Washington State Department of Health
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News and Issues for Washington's Clinical Laboratories

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Calibration and Calibration Verification: What is the difference?

by Linda K. Parisi Department of Health/LQA

The Washington Medical Test Site (MTS) regulations require calibration verification for both moderate and high complexity test systems. The following information reviews calibration and calibration verification requirements.

Calibration is the process of adjusting an instrument, kit, or test system to establish correlation between the instrument's measurement of the substance being tested and the actual concentration of the substance.

The laboratory is responsible for performing calibration as directed by the manufacturer's test system instructions, and when calibration verification of the system (see below) does not produce acceptable results.

Be sure to document in the laboratory's records each time that you perform calibration or maintain the calibration printouts.

Calibration is not required for every procedure such as:
- Manual procedures – such as microbiology cultures and tilt-tube prothrombin time test systems.
- Microscopic procedures – such as KOH preparations, pinworm preparations, urine sediment analysis, all manual cell differential procedures, and manual cytology screening procedures.
- Procedures involving an instrument in which calibration is not practical such as some coagulation procedures.

The test system's instructions should describe the process for performing calibration, the frequency of calibration, and the number, type and concentration of the calibration material to use. In the past, the term "standard" was generally used to mean calibration material. Calibration material is typically a solution of lyophilized preparation that contains a known concentration of the analyte of interest.

Calibration Verification means the testing of materials of known concentration in the same manner as patient samples to assure that the system is accurately measuring values throughout the reportable range. The laboratory has

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the LQA website.

Acute Diarrhea	Lipid Screening
Anemia	PAP Smear Referral
ANA	Point-of-Care Testing
Bioterrorism Event Mgmt	PSA
Bleeding Disorders	Rash Illness
Chlamydia	Red Cell Transfusion
Diabetes	Renal Disease
Group A Strep Pharyngitis	STD
Group B Streptococcus	Thyroid
Hepatitis	Tuberculosis
HIV	Urinalysis
Infectious Diarrhea	Wellness
Intestinal Parasites	

22nd Annual Clinical Laboratory Conference

The 22nd annual Clinical Laboratory Conference will be held on November 9, 2015, at Foster Links Golf Course in Tukwila. This is an excellent opportunity to hear about the status of health care from a variety of experts.

Dennis Weissman, president of Dennis Weissman & Associates, LLC, in Washington, D.C., is the keynote speaker for the Conference. He is presenting ***"More Upheaval Ahead for the Laboratory Market: What to Expect From New Payment and Regulatory Initiatives."*** Driven by a combination of macro market trends such as the shift toward a value-based reimbursement environment, and the legal affirmation of the Affordable Care Act, healthcare providers including clinical laboratories find themselves at an inflection point when it comes both to the delivery and payment of services for Medicare and Medicaid as well as for commercial payers.

For clinical laboratories, the advent of Medicare bundling payment for hospital outpatient pathology services was effective earlier this year. This follows the packaging of most outpatient lab services that began in 2014. In the meantime, the Protecting Access to Medicare Act of 2014 (PAMA) authorized the use of private payer rates to reprice nearly all lab tests on the Medicare Part B Clinical Lab Fee Schedule effective in 2017 with labs required to turn over private payer pricing data to the government beginning next January. Future regulatory deadlines and implementation dates for PAMA were thrown in doubt when CMS was late in issuing proposed guidance on the pricing initiative.

The latest developments affecting implementation of PAMA, as well as other reimbursement and regulatory changes affecting lab and pathology services, including the Food and Drug Administration's draft guidance on laboratory-developed tests (LDTs), will be detailed in this presentation. The speaker will also identify key macro healthcare trends and discuss how they are driving transformational changes in the lab marketplace.

Clinical and Public Health Microbiology - A Tsunami of Change: Culture Independent Diagnostic Testing

James Besser, PhD, is the deputy chief, Enteric Diseases Laboratory Branch at the Centers for Disease Control and Prevention in Atlanta. He will present ***"Clinical and Public Health Microbiology: A Tsunami of Change."*** A new generation of nucleic acid-based culture-independent diagnostic test (CIDT) panels is being introduced that can simultaneously detect multiple disease agents in just a few hours. The diagnostic microbiology landscape will likely be further altered by metagenomics and point-of-care testing in the not-too-distant future. These trends will significantly affect public health programs that depend on clinical laboratory data. This presentation will describe these trends and focus on strategies being taken by public health programs to adapt to the emerging new diagnostic world.

Xuan Qin, PhD, is the Microbiology Division chief at Seattle Children's Hospital. She will present ***"Experience from Seattle Children's Hospital: Adopting Rapid Molecular Assay Systems for the Diagnosis of Infectious Diseases."*** CIDT targeting a broad range of infectious agents simultaneously are able to provide highly sensitive results with one to four hours. Many of the mega-multiplex syndromic panels have become widely available to clinical laboratories. While the rapid CIDT have revolutionized the diagnosis of infectious diseases with obvious patient care and public health significance, the scope of utilization and cost consideration have to be evaluated before and after implementation.

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always been responsible for calibration verification or "checking" calibration for moderate or high complexity testing.

Be sure to document in the laboratory's records each time that you perform calibration verification and maintain those records.

Calibration verification must be completed at least every six months or more frequently if specified in the test system's instructions and whenever any of the following occur:

- When there is a complete change of reagents such as new lot number, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient results, and control values are not adversely affected by reagent lot number changes. Also when a different manufacturer is introduced, calibration verification needs to be done.
- There is major preventative maintenance or replacement of critical parts that may influence the test's performance. This includes when the laboratory sends a test system to the manufacturer for repairs. The laboratory must check the calibration of the repaired test system before resuming patient testing and reporting results.
- Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting of unacceptable control values fail to identify and correct the problem.
- The laboratory has determined that the test system's reportable range for patient test results should be checked more frequently.

Reminder: The laboratory is responsible for verifying calibration on factory-calibrated test systems that cannot be calibrated by the user.

A variety of materials with **known concentrations** may be used to verify calibration. Examples include: proficiency testing samples with known values, patient specimens with known values, or commercially available standards, calibrators, or control materials with known values (i.e. manufacturer's assayed values). For these materials, the laboratory must define acceptable limits for the difference between the measured values obtained, versus the actual concentration of the materials. It is not acceptable to use currently in-use calibrators or controls.

Because the purpose of calibration verification is to check whether the test system is providing accurate results **throughout the reportable range**, three levels must be tested (one at the high range of the reportable range, one at the low end of the reportable range, and one near the midpoint of the reportable range).

If the instrument is factory–calibrated, consult with the manufacturer of the test system.

There are some **exceptions to the calibration verification requirement** as listed below:

- Automated cell counters meet calibration verification requirements if the laboratory follows the manufacturer's instructions for instrument operation, and tests two levels of control materials each day of testing, provided the control results meet the laboratory's criteria for acceptability.
- If the test system's calibration procedure includes three or more levels of calibration material, **and** includes a low, mid, and high value, **and** is performed at least once every six months, then the requirement for calibration verification is also met.

If calibration verification results are unacceptable, you must repeat the test system's calibration procedure. After repeating the calibration procedure, the lab must run controls before resuming patient testing. If the test system is factory-calibrated, consult with the manufacturer of the test system.

Further information about the MTS/CLIA requirements pertaining to calibration and calibration verification can be found at the following websites:

- Refer to Table 90-2 in the MTS WAC available at the LQA website,
- Refer to the CMS CLIA Appendix C – Interpretive Guidelines Calibration and Calibration Verification Procedures (493.1255).
- Refer to the the CMS CLIA Brochure #3 - Calibration and Calibration Verification.

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The Washington State One Health Initiative and Antibiotic Stewardship

Peter Rabinowitz, MD, MPH, is an associate professor at the University of Washington School of Public Health and School of Medicine. He will present ***"The Washington State One Health Initiative."*** This presentation will review the emerging concept of One Health and how Clinical Laboratories play a critical role in One Health efforts. It will provide an update of One Health activities across Washington State including an effort to create an integrated database of antibiotic resistance in humans, animals, and environments.

Scott Weissman, MD, is an assistant professor of pediatrics at the University of Washington and the medical director of the Antimicrobial Stewardship Program at Seattle Children's Hospital. He will present ***"The Role of Clinical Microbiology in the Regional Approach to Antimicrobial Stewardship: A One Health Perspective."*** The human response to the emerging threat of antibiotic resistance must leverage "big data" approaches and electronic connectedness. However, there are many barriers, both human and technical, to aggregating clinical microbiology data. In this session, the presenter will describe these obstacles and the expected value to be unleashed by addressing them.

Pamela S. Becker, MD, PhD, is a professor of medicine at the Institute for Stem Cell and Regenerative Medicine at University of Washington School of Medicine in Seattle. She is presenting ***"Toward Personalized Medicine: In Vitro High Throughput Screen for Cancer Chemosensitivity."*** Dr. Becker will present an overview of the elements of in-vitro chemotherapy sensitivity testing in an adherent high throughput format with the purpose to optimize individualized cancer treatment. The procedures will be reviewed, including cell preparation, standardization with controls, equipment, barcoding of plates, reproducibility, viability assay, calculation of IC50/EC50 and AUC, and data reports.

Who should attend?

Laboratory directors
Laboratory and office managers
Department supervisors
Bench personnel
Billing personnel
Compliance officers

The conference offers something pertinent for everyone whether you work in a physician office laboratory, an independent laboratory, or a small or large hospital.

Location

The conference is held at the Foster Links Golf Course with easy access from Interstate 5 and the airport. **Click here** for information and a registration form for the 2015 conference or contact Leonard Kargacin. The $95 per-person registration fee includes a continental breakfast, breaks and lunch. Make your plans to attend today. You still have time to register.

Does your facility need to register with the FDA?

You do not need to register with the FDA:

- **If your agency is ONLY performing therapeutic phlebotomies or plasma exchanges.**
- **If you are ONLY pooling products or thawing Fresh Frozen Plasma (FFP).**

This clarification provided by Center for Biologics Evaluation and Research Blood Establishment Registration (CBER BER). Further information can be requested using this link.

Calendar of Events

Training Classes:

2015 Northwest Medical Laboratory Symposium
October 14 - 17 Lynnwood

22nd Annual Clinical Laboratory Conference
November 9 Tukwila

2016 ASCLS-WA Spring Meeting
April 14 - 16, 2016 Renton

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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