State Hygienic Laboratory

CLIA CORNER

State Hygienic Laboratory at The University of Iowa Fourth Quarter 2020

In This Issue...

Quality Assessment (QA) Review

The last issue of the CLIA Corner discussed how QA includes the activities, processes, checks, and balances used to ensure continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems. We learned that it is an on-going review process of the laboratory's technical and non-technical functions for all locations/sites where testing is performed. We also reviewed the first QA system, General Laboratory.

Requirements

☑ Written QA policy must includes all four quality systems

☑ QA policies and procedures should include:
- Practices/processes implemented for each QA system
- Review of the effectiveness of corrective action
- Revision of policies and procedures necessary to prevent recurrence of problems
- Discussion of the QA reviews with the appropriate staff

☑ QA practices/processes must include a component that ensures continuous improvement of the laboratory's performance and services through ongoing mechanisms to monitor, assess, and when indicated, correct problems

☑ Policies, procedures and processes that comprise and monitor all four quality systems must be followed and documented

Four QA Systems:

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

The Pre-Analytic Laboratory quality system includes test requests and functions related to specimen submission, handling and referral. Below, each section of the Pre-Analytic system is reviewed and includes QA probes on which to focus.

Test Request:

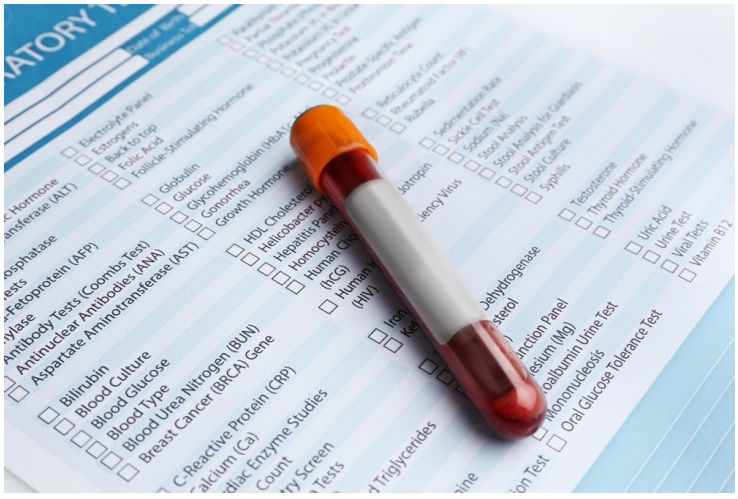
☑ The laboratory must have a written or electronic request for patient testing from an authorized individual.

☑ The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

☑ The laboratory must ensure the test requisition solicits the following information:

- Name and address (or suitable identifier) of the authorized person requesting the test or the laboratory submitting the specimen
- Patient name or unique identifier
- Sex and age or date of birth of the patient
- Test(s) to be performed
- Specimen source, when appropriate
- Date and, if appropriate, time of specimen collection
- For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment or biopsy
- Any additional information relevant or necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable

☑ If the laboratory transcribes or enters test requisitions or authorization information into a record system or a laboratory information system (LIS), the laboratory must ensure the information is transcribed or entered accurately.



QA Probes:

→ **Authorized individuals**

- Written policy defining "authorized individual"

→ **Standing orders**

- Written policies that cover the use of standing orders including what tests are covered and how often they are reconfirmed

→ **Verbal test requests**

- Written policy for requesting written orders within 30 days of the verbal request
- If a written request was not received, the laboratory must have documentation showing its attempt at acquiring one

→ **Test Requisition**

- Use of unique identifiers for patient specimens with shared or similar names, dates of birth, addresses, or gender
- System for ensuring accurate manual entry by personnel into the laboratory information system (LIS)

Specimen submission, handling, and referral:

☑ The laboratory must establish and follow written policies and procedures for each of the following, if applicable:

- Patient preparation
- Specimen collection
- Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source
- Specimen storage and preservation
- Conditions for specimen transportation
- Specimen processing
- Specimen acceptability and rejection
- Specimen referral

☑ The laboratory must document the date and time it receives a specimen

☑ The laboratory must refer a specimen for testing only to a CLIA- certified laboratory or a laboratory meeting equivalent requirements as determined by CMS

☑ If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified above

QA Probes:

→ **Patient instructions**

• Appropriate instructions for patient preparation must be given when needed (fasting, dietary restrictions, twenty-four hour collections, etc.)

• Resources must be available for patients with special communication needs (hearing impaired, English fluency, etc.) to ensure instructions are properly understood

→ **Specimen labeling**

• System for processing two or more specimens simultaneously with the same first and last name or date of birth

→ **Specimen handling, processing, storage, preservation**

• System for identification of tests with special handling requirements for all personnel including those performing collection, processing and storage

•System for processing timed patient specimens

As mentioned in the last CLIA Corner, an effective QA program is the key to a successful laboratory. An example of a Pre- Analytic System QA audit tool can be found on page 5 of this CLIA Corner.

NOTE: This example has been created by the Iowa CLIA State Agency as an aid in laboratory QA processes and is not an official form or tool endorsed by the Centers for Medicare and Medicaid Services (CMS). Laboratories are not required to utilize it, and are free to modify the tool as needed.

Stay tuned for the next issue of the CLIA Corner where we will discuss the third quality system: **Analytic**

COVID Antigen Testing Helpful Hints

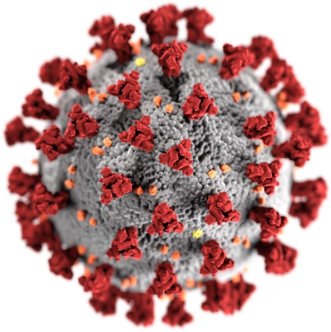
As the SARS-CoV-2 virus continues to infect a large number of individuals, the availability of test systems to detect the virus has grown. One such test system that has risen in popularity and availability is the COVID antigen test system. The FDA has given emergency use authorization for a number of COVID antigen test systems to be used in a waived setting. Here is a list of helpful hints to share with those performing COVID antigen testing:

- Thoroughly read the package insert before performing the test and follow all instructions.
- Store reagents at the recommended temperatures and bring refrigerated reagents to room temperature before use.
- Use the correct volume of reagents, no more and no less than what is specified in the manufacturer's instructions.
- Change gloves between each patient specimen to avoid cross contamination.
- **DO NOT** use viral transport media.
- Test samples within the specified time after collection. *For example, BinaxNOW cards must be tested within 1 hour of collection.*
- **DO NOT** use expired reagents or damaged test cassettes/devices.
- Document proper timing for reading the results when multiple specimens are being processed at the same time.
- Use the test cassette/device within specified time after opening.
- **ALWAYS** keep the test device in a horizontal position when in use.
- Results must be interpreted within specified times frames. *For example, BinaxNOW cards must be read promptly at 15 minutes after the swab is inserted. Do not read results before 15 minutes or after 30 minutes and record the time the results were read.*
- Read results exactly as described in the package insert.
- When complete and between samples, disinfect work surfaces and equipment with an EPA-approved disinfectant for SARS-CoV-2.
- To document competency have staff view the relevant video:

BinaxNOW: https://www.youtube.com/watch?v=nYTePdZBbLU

BD Veritor: https://www.youtube.com/watch?v=wJJRPS7pu44

Quidel Sofia: https://www.youtube.com/watch?v=D7xJ2LQ4IV4



If you would like to be added to our mailing list, email us at:
Kristine-Rotzoll@uiowa.edu or **Melinda-Bochmann@uiowa.edu**

Quality Assessment Audit: Pre- Analytic Laboratory System				
Policy/ Procedure/ Audit Tool Review		**Yes**	**No**	**N/A**
Lab has a written policy/procedure for Pre- Analytic System QA; includes audit criteria **Document corrective action below, if needed:**				
Written policy/procedure matches audit tool **Document corrective action below, if needed:**				
Test Request		**Yes**	**No**	**N/A**
Record review: Choose 5 random patient test requests and review them for completeness and laboratory information system (LIS) transcription accuracy: ordering provider, patient's name, date of birth, test, specimen source (if applicable), date/time of collection, Pap smears only: last menstrual period and history of previous abnormal reports, treatments, or biopsies.				
	Patient 1:			
	Patient 2:			
	Patient 3:			
	Patient 4:			
	Patient 5:			
Has the laboratory identified clients who repeatedly send incomplete test requests? **Document corrective action below, if needed:**				
Did the laboratory receive a written test request within 30 days for all verbal test orders? **Document corrective action below, if needed:**				
Have standing orders currently in use been reviewed and reconfirmed as written in the laboratory's policy? **Document corrective action below, if needed:**				
Specimen Submission, Handling, and Referral		**Yes**	**No**	**N/A**
Are patient preparation instructions available when needed? **Document corrective action below, if needed:**				
Are resources available for patients with special communication needs to ensure that instructions are properly understood? **Document corrective action below, if needed:**				
Record evaluation: Specimens rejected due to specimen handling errors? **Document corrective action below, if needed:**				
Record evaluation: Specimens rejected due to errors with timing requirements? **Document corrective action below, if needed:**				
Has the laboratory identified specimen transport delay issues? **Document corrective action below, if needed:**				
Has the laboratory identified clients who repeatedly send unacceptable specimens? **Document corrective action below, if needed:**				