COLA'S SPRING 2019

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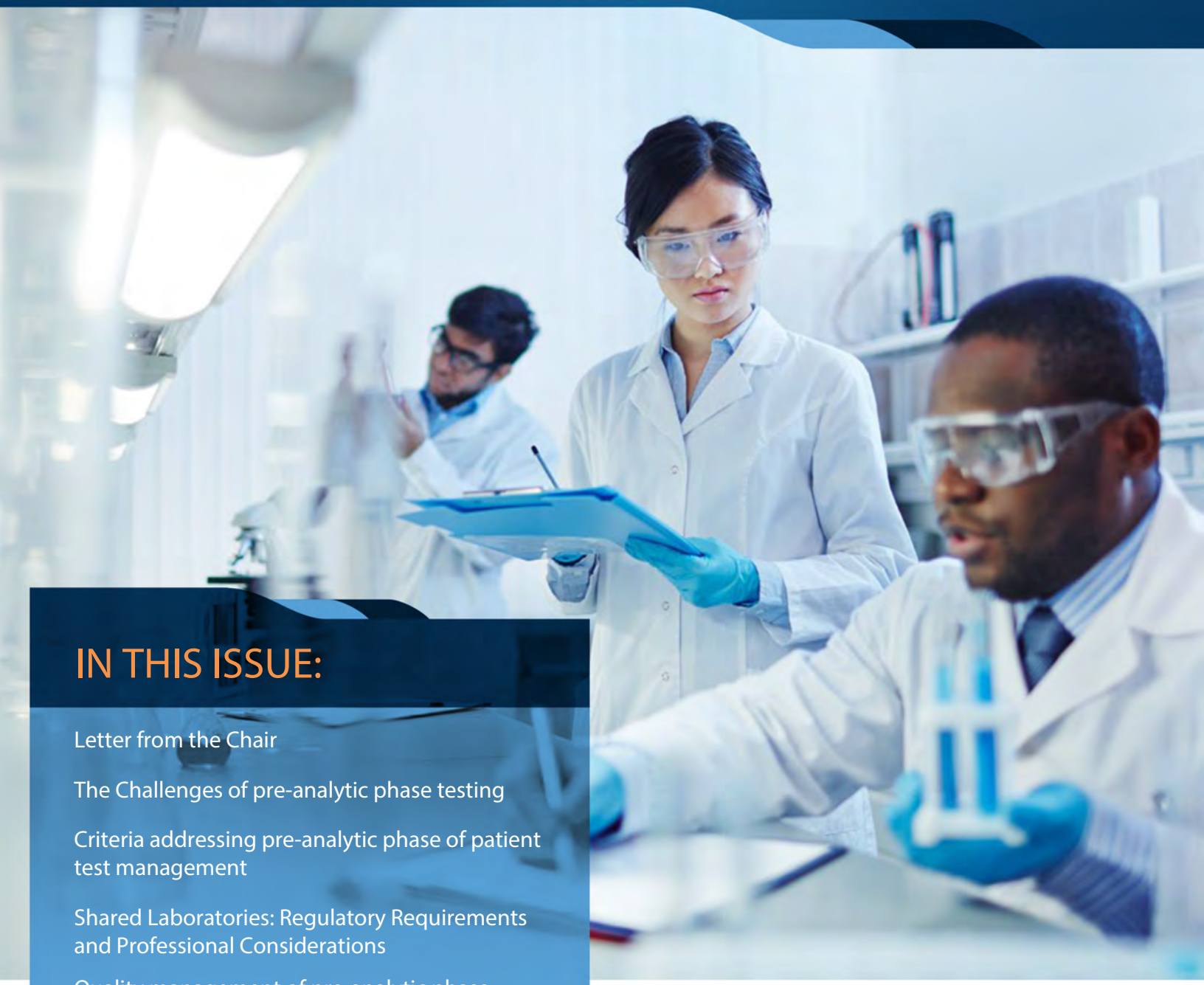

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LETTER FROM THE CHAIR

This primary focus of this issue of COLA Insights is about meeting the challenges of the pre-analytic phase of testing to maximize quality laboratory patient care. This is based on the realization that the majority of errors in the testing process occur in this phase; this has changed the paradigm for quality control, which historically has focused on the analytic phase of testing.

With this in mind, we begin with an overview of the processes within this phase where errors can occur, such as test ordering, patient preparation, specimen collection, and specimen processing, transport and storage. Delving further, we discuss sources of variability within each of these processes that must be taken into consideration: such as appropriate diet and exercise levels as part of patient preparation; inappropriate tests and transcription errors when ordering tests; the need to follow proper patient ID protocol, use the correct collection tubes, and perform proper specimen mixing when collecting test specimens. We then discuss strategies to meet these challenges through the use of Quality Indicators (QI) and Risk Management.

This overview is then followed by a discussion of the importance of management leadership if these challenges are to be met. This includes closely monitoring all laboratory processes; having in place an effective operational error detection system; the performance of root cause analysis whenever there is an increase in error frequency; and ensuring personnel competency.

Our final article of this series includes a summary of applicable COLA criteria that address the pre-analytic phase. The development of specific criteria applicable to the pre-analytic phase is based on the realization that commitments to quality testing must include applicable performance standards. Applicable criteria include a specific grouping for the preanalytic phase, (PRE 1-20); as well as criteria that address pre analytic phase issues within other groupings: pre-analytic criteria within the Procedure Manual Group (APM 1-5); pre-analytic criteria within the Quality Assessment Group (QA 6 – 8); and pre-analytic criteria within the IQCP group for Quality Control.(QC 31.5 and 31.6). Collectively, these cover standards for all preanalytic processes and variable factors discussed above.

As a change of pace, we continue our discussion of enhancing quality laboratory practices, but with our Feature article focusing on "Best Practices for Waived Testing". The continued rapid growth of point of care and remote testing, facilitated by rapid technological advances, all utilizing an increased array of (non-regulated) waived testing, has resulted in increased concerns for patient safety and quality of work. We begin our discussion with an overview of present Federal requirements for laboratories that perform only waived testing; the increasing concerns about the quality of testing performed, and the results of an extensive study by the CDC and CMS highlighting significant deficiencies in quality. We then summarize good laboratory practices applicable to waived testing (in all phases) that, if followed, would raise the level of patient service to that of accredited laboratories.

Our final article of this issue, "So Now What? The Post PAMA World" is part of our "Trending" series designed to present you with the latest information in legislative and regulatory activities occurring on the state and Federal level, how they affect our profession and other future trends in healthcare. The focus here is updating you on PAMA ("the "Protecting Access to Medicare Act"), passed by Congress in 2014. This is brought to you by COLA's new Innovation division, focused on COLA's leadership in this area.

Many of the Medicare payment cuts prescribed by PAMA began implementation on January 1, 2018. Since these cuts will have an impact on laboratory testing, and make it difficult for physicians and other providers to offer testing to beneficiaries, many within the laboratory community, including physician organizations, are fighting to reverse these cuts. Information is provided for joining these efforts, in conjunction with COLA and its advocacy program.

Dr. Richard Eisenstaedt,
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THE CHALLENGES
OF PRE-ANALYTIC PHASE TESTING

INTRODUCTION

Quality in laboratory medicine can be defined as the guarantee that "each and every step in the testing process is correctly performed, thus assuring valuable medical decision making and effective patient care". In recent years, the concept of quality monitoring for laboratory testing has evolved beyond the performance of quality control focused on the analytic phase, to encompass the total testing process, also known as TTP. Beginning with test ordering and ending with result reporting, TTP encompasses the pre-analytical, analytical, and post-analytical phases of testing. The impetus for TTP quality monitoring has been the realization that the majority of errors made in laboratory testing occurs during the pre-analytic phase.

This new paradigm is the result of studies showing that while patient safety remains a challenge in many areas of healthcare, laboratory medicine has been a leader in reducing error, with an estimated total error rate of 0.33%, the lowest in diagnostic medicine . Major advancements in automation and analytical instrumentation have helped reduce laboratory-associated errors over the last decade, but with pre-analytical errors currently accounting for up to 75% of all mistakes, laboratory professionals must keep expanding their focus to what is happening before actual testing, including processes that take place outside of the lab . These activities include test ordering, patient preparation, specimen collection, transportation, preparation, and storage.

Unlike the analytic phase, the processes of the pre-analytic phase often involve personnel that are not under the direct supervision of the laboratory, making it more challenging to control. Ignorance by non-laboratory staff of the importance of the pre-analytical phase, difficulties in observing and tracking activity, and narrow interpretations of the laboratory's role have all contributed to this inaction. Consequently, labs have often focused on improving areas under their direct control while leaving pre-analytical activities to healthcare professionals who have little to no formal training in laboratory medicine. This presents an opportunity for more interactions between non-laboratory staff and laboratory professionals who can educate those involved in laboratory related tasks.

Recognizing the magnitude of errors associated with the pre-analytical phase, regulatory agencies and laboratory medicine associations are also directing more resources for the development of guidelines specific to pre-analytic activities.

PRE-ANALYTIC PROCESSES WHERE ERRORS MAY OCCUR :

Test Ordering

Test ordering is the first step of the pre-analytical process. When the wrong test is ordered, it is not only potentially harmful to patients, but wasteful of time and materials, adding to the expense of the test. Inappropriate tests are ordered for a variety of reasons, including confusion over tests with similar names, unnecessary duplicate orders, transcription errors during order entry, and misinterpreted verbal orders, which occur when physicians do not place test orders themselves.

To deal with problems in this phase of testing, hospital labs must engage hospital physicians and staff to promote appropriate test utilization. This is typically done through a laboratory formulary committee or test utilization committee that draws from hospital-wide resources and influences physicians' test ordering behavior. Institutions lacking these resources or structures should focus on areas that will have the biggest impact, such as monitoring expensive send-outs and duplicate orders. Labs must ensure that such efforts are data driven and closely monitored to track inappropriate test orders, duplicate orders, and errors in test input.

Patient Preparation

Patient preparation is one of the most challenging among the pre-analytical phases because it encompasses variables that typically occur before the individual arrives for his or her sample collection. Patient preparation factors include:

Diet:

Food consumption is a significant source of pre-analytical variability. This effect varies based on the analyte and the time between meal ingestion and blood collection. For example, glucose and triglycerides significantly increase after meals with high carbohydrates and fat, respectively. An overnight fasting period of 8 to 12 hours prior to blood collection is optimal for minimizing variations. However, some meals may have longer-lasting effects and particular foods should be prohibited before performing certain tests. Caffeine, alcohol, vegetarianism, and other specialized diets are also known to have a significant impact on commonly measured analytes. Communicating these requirements to patients is important to ensure appropriate preparation for testing.

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Timing of sample collection

Blood concentrations of various analytes change during the course of the day. These cyclical variations can be significant, so the timing of sample collection should be strictly controlled. For example, serum iron increases by as much as 50% from morning to afternoon, and serum potassium has been reported to decline from morning to afternoon by an average of 1.1 mmol/L. Hormones such as cortisol, renin, aldosterone, and corticotropin are especially impacted by this circadian variation.

Timing of sample collection is especially critical for therapeutic drug monitoring, which requires trough levels for most analytes. Protocols must specify an ideal time of sampling for each test and the actual time of draw must be carefully documented.

Specimen Collection

Specimen collection poses several opportunities for errors. Important factors to consider for reducing variability during this phase of testing include patient identification, collection tube type, sample integrity, sample volume, and venipuncture.

Patient Identification and Specimen Labeling:

Improper patient identification is a major concern due to the possible severe consequences from mislabeling a specimen. When collecting samples, two unique identifiers are required to positively identify a patient; however, this process is not always straight-forward when a patient has altered mental status, or is unresponsive. Where implemented, hospital wristband barcodes, and barcode scanners have significantly reduced rates of misidentification.

It is important to take all appropriate steps to ensure the ID of the patient. This may include assistance from care givers, parents, or legal guardians. Verification of the patient's date of birth will further help reduce errors related to patients who may have similar names.

Once the patient's identity has been verified, it is critically important that the specimen be labeled immediately after collection with the two identifiers, in accordance with the lab's labeling procedures. Do not pre-label blood collection tubes. Specimens must also be labeled with the date and time of collection. It is also important to note that, for specimens collected in cups, such as urine or sputum, the container itself must be labeled, rather than just the lid, as lids can be mixed up during the processing or testing of the specimen.

Collection tube type:

Several tubes are available for specimen collection with different additives and barriers for distinct applications. Additives may promote or inhibit clotting, to produce serum or plasma, respectively. For example, EDTA should not be used for measuring comprehensive metabolic panels because it heavily chelates calcium, and contains large amounts of potassium as a counter ion. This effect is so pronounced that even slight contamination from EDTA can significantly elevate potassium levels and reduce calcium concentrations.

As a result, the order of collecting multiple tubes through the same needle is important and should proceed from tubes with no additives to tubes with very strong additives.

Barriers are typically gel-barriers that separate plasma/serum from cells after centrifugation. This helps stabilize the specimen for transport and storage without the need to aliquot. Refer to the test manufacturer's instructions for specific information on collection tubes, as some analytes may require collection in gel-free tubes.

Venipuncture and collection from catheters:

Improper venipuncture technique during phlebotomy leads to poor quality samples. Applying a tourniquet for >1 minute can cause an increase in the concentration of proteins and protein bound molecules, like serum proteins that are unable to pass through the capillary wall. Total lipids and cholesterol can increase between 5-7% and bilirubin can rise 8%.

When collecting samples from a catheter, contamination and dilution of samples must be avoided. Variation in glucose or electrolyte values may result from collecting blood from an IV or central line. Questionable results from a sample collected through a catheter need to be repeated using a new sample drawn from a different site. Collection of blood through a catheter should only be performed by properly trained personnel.

Specimen volume and proper tube mixing:

All sample collection tubes need to be filled with the appropriate volume. This ensures the proper amount of specimen to the amount of additive in the tube. This is especially important for coagulation tubes in which unfilled tubes (<90%) will have falsely prolonged clotting times. Gently invert all tubes, in accordance with manufacturer instructions.

Specimen Processing, Transport and Storage

Transport can be a significant source of specimen problems. The main variables to consider include agitation, light exposure, temperature, transport time, and placement of samples within the proper transport container. Specimens should be delivered to the laboratory promptly after collection, and time between sampling and analysis reduced to a minimum. In addition, samples should be transported and stored under proper temperature and light conditions, and always in accordance with the manufacturer instructions for storage of the specimen. Storage of samples for add-on testing should be validated for each analyte for the specific storage temperatures used in the laboratory.

The time between collection and centrifugation affects some analytes more than others. When plasma or serum are required, labs should centrifuge samples (and aliquot, if necessary) prior to transportation if the sample is traveling > 1-2 hours to the central lab. Labs need standardized protocols for centrifugation time and speed, because these variables impact specimen integrity. Re-centrifugation should be avoided because it can cause hemolysis and affects gel-barrier integrity. Again, always follow manufacturer instructions.

When referring specimens to another lab for testing, labs should have an agreement with the testing lab that ensures that specimens are transported and maintained at conditions consistent with the testing lab's requirements for the test(s). In particular, make sure that, if locked boxes are used to store specimens for the testing lab, specimens are maintained under proper conditions while awaiting pickup.

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ADDRESSING THE CHALLENGES OF THE PRE-ANALYTIC PHASE

The pre-analytical phase is recognized as the most vulnerable part of the total testing process. Due to their impact on the quality of results of laboratory testing, pre-analytical errors have been included within the greatest challenges to the laboratory professionals, during the last 20 years. The majority of these activities reviewed above occur outside the laboratory, often managed and performed by non-laboratory professionals.

There are several approaches that can be taken by laboratory professionals to assess the potential for error in the pre-analytic phase, taking into account the many activities occurring outside the laboratory environment.

Quality Indicators (QI)

An effective approach to addressing these challenges is the adoption of Quality Indicators (QI), defined as "the measure of how well the laboratory meets the needs and requirements of users and the quality of all operational processes". Monitoring the total number of samples lost or not received, compared to the total number of samples received, is an example of a QI for the pre- analytical phase. Adopting QIs to track and improve performance is essential: what a laboratory does not measure, it cannot improve. Monitoring the pre-analytic processes in this manner enables labs to reliably identify and manage these potential variations. The level of acceptable performance is set by the laboratory, based on the % failure permitted.

Sixteen proposed Quality Indicators for the pre-analytical phase were developed by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) working group named 'Laboratory errors and patient safety'(WG-LEPS). The IFCC WG-LEPS for the pre-analytic phase are shown the table below

TABLE 1 QUALITY INDICATORS IN THE PRE-ANALYTIC PHASE:

QI-1: Appropriateness of test request	Number of requests that include clinical question from the ordering physician (%)
QI-2: Appropriateness of test request	Number of appropriate tests with respect to the clinical question from the ordering physician (%)
QI-3: Examination requisition	Number of requests without physician's identification (%)
QI-4: Examination requisition	Number of unintelligible requests (%)
QI-5: Identification	Number of requests with erroneous patient identification (%)
QI-6: Identification	Number of requests with erroneous identification of physician (%)
QI-7: Test request	Number of requests with errors concerning test input (%)
QI-8: Samples	Number of samples lost/not received (%)
QI-9: Samples	Number of samples collected in inappropriate containers (%)
QI-10: Samples	Number of samples hemolysed (hematology, chemistry) (%)
QI-11: Samples	Number of samples clotted (hematology, chemistry) (%)
QI-12: Samples	Number of samples with insufficient volumes (%)
QI-13: Samples	Number of samples with inadequate sample-anticoagulant ratio (%)
QI-14: Samples	Number of samples damaged in transport (%)
QI-15: Samples	Number of improperly labelled samples (%)
QI-16: Samples	Number of improperly stored samples (%)

Of course, when a laboratory fails to meet the threshold of acceptable performance, corrective actions must be taken, documented and verified as to their effectiveness.

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ANOTHER EFFECTIVE APPROACH IS THE APPLICATION OF RISK MANAGEMENT TO IDENTIFY POTENTIAL ERRORS DURING THE PRE-ANALYTIC PHASE OF THE TTP.

Risk Management

This approach, in which an analysis is performed to determine the potential risk for error through all applicable pre-analytical phase processes involved, including personnel (such as training and competency), specimen handling, transport, and storage (such as correct patient ID and specimen labeling), how tests are ordered, and patient preparation. Once the potential risk for error is identified, then processes can be put into place to either ameliorate or eliminate these potential risks. Of course, this is the basis for Individualized Quality Control Plans (IQCP), which have increased awareness of the importance of including of all phases of laboratory testing when evaluating quality.

SUMMARY OF POTENTIAL ERRORS AND QUALITY FAILURES FOR THE PRE-ANALYTICAL PHASE

SUMMARY:	PRE-ANALYTIC ERRORS:	QUALITY FAILURES
	SOURCE ERRORS:	PROCESS ERRORS
TEST ORDERING	• Similar test name • Duplicate orders • Transcription Entry Errors • Verbal orders misinterpreted	• Requests w/o clinical question • Inappropriate Requests re: clinical question • Duplicate orders • Request with errors re: test orders
PATIENT PREPARATION	• Diet • Posture • Exercise • Timing of Sampling	• Samples Collected at inappropriate time
SAMPLE COLLECTION	• Patient Identification • Sample labeling • Needle size • Sample volume • Sample collection tube • Inadequate tube filling • IV contamination • Order of specimen draw • Specimen clotting • Fist-clenching during phlebotomy	• Requests with errors in patient ID • Inappropriate sample type • Inappropriate collection containers • Insufficient sample volume • Inappropriate sample volume to anticoagulant ratio • Clotted samples • Hemolyzed samples • Lipemic samples • Contaminated samples
SAMPLE PROCESSING, TRANSPORTATION AND STORAGE	• Agitation • Delayed specimen processing • Re-centrifugation • Exposure of samples to environment • Add-on testing	• Damaged samples • Samples transported at inappropriate time for processing • Samples transported under inappropriate temperature conditions • Improperly stored samples • Samples stored or not received

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SUGGESTED STRATEGIES FOR THE DETECTION OF PROCESS ERRORS DURING THE PRE-ANALYTICAL PHASE

Clinical labs have several tools at their disposal to detect pre-analytical errors. These include:

Erroneous result flags:

These are analyte concentrations that do not make physiologic sense, such as a potassium level of 20 mEq/L and calcium of 1.0 mg/dL, which is the typical pattern observed when a specimen drawn into a plasma EDTA tube is transferred to a serum tube. Another example could be a very low Glucose, which could be cause by a significant delay in centrifugation of a serum specimen.

Rules:

This is when a combination of otherwise normal results strongly indicates a problem with the specimen. A good example is detection of intravenous line contamination using the "IF Glucose > 800 mg/dL AND creatinine < 0.6 mg/dL" rule, among others.

Delta checks:

These help expose errors by calculating the difference between a patient's current results and previous results based on a defined time window for certain analytes. If the difference exceeds an acceptable threshold, the sample is flagged for review. This is particularly useful for sample misidentification, but is limited in application to patients with previous results and specific tests.

Serum indices:

Serum indices represent a spectrophotometric estimate of the level of interference from hemoglobin (hemolysis index), bilirubin (icterus index) and lipids and chylomicrons (lipemia index). These are the most common type of interferences to clinical chemistry tests and can serve as indicators for pre-analytical errors related to inappropriate fasting, sample processing, transportation, and storage.

Not all tests are adversely affected by these serum indices, so always follow manufacturer instructions and make sure that specimen rejection procedures for each test provide clear instructions for testing personnel on when specimens should be rejected. It is also important to note that not all specimens with high serum indices are caused by pre-analytic error. Some patients will have lipemic serum even though they have fasted appropriately prior to the blood draw. Abnormal indices should be investigated, to rule out pre-analytic errors, and recollected if indicated. Your lab's procedures should be very detailed in this regard, and should always be aligned with manufacturer instructions.

CONCLUSION

The concept that quality control limited to the analytical phase of testing ensures quality laboratory services is no longer justified by evidence that the majority of laboratory errors occur in the pre-analytic phase of the total testing process. This phase can be visualized as the "iceberg" of laboratory testing, in that the majority of the processes involved occur beyond the purview of the laboratory itself, often involving performance by non-laboratory staff, often in different physical locations, and often managed by non-laboratory staff. This realization has led to ongoing reassessments of where, when and how to measure quality within the total testing process (TTP). The development and application of Quality Indicators (QI), as well as Individualized Quality Control Plans (IQCP) are among the newer tools developed to measure non-analytic, often direct patient centered processes. Challenges remain as standards for measuring acceptable performance continue to evolve, especially for many aspects of patient preparation and test ordering.

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CRITERIA ADDRESSING
THE PRE-ANALYTIC PHASE OF PATIENT TEST MANAGEMENT

INTRODUCTION

A substantial portion of laboratory errors are the result of problems that arise in the pre-analytic phase of the total testing process. While it is important to utilize retrospective reviews of performance, such as Quality Assessment (QA), to detect and correct problems that have occurred, these monitoring efforts are not sufficient to prevent all potential errors. Prevention of these errors also requires knowledge of the many pre-analytical variables that can adversely affect laboratory results.

Ongoing efforts over many years by medical laboratory professionals, regulatory agencies, the healthcare industry, and public stakeholders to identify these variables and how they should be addressed, has evolved into a consensus for performance standards to ensure patient safety and quality lab medicine. These are the bases for the criteria that are part of the laboratory accreditation process, required by accrediting organizations and CLIA.

The COLA Criteria for Quality Laboratory Performance are COLA's guiding principles for achieving a quality-conscious laboratory which takes appropriate action to ensure accurate test results for all tests performed in the laboratory. Studying these criteria can help improve the operation of any laboratory.

THERE ARE MANY COLA CRITERIA FOR THE PRE-ANALYTIC PHASE OF PATIENT MANAGEMENT

This group of criteria looks at the pre-analytic processes, and includes evaluation of activities such as

- Test ordering
- Specimen collection and labeling
- Specimen transport
- Specimen receipt and processing

Included are such things as the proper identification of the patient, labeling of specimens to avoid mix-ups, proper storage of specimens, proper tracking of specimens through different stages of testing, test requisitions and reports, and record storage and retention.

Following are some of the key performance standards for the pre- analytic phase of patient test management:

A Instructions for the collection and handling of specimens must be written. These instructions should be included in your procedure manual.

B All specimens must be uniquely identified through all phases of testing

C All specimens must be accompanied by a requisition which should include the following information:

- The patient's name and a secondary identifier
- Name and address of person requesting the test
- Contact person for reporting critical values (usually the ordering physician)
- The name of the test to be performed
- The date and time of specimen collection
- Any pertinent clinical information to ensure accurate testing
- Test requisitions must be maintained for at least two years

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THE CRITERIA OF THE PRE-ANALYTIC GROUP:

Please note: This is a compilation of the applicable criteria for the analytic phase; each of the criteria listed below are followed by detailed clarifications and discussions within your COLA Accreditation Manual.

PRE 1 Are all specimens accompanied by a requisition?

PRE 2 If an oral request for a test has been made, is it followed with a written requisition within 30 days?

PRE 3 If the laboratory accepts referred specimens from another facility: Do you maintain documentation of attempts to obtain a written test request when the initial request was verbal?

Does the requisition that accompanies the patient specimen contain the following: (PRE 4-9)?

PRE 4 The patient's name and a secondary identifier?

PRE 5 The name or unique identification of the legally authorized requestor, the individual responsible for using the test results, and the address(es) where the report should be sent?

PRE 6 The test (examination) requested?

PRE 7 Clinical information, including gender, age, specimen source (when appropriate), and other relevant and necessary information?

PRE 8 Space for date and time of primary specimen collection?

PRE 9 Space for date and time of receipt by laboratory?

PRE 10 Are ALL test requisitions maintained for at least two years?

PRE 11 Do you have written instructions for specimen collection, labeling, preservation, and conditions regarding specimen transport available for your clients and do you provide updates to your clients as they occur?

PRE 12 Do you have and follow written policies and procedures for the collection and, handling, transportation and storage of specimens?

PRE 13 Is the manual provided by the reference laboratory for specimen collection and handling, either electronic or hard copy, readily available to personnel involved in the collection of specimens?

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PRE 13.1

For specimens sent to a reference laboratory, are there procedures in place that assure that specimens are maintained under storage conditions required by the reference laboratory while the specimens are awaiting pick-up by a courier?

PRE 14

If special tests are performed, do you provide containers with proper preservatives?

PRE 15

If patients collect their own specimens, are they given written instructions describing how to do so?

PRE 16

Prior to the collection of a patient's specimen, is the patient's identity verified using two separate identifiers?

PRE 17

Are all specimens labeled with a unique patient identifier composed of 2 individual identifiers, and the source of the specimen (when appropriate)?

PRE 18

If the patient is not properly prepared for the test according to the laboratory's policy, is the specimen considered unacceptable?

PRE 19

Are all specimens uniquely identified through all phases of testing?

PRE 20

Does the Laboratory have a policy describing what needs to be done if required information is missing from laboratory requisitions?

PRE-ANALYTIC CRITERIA WITHIN THE PROCEDURE MANUAL GROUP:

Does the procedure manual include for each test, where applicable: (APM 1- 5)

APM 1

The test name?

APM 2

Directions for patient preparation; specimen collection preservation, storage and handling? (These may be included in a separate section or manual on specimen collection).

APM 3

Written instructions for the collection and storage of specimens that a patient would collect themselves?

APM 4

Criteria for specimen acceptability and rejection of unacceptable specimen?

APM 5

Instructions for patient and physician notification if a specimen is unacceptable?

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PRE-ANALYTIC CRITERIA WITHIN THE QUALITY ASSESSMENT GROUP:

PRE-ANALYTIC ASSESSMENTS

QA 6

Does the quality assessment review evaluate the laboratory's processes for patient preparation, and for specimen collection, handling, labeling, transport, and acceptability?

QA 6.1

Does the laboratory have a process for monitoring the integrity of all specimens received for testing, specifically for specimen age, and storage and transport temperature?

(This is a significant quality monitor, particularly for labs that receive specimens from other locations and those that perform batch testing. Specimens that are not received or tested within the lab's established acceptability criteria must be rejected. Rejected specimens should be logged and monitored for patterns).

QA 7

Are quality assessment reviews performed to assess requisitions for completeness and relevance of content, including inconsistencies of age, gender, and, when available, diagnosis or pertinent clinical data, and relationship with the requests and/or results of other tests?

QA 8

Are all communication breakdowns between physicians (or other persons authorized to order tests) and laboratory personnel recorded and are corrective actions documented?

PRE-ANALYTIC CRITERIA WITHIN THE QUALITY CONTROL GROUP: the IQCP option

CMS has approved a process which permits laboratories to develop and customize quality control procedures in their unique healthcare settings based upon risk assessment. This option is termed an Individualized Quality Control Plan (IQCP). Laboratories utilizing this equivalent QC option perform a risk assessment to identify potential errors that may occur in any and all phases of the total testing process, including the pre-analytic phase. Thus, prevention of pre-analytic errors has become part of QC.

QC 31.5 R

Did the Risk Assessment include all three phases of testing (pre-analytic, analytic, and post-analytic) when identifying potential errors?

QC 31.6 R

Did the Risk Assessment evaluate potential errors related to the specimen?

Include consideration of applicable elements such as patient preparation, specimen collection, specimen labeling, specimen storage and transport, specimen processing, and unacceptable specimens.

CONCLUSION

Any discussion of the pre-analytic phase alone is, in a sense, an artificial construct, in that the pre-analytic phase does not stand alone, but is part of the total testing process, not only encompassing the analytic and post-analytic phases of testing, but the general organization of the laboratory. The latter includes Personnel, Facilities, Management, Quality Control, and operating systems. All of these impact the quality of patient care, including how effectively the pre-analytic phase can be managed. This summary of COLA criteria thus serves to codify discussions about the definition and importance of pre-analytic phase activities with the actual regulatory requirements for accreditation.

References

COLA 2019 Laboratory Accreditation Manual. Pp. 112 & 150

QUALITY MANAGEMENT
OF THE PRE-ANALYTIC PHASE

INTRODUCTION

The effective management of the pre-analytical phase is only possible through consistently applying a continuous quality improvement approach to all processes involved. This approach means that: 1) laboratory processes are closely monitored; 2) there is an operational and functional error detection system in place; and 3) root-cause analysis is performed whenever there is an increase in error frequency, as a part of the continuous quality improvement. This approach presumes that all pre-analytical steps are scrutinized and challenged by asking some of the questions below :

- Do I know the limitations of this procedure ?
- Do I know how this procedure affects sample quality and test results ?
- Do I know how to control potential sources of error related to this procedure ?
- How is this procedure contributing to the patient care and how does it affect patient outcome ?

The management of the pre-analytical phase should encompass all steps of the total testing process which take place before the analytical phase, and hence include test requesting, patient preparation, sample collection, transport, delivery to the laboratory and handling. Each of those steps is potentially associated with numerous sources of variability and potential for error.

By effective quality management of the pre-analytical phase, the laboratory can reduce the error rate and improve care for patients as well as their clinical outcome. For example, this approach to test requests means that test ordering patterns are assessed for their appropriateness for each particular patient population and patient condition; this may reduce the rate of unnecessary test requests and ensure that the right test is requested for the right patient (i.e., adequate utilization of tests which are necessary/useful in a specific patient population). To properly manage test demand, a laboratory should challenge the current test panel used for a certain condition by questioning whether such panel is in accordance with the recommended diagnostic algorithm and how this testing panel affects patient outcome .

Pre-laboratory strategies should also include attention to personnel competency and performance; including structured training and educational programs for the non-laboratory staff involved with any aspect of the pre-analytic process, This could include not only phlebotomists, but nurses, administrative personnel, even receptionists and other office staff. This would also have to include periodic competency assessments to ensure quality work is maintained

The cooperation and involvement of clinicians is achieved by introducing some key aspects of utilization of laboratory resources in medical and nursing university core curricula. The participation in interdisciplinary groups is promoted, with dissemination of information on laboratory tests and involvement in clinical tests selection.

Other important strategies that are adopted include those related to the software used by clinicians to prescribe testing (i.e., facilitation of access to information and training, communication of test cost at the time of request, prescription guided by expert systems based on specific protocols or profiles, limits to repeat testing practice, elimination of obsolete or redundant testing). The quality indicators of test prescription and cost are reported to the clinicians. Additional within-laboratory strategies include deletion or generation of tests.

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If diagnostic algorithm and guidelines for a certain condition are unavailable, the laboratory should search for the information supporting the use of a certain test or a panel of tests in a particular patient group. As already discussed, numerous interventions have been proposed to address and manage appropriate test utilization. Such interventions are effective tools aimed to reduce costs and waste and improve the patient outcome. It has been demonstrated that through the active intervention by the laboratory staff or Clinical Consultant and bidirectional communication with clinicians a significant savings and reduction in the use of tests can be achieved.

Another good example of the quality management approach to the pre-analytical phase is the implementation and use of sample acceptance criteria in a laboratory. Many laboratories have established their criteria for sample acceptance or rejection However, the crucial question is to establish whether those criteria are correct or not, and if they really fit for the purpose.

Another good point is to find what each laboratory can do to improve their policy for assessing sample quality. Again, the laboratory should challenge its current policy by examining if the procedure in use is recommended by some authority, or whether there is evidence to support the use of that particular procedure. Most importantly, the laboratory should investigate how the procedure in use affects the patient outcome. Not a single step should be taken for granted. Not a single decision should be made in the lack of proper evidence .

Unfortunately, the laboratory often faces the lack of data in cases when there is a need to address a certain pre-analytical issue or problem. When evidence does not exist, the laboratory should perform its own validation or verification study to address the issues of interest.

For example, below are some strategies that laboratories use to assess the quality of specimens/samples collected, as part of their assessment of pre-analytical activities:

STRATEGIES FOR THE DETECTION OF PRE-ANALYTICAL SAMPLE COLLECTI ON ERRORS

Erroneous result flags: 1

These are analyte concentrations that do not make physiologic sense, such as a potassium level of 20 mEq/L and calcium of 1.0 mg/dL, which is the typical pattern observed when a specimen drawn into a plasma EDTA tube is transferred to a serum tube.

Critical result flags: 2

These are results that are potentially life-threatening, such as a critically high Potassium, a critically low Glucose, or a critically low Hemoglobin. Critical value thresholds are determined by the Lab Director. Some critical values may be a result of pre-analytic errors. If a critical value is determined to be due to a pre-analytic error, this should be documented and any patterns of occurrence identified so that additional errors can be prevented by providing retraining or updating specimen collection and processing procedures.

Rules: 3

This is when a combination of otherwise normal results strongly indicates a problem with the specimen. A good example is detection of intravenous line contamination using the "IF Glucose > 800 mg/dL AND creatinine < 0.6 mg/dL" rule, among others.

Delta checks: 4

These help expose errors by calculating the difference between a patient's current results and previous results based on a defined time window for certain analytes. If the difference exceeds an acceptable threshold, the sample is flagged for review. This is particularly useful for sample misidentification, but is limited in application to patients with previous results and specific tests.

Serum indices: 5

Serum indices represent a spectrophotometric estimate of the level of interference from hemoglobin (hemolysis index), bilirubin (icterus index) and lipids and chylomicrons (lipemia index). These are the most common type of interferences to clinical chemistry tests and can serve as indicators for pre-analytical errors related to inappropriate fasting, sample processing, transportation, and storage.

Obviously, there is a need for continued effort by laboratory professionals, professional associations, physician groups, and regulatory agencies, both nationally and even globally, to share experiences and address some common pre-analytical issues and problems, to mutually benefit from each other and continue to develop quality guidelines.

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BEST PRACTICES
FOR WAIVED TESTING

INTRODUCTION

The Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) created the concept of "waived tests" which are defined as tests that are so simple to perform, and produce accurate results so reliably as to render the likelihood of erroneous results negligible; and which also pose no reasonable risk of harm to the patient if the test is performed incorrectly. Thus, these tests are exempt from federal requirements for personnel qualification, training, and competency assessment; quality control (except as specified by the manufacturer), proficiency testing, quality assessment, and the need for routine inspection

CLIA waived regulated laboratories operate under a Certificate of Waiver. There are just four CLIA requirements for these labs:

1. Renew their Certificate of Waiver every two years;
2. Perform only waived testing
3. Follow instructions in the most current manufacturer's product insert without modification, when performing the test;
4. Permit announced or unannounced inspection by CMS representatives.

As a result, laboratory professionals have long expressed concern about the quality of testing performed in these laboratories. This concern has only grown with the rapid proliferation of waived tests, along with point of care /remote testing sites.

As a response to these concerns, going back to the 1990's, both CMS and the CDC conducted random surveys of waived laboratories between 2001 and 2004. These labs had significant quality issues, including the lack of available written procedures; lack of adequate training, lack of quality control being performed as required; the lack of a proper regard for reagent expiration dates and storage requirements; and the failure to enter results of tests performed into electronic medical records.

While the majority of Certificate of Waiver laboratories were aware of these issues, and followed some practices to ensure the accuracy and reliability of their testing, lapses in quality were identified at certain sites, some of which could result in patient harm. For example, 5% of these laboratories surveyed by CMS were determined to be performing tests that were not actually "waived," and were therefore outside the scope of the laboratory; and thus were performed in the absence of CLIA-required quality measures.

Additionally, of the Certificate of Waiver facilities CMS surveyed:

12% did not have the most recent instructions for the waived test systems they were using

21% reported they did not routinely check the product insert or instructions for changes to the information

21% did not perform Quality Control testing as specified by manufacturer's instructions

18% did not use correct terminology or units of measure when reporting results

6% failed to adhere to proper expiration dates for the test system, reagents, or control materials

3% failed to adhere to the storage conditions as described in the product insert

6% did not perform follow-up confirmatory tests as specified in the instructions

5% did not perform function checks or calibration checks to ensure the test system was operating correctly

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Although not usually specified in the product insert (and therefore not a CLIA requirement), proper documentation and recordkeeping of patient and testing information are also important elements of good laboratory practices. CMS surveys of the Certificate of Waiver sites indicated that:

45% did not document the name, lot number, and expiration dates for tests performed

35% did not maintain logs with records of their Quality Control testing

31% did not maintain a log or record of tests performed

9% did not require a requisition or test orders be documented in a patient chart before performing a test

Among the waived laboratories surveyed, the study also found :

- High staff turnover
- Lack of formal laboratory education
- Limited training in test performance & quality assessment
- Lack of awareness concerning “good laboratory practice”
- Partial compliance with manufacturer’s Quality Control instructions (approx. 55% - 60%)

To be effective, strategies for addressing these issues through good laboratory practice must start even before the testing process, all the way back to assessing the laboratory structure, organization, and purpose. These include:

1 RECOMMENDED CONSIDERATIONS WHEN IMPLEMENTING NEW WAIVED TESTING, OR IMPROVING THE PRESENT TESTING

Management Responsibility and Commitment

Each testing site should identify at least one person responsible for testing oversight and decision-making. In POLs, this might be a physician or someone in a senior management position who has the appropriate background and knowledge to make decisions about laboratory testing.

Personnel Needs

Personnel competency and turnover are important factors affecting the quality and reliability of waived testing results. While no CLIA requirements exist for waived testing personnel qualifications, all applicable state or local personnel regulations must be met.

Personnel issues to consider include assessment of present staffing levels and training to ascertain whether employees have sufficient time and skills to reliably perform all activities needed for testing.

Personnel Training

Personnel should be trained and competent in each test they will perform before reporting patient results. The site director or other person responsible for overseeing testing should ensure that testing personnel receive adequate training and are competent to perform the procedures for which they are responsible. Document these efforts.

Competency Assessment

To ensure testing procedures are performed consistently and accurately, periodic evaluation of competency is recommended, with retraining, as needed, on the basis of results of the competency assessment. Competency can be evaluated internally by methods such as observation, evaluating adequacy of documentation, or the introduction of mock specimens by testing control materials or previously tested patient specimens. External quality assessment or evaluation programs, such as voluntary PT programs, are another resource for assessment.

Written Test Procedures

It is good laboratory practice to develop written policies and procedures so that responsibilities and testing instructions are clearly described for the testing personnel and facility director. The testing procedures also form the basis of training for testing personnel. These procedures should be derived from the manufacturer's instructions, and should include directions for specimen collection and handling, control procedures, test and reagent preparation, and instructions for test performance, interpretation, and reporting.

A comprehensive procedure manual is a valuable resource for waived testing sites. New testing procedures should be reviewed and signed by the site director before incorporating them into the procedure manual. The manual should be updated as tests or other aspects of the testing service change and should be reviewed by the director whenever changes are made. When procedures are no longer used, they should be removed from the manual. The manual should always be readily available.

This is a basic, but broad list of actions that a Certificate of Waiver facility can take, even before the lab is operational. It indicates the systemic nature of any laboratory operation. Quality failures often are not due to just a single factor, but to a multiplicity of factors that need to be addressed, for a successful outcome.

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2 RECOMMENDED PRACTICES: THE PRE-ANALYTIC PHASE :

Test orders

Confirm that the written test order is correct. If there is a question, check with the ordering clinician before proceeding.

Patient identification

Identify the patient before the specimen is collected. Since names can be similar and lead to confusion, use birth dates, middle initials, identification numbers or other means to ensure the specimen is collected from the correct patient.

Pretest instructions and information

Some tests require special preparation on the patient's part (e.g. fasting), or that the patient collect the specimen (e.g. urine or stool). Provide the patient with pretest instructions when appropriate, and verify that patients have received and understood the instructions before collecting or accepting the specimen.

Specimen collection and handling

The product insert provides details on proper collection, handling and storage of patient specimens.

- **Collect waived test specimens exactly as described in the test system instructions.**

  Improperly collected, stored, or compromised specimens should not be tested. The person collecting the patient specimen or giving the collection instructions should have a thorough understanding of the specimen type, proper collection method, and handling necessary to assure a quality specimen for testing.

- **Use the appropriate specimen collection device or container.**

  These devices are integral to the test system; they might be provided by the manufacturer or specified in the product insert and purchased separately. Containers and collection devices can contain materials that affect the specimen or are part of the test, and should not be substituted or altered.

- **Finger-stick and venipuncture collection devices are for one-time use only.**

  To avoid transmission of blood borne pathogens, appropriately discard sharps, lancets and platforms for spring-loaded lancets, and disinfect instruments and surfaces contaminated by blood or body fluids.

- **Specimens need to be adequately labeled to prevent mix-up.**

  To prevent errors, always label specimens as soon as they are collected with pertinent patient information. Do not pre-label blood tubes. For specimen cups, such as those used for urine specimens, be sure to label the container itself, rather than just the lid, to avoid mix-ups.

RECOMMENDED PRACTICES: THE ANALYTIC PHASE :

Quality Control (QC) testing

provides assurance that the test system has performed as expected, and alerts the user when problems occur which may affect patient results. QC testing is designed to detect problems that might occur because of operator error, reagent or test kit deterioration, instrument malfunction or improper environmental conditions

- **Internal, procedural or built-in controls**

  are designed to verify that certain aspects of the test are working properly, and that sufficient specimen was added. Certain systems might have electronic internal controls to monitor electronic functions.

- **External controls**

  mimic patient specimens and monitor the testing process from specimen application to result interpretation. They might be provided as liquid or other materials similar to patient specimens and might be included with the test system or purchased separately. Carefully read the product insert to understand the manufacturer's requirements for QC performance. At a minimum, external controls should be tested with each new shipment of test devices, when testing with a new lot number, and by each new operator before conducting patient testing. Controls should be tested either before or concurrent with patient specimens by the same personnel who routinely perform patient testing.

  If control testing fails to perform as expected, patient testing should not be performed or results should not be reported until the problem is identified and corrected.

  QC test results should be recorded and monitored. Records of control results should be periodically reviewed by the person responsible for testing oversight to detect shifts or changes in performance over time which may affect patient results.

Performing the test.

- **Follow the steps** in the test procedure exactly as described in the manufacturer's product insert.

- **Test controls** at the frequency determined by the waived site requirements

- **Pay attention to timing.** Time intervals shorter or longer than those specified can result in false positive, false negative or invalid results.

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Test results interpretation.

Results can be recorded directly in a patient's chart, in log books, or on a separate report form. Interpretation of the results should be in accordance with instructions in the product insert.

- **Quantitative tests provide numerical results generated by the test device or instrument.**
  No interpretation is necessary to read the result.

- **Qualitative tests detect whether a particular substance is present or absent.**
  Results are generally interpreted as positive, negative or invalid. Invalid results indicate a problem with the specimen, test system or user technique. Guides for interpretation such as diagrams, color photographs and color-comparison charts are often part of the product insert and quick reference guide.

Resolving problems.

If a test result is not acceptable or requires repeat testing (e.g., out of range or invalid), record the initial result, noting it was unacceptable, take steps necessary to resolve the problem, then repeat the test and record the correct result. Good laboratory practices include recording what happens, whether acceptable or not, and what is done to correct problems encountered during testing. Results should not be reported until the problem is resolved.

Follow the steps in the product insert to resolve problems with the test results. If repeat testing does not resolve the problem, contact the manufacturer or technical representative.

- **Quantitative test results** should be recorded using the units of measurement of the test system.

- **Quantitative test results** should be recorded using interpretive words or abbreviations instead of symbols to help avoid clerical errors
  (e.g. "negative" or "neg" instead of just a minus sign).

RECOMMENDED PRACTICES: THE POST-ANALYTIC PHASE

Reporting Test Results

Patient reports should be legible and reported in a timely manner to the appropriate person. Verbal reports of test results should be documented and followed by a written report.

Critical values are test results necessary for patient evaluation or treatment that require immediate notification to the clinician. Each site should define the critical values, if appropriate, for the tests in use and ensure that testing personnel are aware of these values and the procedure for alerting the clinician. Procedures should be in place to ensure documentation of critical values and timely notification of the proper medical personnel.

Confirmatory testing.

The product insert should explain when additional testing is needed to confirm a waived test result or when the test is to be used as part of a multi-test algorithm (e.g. throat culture needed to confirm a negative result for rapid group A strep antigen). There should be written policies and procedures to ensure that all confirmatory and supplemental testing is performed when needed. When collecting specimens for referral to another laboratory, the instructions provided by the reference laboratory must be followed, and the appropriate request form completed.

Maintaining records of referred testing

is important for patient care and follow-up. Logs and other records should have sufficient information to track and retrieve the test results and reports, such as:

- Information linking the referred specimen to patient identification.
- The name and contact information for the referral laboratory.
- The test name and date referred.
- Complete test results and the date received.
- The date the final report is issued.

A designated employee should be responsible for ensuring that all tests ordered from a referral laboratory are returned and charted appropriately for review by the ordering clinician.

Documents and Records

Documentation is essential to assure quality waived testing. Proper documentation is necessary for monitoring and assessing test performance, identifying and resolving problems that could affect patient testing, retrieving and verifying information, and maintaining adequate patient and personnel records. Log books or electronic systems can be used for maintaining and tracking information. In some cases, records might be part of the patient's medical chart.

Quality Assessment

Good laboratory practices can be expanded to include activities to evaluate and improve the quality of waived site testing utilizing both internal and external quality assessment activities. Results from these assessment activities should be documented and evaluated, noting any irregularities and the actions taken to resolve problems or improve processes or procedures.

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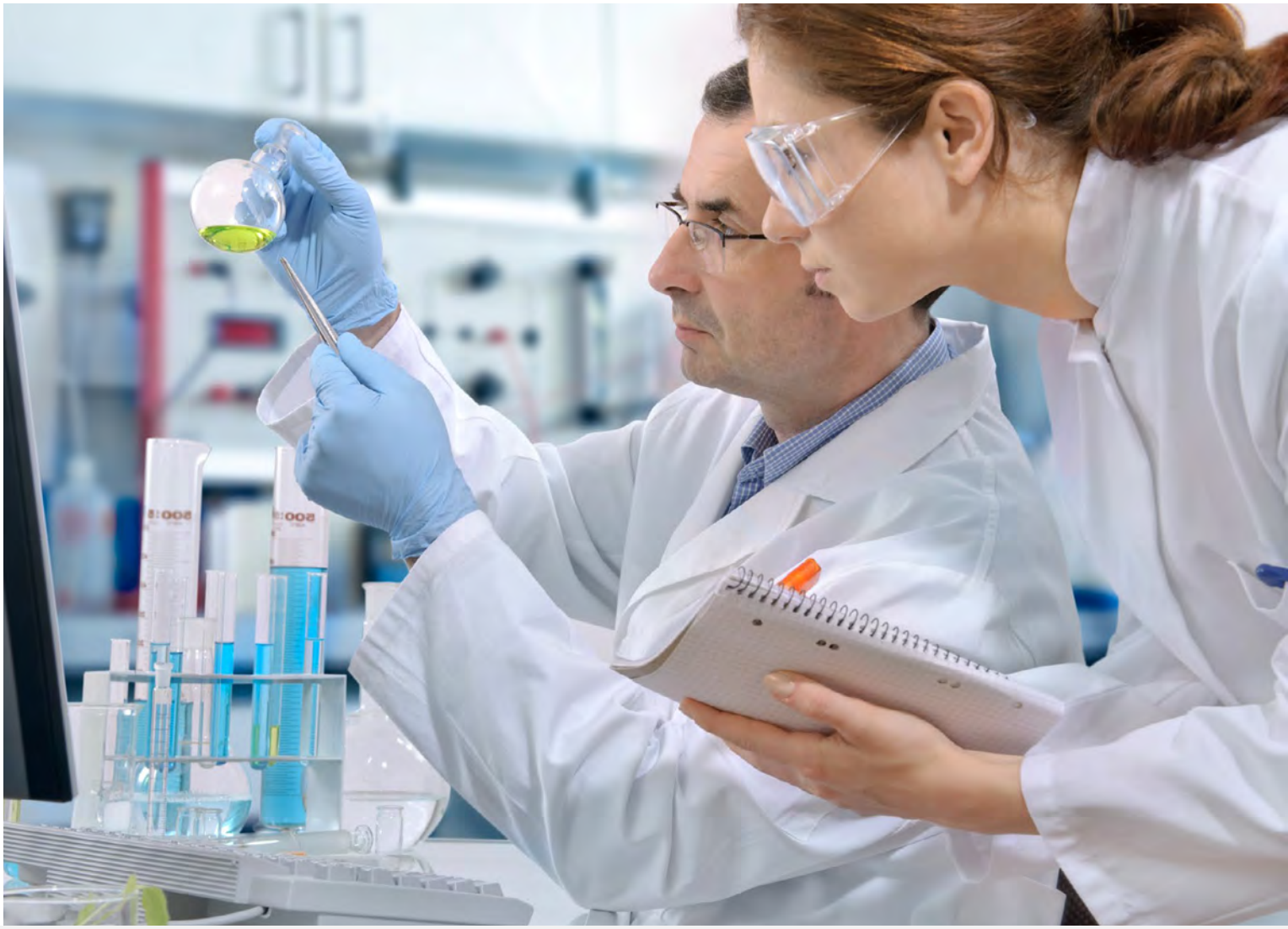
CONCLUSION

The findings of multiple surveys of sites performing waived testing throughout the United States have shown widespread lapses in quality. These studies highlight the need for additional education, training, and planning related to waived testing for Certificate of Waiver site directors and testing personnel.

This review is intended to serve as a guide for incorporating good laboratory practices at waived testing sites. Continued surveillance and monitoring of waived testing performance by those in management is necessary to ensure the effectiveness of these good laboratory practice recommendations.



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TRENDING PAMA UPDATE

By: Brian Reuwer - Senior Healthcare Policy Analyst for COLA

The Centers for Medicare and Medicaid Services (CMS) is charged with implementing the Protecting Access to Medicare Act (PAMA), which was enacted by Congress in 2014. While this law was broad in scope, one particular section of the new law changed the way Medicare determines rates for the Clinical Laboratory Fee Schedule (CLFS).

Under PAMA, CMS requires all laboratories, who meet a certain definition, to report to the Agency the payment rate, volume of testing and specific HCPCS code for each private payer from which they receive payments under the CLFS. The law establishes that the Medicare payment amount for a test will generally be equal to the weighted median of the private payor rates determined for the test.

The first period that laboratories were required to collect data was from January to June of 2016. The data that was collected for this period was used by CMS to calculate the new rates for the 2018 CLFS. Unfortunately, this effort resulted in significant cuts for many of the routine tests performed every for diagnosis and treatment of patients. While some tests did receive a higher level of reimbursement, over 75% of the CLFS saw payment reductions, with many test payment rates reduced over 30%, with the cuts being phased in over several years.

COLA has been gathering impact data and patient stories related to cuts in Medicare's Clinical Laboratory fee Schedule. This data has been widely referenced in advocacy efforts on the Hill.
To learn more about the impact of PAMA on patients and rural communities, visit:
http://www.nearpatienttestingmatters.org/

Changes to the Applicable Laboratory Definition

CMS is now starting its second round of data collection for the upcoming rate setting cycle. It is significant to note that CMS has changed the definition of a laboratory required to report private payor rates since the last reporting cycle.

Changes in the Applicable Laboratory Definition

By way of review, the original definition of an "applicable laboratory" is an entity that: Is a laboratory as defined under the Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of a laboratory. The laboratory bills Medicare under its own National Provider Identifier (NPI) (for hospital outreach laboratories: bills Medicare Part B on the Form CMS-1450 under TOB 14x.); the laboratory must meet a "majority of Medicare revenues," threshold, where it receives more than 50 percent of its total Medicare revenues from one or a combination of the CLFS or the physician fee schedule in a data collection period; and the laboratory meets the "low expenditure" threshold where it receives at least $12,500 of its Medicare revenues from the CLFS in a data collection period.

In the most recent changes, Medicare Advantage is no longer included in the "majority of Medicare revenues" calculation which will have the effect of more laboratories reaching the Medicare revenue threshold. Specifically, CMS believe this will result in more hospital outreach laboratories reporting data which is why they will now accept form CMS-1450 under TOB 14x billings as evidence of eligibility. This is important to note because if your laboratory was not eligible to report in the last data collection period for PAMA, it may very well be now.

Data Collection, Reporting Schedule and Possible Fines

If your laboratory is an "applicable laboratory" as defined above, your laboratory will be required to record commercial claims data. The schedule is outlined below:

- The data collection period started January 1, 2019 and goes through June 30, 2019. "applicable laboratories" will be required to record all commercial claims data through this period.
- The data will then be reported to CMS by the "applicable laboratory" starting January 1, 2020, through March 31, 2020. CMS will alert laboratories how to do this before the end of 2019.
- The data being reported will be used to calculate revised private payer-based CLFS rates that will go into effect January 1, 2021.

CMS developed a presentation on the next round of reporting. You can find the presentation here, along with links to other pertinent information.

https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2019-01-22-CLFS.html
Finally, all indications are that CMS will step up enforcement actions against laboratories that do not report PAMA data. Under the law, CMS may fine "applicable laboratories" up to $10,000 a day for each day they are out of compliance. Previously, CMS declined to fine laboratories that did not report data or did so incorrectly but we do not expect them to exercise the same discretion in this collection and reporting period. If you have questions about any of the information above please feel free to contact COLA's Senior Healthcare Policy Analyst Brian Reuwer at breuwer@cola.org or you can call him at (800) 981-9883.

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