Reducing Phlebotomy Recollections

How often do the samples you draw have to be recollected? It's maddening, isn't it? If all the reasons the laboratory rejects your blood samples are the bane of your very existence, cheer up. There's hope. Nearly every cause of sample rejection is preventable. Here's how to become a better phlebotomist by reducing your personal recollection rate. In this article, we will discuss the most common causes of blood sample rejection and propose proactive measures everyone who draws blood can take to prevent them.

**Hemolysis**

Knowing what causes hemolysis is key to preventing it. As much as you might like to think the laboratory hemolyzed your perfectly drawn sample, the truth is that hemolysis almost always occurs during collection, not transportation and not processing. The most common causes of hemolysis are:

*Improperly placed needles*—consider red blood cells to be tiny, fragile, glass orbs. Under normal circumstances when the needle is positioned in the center of the vein, the cells flow freely through the opening when the plunger of the syringe is pulled back or the tube is pushed fully into the tube holder. However, if the needle is only partially in the vein, the beveled opening is narrowed significantly. The force created by the vacuum or plunger pressure is then concentrated and becomes too turbulent for the fragile red blood cells to endure, and the cells rupture as they pass through the smaller opening. The same thing happens if a 25-gauge needle is used or the vacuum or pulling pressure draws the interior wall of the vein down onto the beveled opening, collapsing the vein.¹

When red cells rupture, they spill their contents (hemoglobin) into the serum or plasma, tingeing the serum or plasma red. The redder the liquid, the greater the number of cells that were ruptured. The problem is that hemolysis can’t be detected until the sample is centrifuged and the liquid portion of the blood observed. That’s when you’re notified the sample was hemolyzed and needs to be recollected. The good news is that you can take steps to prevent it. The cure: If blood trickles into the tube slowly, or enters the syringe at a snail’s pace, either the needle is not placed properly within the vein, or the vein has collapsed. If a tube holder is being used to collect the sample, a sluggish draw can also indicate the collection tube has lost some or all of its vacuum. Therefore, simply changing tubes may result in a faster fill. If not, or if a syringe is in use, release the pulling pressure from the plunger (or remove the tube from the tube holder’s interior needle). If vein collapse is suspected, increase the angle of the needle slightly so that the beveled opening is farther from the upper

CONTINUED
REDUCING PHLEBOTOMY RECOLLECTIONS, CONTINUED

...wall of the vein, and reapply the tube or plunger pressure. If improper needle placement is suspected, relocate the needle according to the CLSI venipuncture standard and your facility’s policies.

(Note: relocating a needle inappropriately can cause patient injury. Always follow your facility’s procedure manual, which should reflect the CLSI venipuncture standard H3.)

Vigorous mixing—tubes should be gently and slowly inverted down and back up. When shaken, the fragile red blood cells can rupture and hemolyze the sample resulting in a recollection. Always mix tubes immediately and slowly, with respect for the delicate structure of the red blood cell membrane. Wet alcohol—make sure the alcohol dries on your patient’s skin prior to inserting the needle and you’ll prevent the introduction of a hemolytic agent into the sample.

Tourniquet time—studies show hemolysis can occur in the patient’s veins before the puncture is even performed if the tourniquet is left on longer than one minute. Minimize tourniquet application and you’ll minimize your hemolysis rate, too.

Line draws—draws through a vascular-access device like a central line or during an IV start always risk hemolysis. That’s because IV canulas are not designed for withdrawing blood. Studies show up to 60% of samples drawn through a 22-gauge canula will be hemolyzed. Avoid line draws and draws during an IV start whenever possible to prevent recollections that are inevitable. If it can’t be avoided, at least use a syringe instead of a tube holder. Depending on the tube holder in use, some more than double the likelihood of hemolysis when attached to an IV line.

Forcefully filling tubes—when you fill tubes, do you angle the stream toward the side of the tube or do you allow it to strike full force on the bottom? When you evacuate a syringe into a tube, do you push on the plunger? Both will increase your hemolysis rate. One study found five percent of all hemolyzed samples were hemolyzed because the tubes were forcefully filled. If you don’t angle the tube, you’re not minimizing the pressure the delicate red cells are subjected to. If you push on the plunger, you’re increasing it. Make these minor adjustments to your routine and you could significantly reduce your own personal specimen rejection rate.

Pulling a syringe plunger too hard—remember, red cells are tiny, fragile orbs. One study that analyzed 500 hemolyzed specimens found that 78% of them were due to being drawn too vigorously into a syringe. Pull, but pull slowly. And don’t forget to break the seal of the plunger prior to using the device whenever you draw with a syringe. Failure to loosen the plunger can lead to a sudden rush of blood through the needle’s beveled opening when the seal breaks during the draw.

CME Learning Objectives
Following completion of the self-instructional material, the participant will be able to:

1. Identify common causes of venipuncture sample rejection and describe procedures to avoid rejected samples.
2. Understand definitions for the terms Competency and Training; identify methods of how each are assessed and/or evaluated; determine who is required to participate in a Competency Assessment; and examine the outcomes of lack of Competency and Training in patient care.
3. Describe CLIA requirements for waived laboratories: identify key functions for quality monitoring; and develop log sheets for quality assurance recordkeeping.
**Clotted samples**
Clotting is the most common reason hematology samples are rejected. When tubes containing an anticoagulant are not promptly filled (in the case of syringe draws) or adequately mixed after collection, clots within the sample may form. To rid yourself of recollections due to clotted specimens, fill all tubes to their stated volume and mix slowly. Completely invert the tube according to the tube manufacturer’s recommendations, and allow the air bubble within the tube to rise to the top before inverting again. For EDTA tubes, most manufacturers recommend five to 10 inversions.

**Quantity insufficient (QNS)**
When the volume of blood collected falls short of what is required, a recollection can’t be far behind. For tubes containing an anticoagulant, there’s a delicate balance that must be struck between additive and sample to ensure accurate test results. Sodium citrate tubes are the most sensitive to underfilling, requiring a fill volume of at least 90% of their stated capacity. One cure for “QNS” is to use pediatric-size tubes when small sample volumes are anticipated.

**Improper ID/labeling**
When collectors fail to properly identify and label the blood samples they submit to the laboratory for analysis, the facility’s specimen rejection policy is put to the test. It can be tempting to accept a perfectly filled tube with questionable identification. Especially when one little assumption about the origin of the specimen is all it takes to connect the dots between sample and test request. But little assumptions can lead to huge liability. Rejecting unlabeled or improperly labeled samples is the only way to protect patients from the catastrophic consequences that can occur when assumptions are made and specimens are misidentified. Never label specimens that have been collected by someone else. To prevent unnecessary recollections, make it your habit to completely and permanently label all specimens you draw at the patient’s side and have the patient verify the information, where feasible. It’s a habit you’ll never want to break.

**Wrong tube**
All tubes are not created equal. Make sure you are familiar with the specimen requirements for every test you draw before you draw it. Knowledge is power and in the realm of phlebotomy, knowledge of your facility’s specimen collection manual will help you draw the right specimen at the right time in the right tube, reducing your recollection rate.

**Improper transport**
Transporting blood improperly can subject samples to temperature extremes and other conditions that threaten specimen rejection. Depending upon the

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**Competencies vs. Training:**

What is the difference and how do they affect your laboratory?

By Maria S. Hardy, IMA (ASCP), Technical Writer COLA Resources, Inc. (CRI)

**(Author Disclosures: No relevant financial affiliations disclosed)**

“You are what the French call Les Incompétent,” became one of the famous lines from the 1990 movie Home Alone. It was a conversation between siblings, where one was making a generalization of the other about his ability (or lack thereof) to pack his own suitcase and basic life skills as an eight year old. But as the movie unfolds the movie’s main character Kevin proves not only is he competent at taking care of himself, but a quite ingenious and resourceful young man. Competency is an ability or skill defined by Merriam Webster Learner’s Dictionary. It is defined by CMS as “…the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly.”

Competency is very often confused with the term training. Training, again defined by Merriam Webster Learner’s Dictionary, is “a process by which someone is taught the skills that are needed for an art, profession, or job.” To be clear, once you have been trained on a skill you can then be assessed for competency on that skill. Simply because you have been taught something does not necessarily mean that you can perform the task correctly. We have always heard the adage ‘Practice makes perfect’, so let’s take it further and say that ‘Perfect practice makes perfect performance.’ If you learn how to do something incorrectly, you will perform the task incorrectly. It is the equivalent of learning how to do something correctly and then performing the task incorrectly.

Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by federal regulation. Even among larger laboratories with more formal structure, there has historically been little uniformity as to what constituted a valid assessment of competency. In recent years, there’s been a regulatory emphasis on competency assessment, as an important quality tool to reduce laboratory errors.

According to CMS, “While training is important to ensure competency, training is a process to provide and develop the knowledge, skills, and behaviors to meet established requirements. Documentation of training does not satisfy the requirement for documented competency assessment...Competency is the application of the knowledge, skills and behaviors for performance. The difference between training and competency is that training happens”

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**REFERENCES**


before someone begins testing and competency assessment confirms that they are doing the testing correctly.”

**What qualifies as training?**

CMS provides guidance on what constitutes training for testing personnel. Training may include, but is not limited to, attendance at:

- Seminars given by experts in the field, e.g., a lecture about antibiotic resistance given by the infection control officer of a local hospital;
- On-site or off-site instrument trainings given by a manufacturer, e.g., a week-long training course given at the manufacturer’s headquarters, or training by a manufacturer’s technical representative on an instrument purchased by a laboratory;
- Technical training sessions, workshops, or conferences given by a professional laboratory organization, e.g., CAP, ASMT, AACC, and ASCT;
- Technical education classes or specialty courses that include hands-on test performance, e.g., parasitology, bacteriology, cytology, given by CDC, a State Health Department, or professional laboratory organizations;
- A formal laboratory training program; or
- In-services offered by a local hospital laboratory staff, pathologist, or medical technologist to a physician’s office personnel.

**Who should participate in a competency assessment?**

Personnel should not be offended or insulted when asked to participate in a Competency Assessment. Accrediting Organizations’ (AO), as well as CLIA, require Competency Assessment as part of your laboratory’s Accreditation requirements. The new CMS IQCP Guidelines include Competency Assessments as part of a laboratory’s Individual Quality Control Plan. In determining who should participate in a Competency Assessment the decision is based on a few factors. Some AO’s criteria mandates that “All staff are to be included in this process from personnel involved in specimen collection and processing to those responsible for supervision and compliance.” Under CLIA regulations, all testing personnel must have their training documented and their competency verified.

Ask the question “Does your Laboratory Director or Technical Supervisor/Technical Consultant follow written policies and procedures to periodically evaluate personnel performance and competency of all staff involved in pre-analytic, analytic, and post-analytic phases of testing, as well as those responsible for supervision and consultation?” That is the concept of who needs to participate in a Competency Assessment.

According to CLIA regulations “Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: clinical consultant (CC), technical consultant (TC), technical supervisor (TS), general supervisor (GS) and testing personnel (TP). Clinical consultants, technical consultants, technical supervisors, and general supervisors who perform testing on patient specimens are required to have the six required methods in their Competency Assessment in addition to a competency assessment based on their Federal regulatory responsibilities. (42 CFR 493.1413(b)(8) and 493.1451(b)(8)).

The CMS letter to State Survey Agency Directors regarding the CLIA Brochure #10 What Do I Need to Do to Assess Personnel Competency?, further states “Note: If the laboratory director (LD) is the only individual testing and reporting test results, they must establish and document a minimal level of proficiency in order to ensure that they maintain the required competency for accurate and reliable testing and reporting. This may be achieved through proficiency testing (PT) or peer review (CR600, Diagnostic & Educational Laboratory v. HCFA). This is an update to our current policy.”
CLIA currently does not require Testing Personnel who perform waived testing to participate in Competency Assessments, but some AO’s require that “The laboratory must verify that non-laboratory personnel performing waived testing have completed an initial competency assessment prior to testing, a six month evaluation of competency, and annual competency assessments thereafter while they are performing testing.”

When should a competency assessment be performed?
“Evaluations should occur semi-annually for the first year and annually thereafter for all testing personnel, supervisors and technical consultants.”

“Evaluating and documenting competency of personnel responsible for non-waived testing is required at least semiannually for the first year. Thereafter, competency assessment must be performed at least annually. Competency assessment can be done throughout the entire year by coordinating it with routine practices and procedures to minimize impact on workload.”

More importantly the regulations mandate that personnel must not report test results for patient specimens until, training is complete and competency is verified for each test procedure they perform.

To ensure that your laboratory testing personnel can successfully complete a Competency Assessment, training them properly from the start is fundamental. For quality test performance in your laboratory, training must ensure that all testing personnel are familiar with the following for each test procedure:

- The test name and purpose of the test
- The equipment necessary to perform the test
- Specimen collection and handling
- Preparation, labeling, use, and storage of reagents, standards, and controls
- Special requirements, safety procedures, etc.
- Instrument maintenance, function checks, and calibration, when applicable
- Step-by-step performance of the test procedure
- Quality control procedures including what constitutes acceptable results and when to report patients
- How to recognize and interpret inconsistent results and test system problems and perform troubleshooting
- Recommended corrective action when controls are unacceptable
- Necessary calculations and derivation of results, when applicable
- Reference ranges and critical values
- Result reporting
- Quality assessment procedures

Training and personnel evaluation are not the same as competency assessment. Personnel evaluations evaluate other behaviors and attributes as they relate to the position or job (such as internal or external customer service).

Who should evaluate competency?
First it is important to have competent individuals assess the competency of the personnel under review. The reviewer should not be the Office Manager, the Nursing Supervisor, or others who do not perform lab testing. CLIA gives this responsibility to the TC (moderate complexity) or TS (high complexity). Competency must be evaluated by qualified individuals (TC/TS/GS). Other competent staff members may assist with portions of the competency assessment—but the TC/TS/GS/LD MUST evaluate the overall results of the competency assessment and sign off on the final document.

How is the competency assessment performed?
The following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing:

1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
2. Monitoring the recording and reporting of test results;

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1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
2. Monitoring the recording and reporting of test results;
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

4. Direct observations of performance of instrument maintenance and function checks;

5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

6. Assessment of problem solving skills.

Competency assessment, which includes the six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform. It is also good to know that Proficiency Testing (PT) performance may be used as part of your competency assessment; however use of PT performance alone is not sufficient to meet all six required methods.

The Competency Assessment documentation must include the results of the Assessment, who performed the Competency Assessment, who evaluated the testing personnel, and Conclusions. Conclusions should indicate ‘Is the person deemed competent?’ Are there any necessary remedial action(s) to be taken, re-assessment of personnel if necessary, and has the Competency Assessment been reviewed and bears the signature of TC/TS/GS/LD?

In summary, by taking the necessary documented steps to properly train then assess the competency of testing personnel, your laboratory is ensuring regulatory and Accreditation compliance. Testing patient samples are critical for proper patient care. The testing processes may not be as easy as packing a suitcase, or using household items to defend one’s home against burglars, but they can be simplified, verified and validated. Each step is critical in its successful completion to provide quality patient care and creates a competent and capable laboratory staff.

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Helping Waived Labs with CLIA Compliance

By Tim Dumas, CLS, CRSP • President, Tim “The Lab Guy” Consulting • www.timdumas.com

My purpose here is to give assistance with ideas, procedures and recommended logs that can help a CLIA Waived (CW) lab comply with the regulations.

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. These requirements are based on the complexity of the test and not the type of laboratory where the testing is performed.

On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.

I will assume for this article that you are already a registered lab with CLIA, performing Waived tests. I would like to recap a few of the basics about CLIA-waived labs.

Under CLIA, a laboratory is defined as “a facility that performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings.”

I will be specifically addressing waived tests which are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.”

All lab testing requires a CLIA certificate regardless of how many tests you perform, even if you do not charge the patient or bill Medicare or other insurances. Only those tests that are CLIA-waived can be performed by a laboratory with a Certificate of Waiver.

Here’s a short list of requirements that must be done by a CLIA lab.

- Enroll in the CLIA program by obtaining a certificate;
- Pay the certificate fee every two years;
- Follow the manufacturers’ instructions for the waived tests you are performing;
- Notify your State Agency of any changes in ownership, name, address or director within 30 days, or if you wish to add tests that are more complex.
- Permit inspections by a CMS agent, such as a surveyor from the State Agency. However, your laboratory is not subject to a routine survey or inspection.

Sounds simple enough, But a recent survey of waived labs showed that many labs are out of compliance. COLA has already added more scrutiny to the waived test being performed in Moderately complex labs and I believe CMS will do the same within a few years.

I want to give a little more detail as to how a waived lab may comply with potential for more scrutiny from CMS/COLA for waived testing. So, let’s start with “good laboratory practice.”

These are basic tasks that we in the lab do to ensure that all lab results are accurate, consistent and reliable. Currently, CLIA requires any office performing waived lab tests to only follow the manufacturer instructions. The manufacturer’s instructions are based on “Good Laboratory Practice.”

The test kits are tested under ideal laboratory conditions. But rarely does the office lab get to meet those idyllic conditions. So it is important that the lab try to achieve the recommended conditions for testing.

All the information needed to perform the test and all the requirements are contained in the package insert. Manufacturers’ instructions give the guidance for storage, temperature, controls, training and procedure. Each of these steps should be monitored and documented.

You know the rule. If you didn’t write it down, it didn’t happen.
HELPING WAIVED LABS, CONTINUED

I recommend the package insert be saved in a procedure binder. You can put the “in use date” on it and review it once a year for changes. If you switch to a new test it should be noted and every one trained on the new method. Don’t forget to document this.

It’s a good idea to put one person in charge of the lab; I don’t mean to run all the tests, but someone to be responsible for all the following documentation. Give them time each month to review and address any issues that may come to light. This person will make the lab director’s job much easier.

The following are areas to be monitored and some examples of logs sheets (or better yet spreadsheets) to accomplish these tasks.

Listed are the minimum recommended documentations that should be maintained:

1. **Date:** This should be recorded on the kit when it was received. Note the expiration date (make sure you will use the number of tests in the kit before it expires.) **Record Date** on the box when it is opened and put into use. It’s a good practice to note also on the box that the controls were done. (See “controls” below).

2. **Storage and climate control:** Most kits can be stored at room temperature. Others need to be refrigerated. Either way the temperature of the room and refrigerator should be documented daily. Thermometers are inexpensive; place one in the fridge and one in the room close to the testing area. Develop a log to keep record. Paper or digital? Almost all offices have a computer. I prefer digital. It’s easy to create a spread sheet or it can even be noted in an Outlook calendar. See Box 1.

**BOX 1**

<table>
<thead>
<tr>
<th>LAB</th>
<th>Temperatures</th>
<th>Lab Cleaning</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Fridge 1</td>
<td>Freezer 1</td>
</tr>
<tr>
<td>Range</td>
<td>2-8°C</td>
<td>-20 to -10°C</td>
</tr>
<tr>
<td>Wednesday, January 01, 2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thursday, January 02, 2014</td>
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<td></td>
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<tr>
<td>Friday, January 03, 2014</td>
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<td></td>
</tr>
<tr>
<td>Saturday, January 04, 2014</td>
<td></td>
<td></td>
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<tr>
<td>Sunday, January 05, 2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monday, January 06, 2014</td>
<td></td>
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</tr>
</tbody>
</table>

3. **Controls:** One of the reasons Waived kit tests are considered foolproof is that they have a built in control for each test cartridge. The manufacturer will usually require that a Positive and Negative external control be performed and documented (see Box 2) when the kit is opened or with each new lot number. The reason for this is during shipping and storage they have no control over the extreme temperatures or moisture that the kits might come in contact with. Furthermore, it is a good lab practice to double check your tools before you use them. Most kits come with the required controls. If they do not, be sure to check with your distributor to find external controls to meet regulations.

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HELPING WAIVED LABS, CONTINUED

BOX 2

<table>
<thead>
<tr>
<th>Test/ Kit:</th>
<th>Rapid Strep</th>
<th>Manufacturer:</th>
</tr>
</thead>
</table>

Controls are to be run with each new lot or when results are in question.

<table>
<thead>
<tr>
<th>Date opened</th>
<th>Expiration Date</th>
<th>Reagent Lot #</th>
<th>Control Lot #</th>
<th>Pos QC Results:</th>
<th>Neg QC Results:</th>
<th>Acceptable?</th>
<th>Tech:</th>
</tr>
</thead>
</table>

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<tr>
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<th>Expiration Date</th>
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<th>Neg QC Results:</th>
<th>Acceptable?</th>
<th>Tech:</th>
</tr>
</thead>
</table>

4. **Training:** The number one citation is lack of training or at least documented training.

Make a training log (see box 3), it should include:

BOX 3

<table>
<thead>
<tr>
<th>Lab Name:</th>
<th>best lab in the world</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>best city in the world, USA</td>
</tr>
<tr>
<td>Test/ Kit:</td>
<td>Rapid Strep</td>
</tr>
<tr>
<td>Manufacturer:</td>
<td></td>
</tr>
</tbody>
</table>

Observe and evaluate testing personnel for the following:

- Collect specimens appropriately
- Notes the expiration date
- Performs quality control
- Performs function checks/maint.
- Ensure test limitations are observed
- Know how to perform the test
- Label and store specimens correctly
- Know how to document results
- Know how to report results
- Able to identify inaccurate results or test system failures
- Can send specimens for confirmation

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing Personnel</td>
<td></td>
</tr>
<tr>
<td>Date Trained</td>
<td></td>
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<tr>
<td>Trained BY:</td>
<td></td>
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</table>

The above signature approves that the testing personnel is competent and qualified to perform the stated lab test.

CONTINUED
5. **Proficiency Testing** is not required for waived lab test, but it is a great system to assure that your results are accurate. Proficiency test samples come three times per year. PT consists of two or more samples of each test you perform. The results are unknown. After the lab sends in the results, the results are compared to all the other labs in the country running the same method/test as their labs. Scores are in relation to the collective average. The system allows for quality management of the analyzer, test system and the personnel. The cost of PT is not significant.

The above guidelines will be a good start to ensure that the results the lab is putting out are reliable and consistent. It sets a standard that all testing personnel can follow and feel confident in their ability when it comes to the lab. The paperwork does not take as much time as most people think, especially when it becomes habit.

**RESOURCES**

For a comprehensive guide I would recommend going to the CDC webpage http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm


You may also find helpful information on the CLIA web site at www.cms.hhs.gov/clia under “Certificate of Waiver Laboratory Project.”

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- Includes all PPM specimen types, plus blood cell identification and Gram stains
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Continuing Medical Education (CME) Information

AAFP-PT emphasizes the importance of voluntary laboratory improvement and provides all participants with the educational benefits for total quality assurance. AAFP-PT takes pride in offering educational programs and reference tools for our participants. Physicians and their staff can earn continuing education credit for their participation, review and/or management of the AAFP-PT proficiency testing process in their office lab. In order to earn continuing education credit, participants must also complete our educational materials that are specifically developed for the physician's office lab. Physicians are eligible to receive up to 9 AAFP Prescribed credits. AAFP-PT is also approved as a Provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program. This is a benefit offered to all participants at no additional cost!

How to Obtain CME
2. Click “PT CME Quizzes.”
3. Enter ID number or user name and password.
   First-time participants must do the following:
   a) Click “not a member or paid subscriber?”
   b) Click “Need to create an account?”
   c) Enter email address.
   d) If not found in system, click “continue to register.”
   e) Enter personal information and click “continue.”
   f) Choose a user name and password. Note this information for future use.
4. Click “Done”
5. Click “Enter the Site”
6. All currently active quizzes will be listed. Choose the desired test and click “Take the Quiz!”

How to Complete and Submit CME
1. Read the questions and click in the circle next to the correct answers. Repeat for all questions.
2. Click “Submit” when done.
3. Review your score and click “Submit your quiz rests.”
4. Complete the posttest evaluation and click “submit answers.”
5. From the “Thank you screen,” click “View letter of participation” to obtain documentation of your CME credits.

How to Obtain CME Documentation for previous events (Letters of Participation)
1. Go to www.aafp.org/cmecertificate.
2. Enter ID number or user name and password in boxes at upper right side of page and click on the green arrow to enter.
3. Click “CME Proof of Participation” on left side of screen.
4. All completed CME will be listed. Click “Print Letter” next to each event for which you are claiming credit.
5. Submit copies of this documentation to your accrediting agency as required.

The due dates for claiming CME credit are strictly enforced.

CME DUE DATES and P.A.C.E.® COURSE CODES
Event 2013-C | September 30, 2014 ....... 254-003-13
Event 2013-A | February 28, 2015 ........... 254-001-14
2014-B CME Questions

Deadline for credit is May 31, 2015 — Only employees of laboratories currently enrolled in AAFP-PT are eligible to participate in this CME activity.

The material necessary to review to answer the following questions may be found in this issue of P.O.L. Insight. Answers may be submitted at www.aafp.org/pt/cme. The Accreditation information is located on the page 14 of this issue.

1. Which of the following statements about hemolysis is true?
   a. Tingeing of the serum or plasma occurs due to the presence of hemoglobin.
   b. Hemolysis cannot be observed until the specimen is centrifuged.
   c. Knowing what causes hemolysis is key to preventing it.
   d. All of the above

2. Studies have shown that up to ___ of samples drawn through a 22-gauge canula will be hemolyzed.
   a. 30%
   b. 40%
   c. 50%
   d. 60%

3. Which of the following additive tubes is the most sensitive to underfilling?
   a. Sodium citrate
   b. EDTA
   c. Sodium heparin
   d. Lithium heparin

4. When citrate tubes for protimes are chilled prior to testing, inaccurate results can occur due to:
   a. cold activation of Factor VII.
   b. a rise in antithrombin activity factor V.
   c. circulating levels of C-reactive protein.
   d. impaired fibrinolysis.

5. True or False: A sluggish draw may indicate that the vein has collapsed.
   a. True
   b. False

6. Hemolysis can occur if the tourniquet is left in place for more than _____ minute(s).
   a. 5
   b. 3
   c. 1
   d. 10

7. EDTA tubes should be inverted ________ times to avoid clotted specimens.
   a. 1-2
   b. 3-5
   c. 5-10
   d. never invert EDTA tubes to mix

8. True or False: Routine coag samples should be always be transported on ice.
   a. True
   b. False

9. True or False: IV cannulas are designed for drawing blood.
   a. True
   b. False

10. Forcefully filling of tubes is responsible for _____ % of hemolyzed samples.
    a. 5
    b. 10
    c. 15
    d. 25

11. The following activities qualify under CLIA as Training:
    a. conferences given by a professional laboratory organization
    b. A formal laboratory training program
    c. On-site instrument trainings given by a manufacturer
    d. All of the above

12. If the laboratory director (LD) is the only individual testing and reporting test results, they must establish and document a minimal level of proficiency in order to ensure that they maintain the required competency for accurate and reliable testing and reporting.
    a. True
    b. False

13. The CMS definition of Competency is:
    a. Attending seminars given by experts in the field
    b. the application of the knowledge, skills and behaviors for performance.
    c. In-services offered by a local hospital laboratory staff
    d. A formal laboratory training program

14. According to CMS training is a process to provide and develop the knowledge, skills, and behaviors to meet established requirements.
    a. True
    b. False
15. Proficiency Testing (PT) performance may be used as part of your competency assessment; however use of PT performance alone is not sufficient to meet all six required methods.
   a. True
   b. False

16. Best practices for proper training of testing personnel should include the following:
   a. Quality control procedures including what constitutes acceptable results and when to report patients
   b. Reference ranges and critical values
   c. Result reporting
   d. All of the above

17. The new CMS IQCP Guidelines include Competency Assessments as part of laboratory’s Individual Quality Control Plan
   a. True
   b. False

18. Under CLIA regulations, all testing personnel must have their training documented and their competency verified.
   a. True
   b. False

19. According to CLIA Competency may be evaluated by the following qualified individuals.
   a. Technical Consultant (TC)
   b. Technical Supervisor (TS)
   c. General Supervisor (GS)
   d. All of the above

20. According to CLIA regulations “Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations:
   a. Clinical Consultant (CC)
   b. Technical Consultant (TC)
   c. Technical Supervisor (TS)
   d. General Supervisor (GS)
   e. Testing Personnel (TP)
   f. All of the above

21. True or False: The final CLIA regulations were became effective in 2003.
   a. True
   b. False

22. True or False: If a laboratory does not charge or bill Medicare or other insurers for testing, they can ignore CLIA regulations.
   a. True
   b. False

23. Tests that are defined as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result” are categorized as ______________ under CLIA ’88.
   a. Waived
   b. Moderately complex
   c. Highly complex
   d. None of the above

24. Laboratories must notify their state or accrediting agencies of changes to name, location, medical director, or test menu within ____________ days.
   a. 10
   b. 30
   c. 60
   d. 90

25. True or False: Laboratories performing waived testing are required to follow the manufacturer’s instructions.
   a. True
   b. False

26. Package inserts provide instructions for which of the following?
   a. Kit storage
   b. Controls
   c. Testing procedure
   d. All of the above

27. Laboratory room and refrigerator temperatures should be monitored ____________.
   a. Weekly
   b. Monthly
   c. Daily
   d. Annually

28. True or False: Waived test have built-in controls and do not require external quality controls.
   a. True
   b. False

29. True or False: In the eyes of an inspector, undocumented training is the same as no training, leading to a citation.
   a. True
   b. False

30. True or False: Proficiency testing is a great way to determine that testing is performed correctly and accurately.
   a. True
   b. False
TO EARN CME, answer the questions included WITH THIS ISSUE OF INSIGHT and submit the test answer online at WWW.AAFP.ORG/PT/CME and click on PT CME Quizzes.

Continuing Education Information

This enduring material activity, AAFP-PT POL Insight, has been reviewed and is acceptable for up to 9 Prescribed credits by the American Academy of Family Physicians. AAFP accreditation begins March 2, 2014. Term of approval is for one year from this date with the option of yearly renewal. Each issue is approved for 3 Prescribed credits. Credits may be claimed for one year from the date of each issue. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The AAFP is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

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AAFP-PT is approved as a Provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program. AAFP-PT is also an approved provider for California clinical laboratory licensees under the P.A.C.E.® Program. The level of instruction for this event is Basic. This event is worth 4 P.A.C.E.® Contact Hours.

2014-B CME Answers

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All staff and Advisory Board members involved in planning and developing content for this publication have submitted conflict of interest disclosures in advance. No relevant financial affiliations disclosed.
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