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

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2014 Top 10 Most Frequently Cited Deficiecies

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The Washington State Department of Health, Laboratory Quality Assurance (LQA) team inspected 266 laboratories in 2014 under the Medical Test Site (MTS) licensing program. This article outlines the top 10 deficiencies cited during 2014. The MTS Washington Administrative Code (WAC) citation appears after each item.

No. 1. Personnel Competency Evaluation {WAC 246-338-060(3)(b)(iv)}: The MTS director must evaluate, verify, and document the competency of technical personnel who perform test procedures and report test results.

Compliance Tips:
- Have a written policy defining personnel competency testing for your facility.
- Make sure your policy incorporates direct observation, review of records, performance of maintenance, assessment of test performance through testing previously analyzed samples, blind samples, or external proficiency testing samples, and problem-solving skills.
- Document the initial training of new testing personnel, assess competency at about six months and annually thereafter.
- Document remedial action for personnel failing the competency assessment.

No. 2. Proficiency Testing to include Proficiency Testing (PT) failures {WAC 246-338-050(1)(a)}: Participation in proficiency testing (PT) is required for all regulated analytes tested in your laboratory. The **LQA website** has information about PT requirements and a list of the regulated analytes under the "MTS Proficiency Testing" option on the left side of the screen. For non-regulated analytes, the laboratory can enroll in PT or use an alternative method (biannual verification) to comply with the regulation. PT is not required for waived tests, but is recommended as good laboratory practice.

Compliance Tips:
- Enroll in PT for all regulated analytes each year.
- Enroll in PT or develop a biannual verification (BV) policy for non-regulated analytes; test at least two samples per analyte twice per year.
- Check the attestation statements for signatures of the laboratory director (or designee per delegation policy) and the testing personnel.
- Document the review of PT or BV results and any remedial action to correct problems.

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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	

Carbapenem-Resistance Enterobacteriaceae - Updated Surveillance Case Definition

Carbapenem-resistance Enterobacteriaceae (CRE) are highly antibiotic resistant bacteria that have been identified as an urgent threat by Centers for Disease Control and Prevention (CDC). The Washington State Department of Health began surveillance for CRE in 2012 and is one of 19 state health departments that perform surveillance for CRE.

The department's Office of Communicable Disease Epidemiology provides consultation and education on CRE for local health, facilities, and laboratories. The department tracks CRE and carbapenemase-producing CRE (CP CRE) and includes an annual summary in the **Communicable Disease Surveillance Report** published on the department's website.

As of May 1, 2015, we adopted a new surveillance case definition proposed by CDC and the Council of State and Territorial Epidemiologists (CSTE). A standardize case definition allows comparison of CRE cases among states and better ensures accuracy of national statistics. Until now, there has been no uniform definition used by the states performing CRE surveillance.

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The new Washington state **CRE surveillance case definition** is:
E. coli, *Klebsiella spp*., or *Enterobacter spp*. resistant to any carbapenem (minimum inhibitory concentrations of ≥4 mcg/ml or ≤19 mm for meropenem, imipenem, and doripenem or ≥ 2 mcg/ml or ≤18 mm for ertapenem).

Laboratories are asked to submit isolates meeting the CRE case definition above to the Public Health Laboratories (PHL). Isolate submission should be accompanied by a Public Health Laboratories **PHL microbiology submission form** and local antimicrobial susceptibility test result.

At the PHL, isolates will undergo multiplex PCR assay for carbapenemase genes. The PHL tests for five common carbapenemases: *Klebsiella pneumoniae* carbapenemase (KPC), New Delhi metallo-β-lactamase-type 1 (NDM-1), Verona integron encoded metallo-β-lactamase (VIM), imipenemase metallo-β-lactamase (IMP), and oxacillinase-48 (OXA-48). Results will be sent to the submitter. Department of Health Communicable Disease Epidemiology will communicate results to the local health agency and the facility infection control program.

Organisms other than Enterobacteriaceae that are suspected to produce a carbapenemase, such as Acinetobacter and Pseudomonas, are reportable as "Rare Conditions of Public Health Significance."

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No. 3. No Remedial Action Taken {WAC 246-338-080(3)}: Document all remedial action in response to failures in quality control, quality assurance, personnel, proficiency testing, and transfusion reaction investigation. This deficiency is also cited when the laboratory fails to recognize that it has a failure and/or does not take effective action to correct the problem.

Compliance Tips:
- Establish an effective mechanism to recognize that problems exist, and document appropriate corrective action.
- Review documentation regularly and record that review.
- Document, document, and document.

No. 4. Record Retention {WAC 246-338-070(8)}: The MTS must retain records, slides, and tissues as described in Table 070-1, under storage conditions that ensure proper preservation.

Compliance Tips:
- Write and follow a record retention policy for your facility.
- Records must be available during onsite inspections. If some records are stored offsite, be prepared to quickly retrieve records requested by the inspector.

No. 5. Preventative Maintenance Activities {246-338-090(2)(b)}: The MTS must establish criteria for and maintain appropriate documentation of preventative maintenance activities.

Compliance Tips:
- Review necessary preventative maintenance required by the manufacturer for all instruments and/or methods.
- Establish a schedule for preventative maintenance activities as required by the manufacturer of instruments or methods.
- Review preventative maintenance logs, either electronically or manually, regularly to ensure that preventative maintenance is documented as per manufacturer requirements.
- Document remedial action when preventative maintenance activities are not performed as required by the manufacturer.

No. 6. Temperature Records {WAC 246-338-090(2)(a)}: Establish written criteria for and maintain appropriate documentation of temperature-controlled spaces and equipment. Include the monitoring of room temperature for reagents stored at room temperature or if the manufacturer specifies a specific temperature range. Temperature storage and ranges are found in the package insert and/or on the reagent box.

Compliance Tips:
- Establish acceptable temperature ranges.
- Record temperatures on each day of business, including room temperature if specified for reagents, supplies, or equipment.
- Document corrective action taken when temperatures are outside acceptable limits.
- Re-record temperatures several hours after an adjustment to the thermostat.
- Make sure that thermometers are calibrated and reading accurately.

No. 7. Personnel Education and Training {WAC 246-338-060(3)(b)(i)}: The MTS director must evaluate, verify, and document the education, experience, and training for all testing personnel. This deficiency will be cited if there is no documentation showing that the testing personnel are qualified to perform laboratory testing or if there is no documentation of initial training for new testing personnel.

Compliance Tips:
- Establish a hiring protocol that includes documentation that testing personnel are qualified to perform moderate or high complexity testing by having copies of diplomas or transcripts on-site.
- Verify that current personnel have documentation on record that they are qualified to perform laboratory testing.
- Establish a protocol to have any qualification documentation that is in a foreign language translated into English so that the surveyor will be able to read qualifications.

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• Foreign transcripts must be reviewed by an approved transcript evaluation agency to determine U.S. degree equivalency.
• Develop an initial testing personnel training document and complete that before performing patient testing.

No. 8. Testing Site Information on Reports {WAC 246-338-070(3)(c)(i)}: The name and address of the MTS, or when applicable, the name and address of each testing site performing each test, must be on the final patient report.

Compliance Tips:
• Print and review reports for accuracy of test results and the location of test performance.
• Review reference laboratory results upon receipt for location of test performance.
• If there is electronic transmission of results, be sure to confirm that each test or group of tests is identified as to location of actual performance.
• Validate that all results have the correct location of test performance for new information or electronic medical records systems.

No. 9. Director did not maintain an ongoing quality assurance (QA) program {WAC 246-338-060(3)(a)(ii)}: The laboratory director is responsible for establishing and approving policies and procedures for an ongoing quality assurance program. This must be in writing and monitored on a regular basis.

Compliance Tips:
• Upon opening a new laboratory or changing license type to a moderate or high complexity laboratory, the laboratory director must develop a quality assurance program that monitors quality of laboratory test results.
• Upon upgrading or changed test menu, method, or equipment, the laboratory director should review the quality assurance program and adjust it according to requirements of the manufacturer or regulations.
• Review the QA program on a regular basis, at least annually, to verify that the QA plan is still accurate and being followed by the laboratory staff.

No. 10. Equipment Function Checks were not completed as required {WAC 246-338-090(2)(c). The laboratory must establish written criteria for and maintain appropriate documentation for equipment function checks.

Compliance Tips:
• Review all manufacturer product inserts and regulations to identify function checks required by the manufacturer or regulating organizations. Establish a schedule to perform these function checks and record that they have been performed.
• Review schedule for function checks when new tests, methods, or equipment are installed and put into use. Follow manufacturer product inserts and regulatory requirements.
• Rotate these function checks among all testing personnel who are responsible for instrument performance.
• Review documentation to validate that equipment functions checks are being performed as required.

LQA asks that each laboratory review the MTS regulations carefully so they can meet the requirements. See the **LQA website** for additional information about the MTS licensing program and other resources.

22nd Annual Clinical Laboratory Conference

November 9, 2015

8:00 am - 4:30 pm

Foster Links Golf Course
Tukwila, WA

Mark your calendar now!

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 21 - 23, 2016 Vancouver, WA

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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