

COMPETENCY TIPS FOR POINT-OF-CARE TESTING

Thorough training is critical for the operation of all laboratory equipment to provide quality results on a consistent basis. This is even more important when point-of-care testing (POCT) is performed by non-laboratorians. The individuals who perform POCT have the knowledge and skills to master these clinical tasks. To ensure a successful POCT program, a well-thought-out and well-prepared competency-based training program is essential.

Lay the foundation of a laboratory training program by identifying what the trainees must know, as well as what tasks are critical for successful performance. Do this by:

- Determining the required competencies
- Specifying the learning objectives
- Identifying the desired learning outcomes
- Identifying and developing metrics to document competencies
- Demonstrating the competencies

Because POCT is becoming more common, it is essential that non-laboratory staff understand the critical importance of certain factors such as:

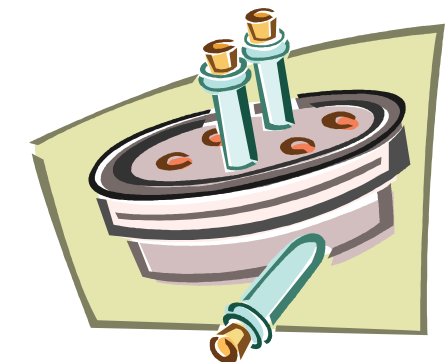
- Proper and consistent performance of quality control
- Proper and consistent performance of the procedure
- Review of the results with re-checks as necessary and appropriate

This educational aspect is a responsibility that the laboratory must not only accept, but also strongly espouse.

The College of American Pathologists POCT Checklist provides very detailed guidelines for the provision of POCT testing. Among them are:

- Participation in a third-party proficiency-testing program
- Integration of proficiency testing within the routine workload
- A written quality management program for POCT
- A complete procedure and policy manual in the work area where testing is performed
- Procedures for patient identification, patient preparation, specimen collection and more
- Entry of test results in the permanent record including identification of the operator, date and time of test and more
- Provision of reference (normal) ranges
- Proper labeling and dating of reagents, control solutions and more, and their use within the appropriate dates
- A list of approved operators and tests they are authorized or competent to perform

Meeting all of these standards may seem overwhelming, but each is critical to quality patient care.



CENTER STAGE



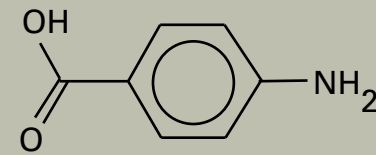
Michelle Friesen of the Avera Sacred Heart Laboratory represented the South Dakota Chapter of American Society for Clinical Laboratory Science at the Legislative Days events in Washington, D.C., in March. She met with South Dakota's delegation to discuss current

laboratory issues.



Avera McKennan Regional Laboratory is proud to announce Sheila Rezac as the new Laboratory Support Service Coordinator. In her new duties, Sheila will coordinate all day-to-day operations of the Client Service Department and the

Rapid-Response Patient Service Centers.



Answer: Para-amino-benzoic acid (PABA)
This common sunscreen absorbs ultraviolet light. The United States does not have mandatory standards for determining the sun-protection factor (SPF). Most commercially available sunscreens with PABA do not provide as much protection against ultraviolet "A" radiation, which causes DNA damage, as they do against ultraviolet "B" radiation, which causes typical sunburn. The FDA is considering regulating these products in the future.

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Avera Laboratory Network *Lab Links* is published quarterly to provide information of interest from labs of the Avera Laboratory Network. Questions may be directed to your Avera Laboratory Network representative.

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PERSONALIZED MEDICINE – THE USE OF PHARMACOGENETICS IN TREATMENT

There is a new frontier in medicine called “pharmacogenomics,” and, while controversial, it is evolving. The use of genetic information to help determine drug responsiveness, effectiveness and appropriateness is rapidly unfolding as studies help elucidate the clinical applications of the testing and bring them to the mainstream.

Some experts say that most drugs, whatever the disease they are used to treat, work for about half of the people who take them. Not only is much of the nation’s approximate \$300-billion annual drug spending wasted, but also countless patients are exposed unnecessarily to side effects. With such a situation, it is no wonder that there is so much riding on the promise of “personalized medicine,” in which genetic screening and other tests give doctors more evidence for tailoring treatments to their patients. This could improve care and produce significant monetary savings.

Many policy experts are calling for more studies to compare the effectiveness of certain treatments. One drawback to the studies is a one-size-fits-all mentality, where the

“winning” treatment is recommended for everybody. Personalized medicine goes beyond that by determining which drug is best for the individual patient instead of treating everyone the same in hopes of benefiting the majority.

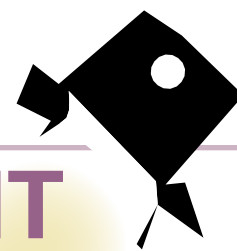
Examples of such testing include genotype testing of CYP450 for genetic variants of alleles such as 2C19, and 2D6 for a variety of drugs such as: anti-psychotics, anti-depressants, proton-pump inhibitors, beta blockers, anti-convulsants and chemotherapeutic drugs. Alleles 2C9 and VKORC1 are tested for warfarin metabolism. This genotype testing can determine a patient’s ability to metabolize a drug and thus whether it is the appropriate treatment.

One of the newer applications is chemotherapy agents. For example, the colon cancer drugs Erbitux and Vectibix do not produce results for about 40 percent of patients whose tumors have the genetic mutation UGT1A1. There was a recent FDA-sponsored meeting to discuss whether patients should be tested to narrow the use of the drugs, which can cost \$8,000-\$10,000 per month. A recent

Mayo Clinic study on Tamoxifen recommends testing the CYP450 2D6 gene for postmenopausal women about to begin therapy.

An editorial in the *New England Journal of Medicine* discussed the use of CYP450 2C19 for patients receiving clopidogrel. Individuals with the 2C19*2 allele have a reduced response to clopidogrel. This can cause a loss of function in patients after coronary stent placement and after myocardial infarction without ST elevation.

It may take 20 to 30 years before all of this becomes part of the standard of care. Until this happens, we will encounter some insurance companies that will not cover the tests and some drug manufacturers that will resist efforts to develop tests because testing may show that older, generic drugs may be as effective as new drugs when the patient is properly tested for metabolic processes.



REGIONAL SERVICE CENTER SPOTLIGHT

Each quarter, one of our regional service centers will be featured in a “Regional Spotlight.” In this issue, we are sharing information on the Avera St. Luke’s Hospital Laboratory.

Avera St. Luke’s Hospital Laboratory takes pride in its knowledgeable and experienced personnel. More than 60 percent of our staff have been working in the laboratory field for more than 20 years. Not only do we have many experienced individuals to serve our customers, but also we share that expertise by acting as a clinical site for several colleges and universities to ensure the profession continues to have exceptional laboratorians. Our Laboratory is proud to donate time by providing cytology services to the under-served women of Haiti through Avera’s medical mission work in the Grand Anse region of Haiti. Our knowledge, experience and technology, along with our commitment to customer service, allow us to provide exceptional laboratory services to our customers.

AVERA
ST. LUKE’S HOSPITAL
LABORATORY

PASSIONATE ABOUT YOUR WORK

When we have passion for what we do and find our work meaningful, we feel personal fulfillment. Remember when you started out in the laboratory and every day was exciting? Remember when you learned something new each day, and you actually hungered for learning and new things? Do you still feel that way?

Over time, routine can fade our passion. What was once new and unique becomes commonplace. Cutting-edge ideas and philosophies, viewed through experience, disappointments and the cynic’s glasses, begin to look like yesterday’s news.

Especially in these tough financial times, step back and take a look at what you can do to re-ignite your passion for your chosen career. Some suggestions for re-kindling this spirit are from an article by Gary Bradt in the January 2009 issue of *Advance for Laboratory Administrators*. His suggestions and some from others in the field can help change your perceptions and re-light that fire.

- Think back to why you chose this profession. Take responsibility for that decision and begin to stoke your own fire.

- Re-define your passion. Often what motivated you to enter a career is no longer what is important or motivates you now. As you have grown chronologically and emotionally, your values have changed. Is excellence your new motivator? Perhaps it is contributing time, effort and energy to others, such as students, schools or professional associations.
- Embrace change and discomfort. Think about changing your focus. Perhaps mentoring younger peers or students is an option. Often, exploring new and untested territories creates a renewed passion for your work. This can be risky but rewarding. Look at new ideas, new technologies and new ways of doing what you have always done. Change is always uncomfortable, but it is needed for growth. Remember, “If you always do what you’ve always done, you’ll always get what you’ve always got!”
- Expand your horizons. Don’t just stick with the routine. Seek out new areas for learning. The field of laboratory medicine is constantly evolving. New methods, concepts and ideas abound. Look beyond the “hows” to the “whys.” Read medical journals to learn “why” certain tests, procedures or medications are used and “how” the laboratory contributes to the overall care of the patient.

THE VALUE OF PROCESS STANDARDIZATION

In the exercise of the Avera value of stewardship, one of the first things to evaluate in the laboratory is process standardization. While this may sound quite basic, research has shown that in most laboratories there still are many technically trained personnel who vary in how they perform certain duties.

One of the basic tenets of the Toyota Production System, or LEAN as some call it, is the process called “standard work.” A standard work document is a carefully crafted document that is the result of a rigorous examination of the steps required to perform and properly complete an operation. This examination frequently involves videotaping the operation with all of its sub-steps, as well as dissecting the results of the video. From this comes an efficient, cohesive and rational standard for performing the operation. This standard work becomes the way

all employees perform the operation. Among some of the benefits are the reduction of:

- Variation in outcomes
- Errors
- Variation in turnaround times for the operation

Another of the basic tenets of the LEAN is the collection and display of performance metrics. “If you don’t measure it, you can’t improve it!” is a cardinal rule in performance improvement. Among the common metrics in laboratories are:

- Collection-to-receive times
- Receive-to-report times
- Testing-error rates (defined as completed results that have to be changed upon retesting)
- Clerical-error rates

Many of these metrics are already a part of laboratory performance. All

that is needed is to graph and post them for everyone to see. For example, many LEAN labs measure turnaround times for key analytes by the hour.

Such metrics allow for monitoring performance over time. By tracking the number of tests per hour, staffing can be adjusted to demand. This helps avoid over or under staffing. This staffing to demand, also called level loading, maximizes staff and reduces the number of hurry-up-and-wait scenarios that are common in health care.

Much of the value in process standardization comes in viewing processes from the customers’ points of view. When customers’ expectations are met, satisfaction and customer loyalty improve. Furthermore, communication with customers helps avoid unrealistic expectations.