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

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Medical Test Site Notification Requirements

by Linda Parisi, Department of Health/LQA

WAC 246-338-026 requires medical test site (MTS) owners to notify the Department of Health/Laboratory Quality Assurance (LQA) about changes that occur within your medical test site.

Laboratory owners must notify the department in writing at least 30 days before the closure or opening of a medical test site.

The owner must notify the department within 30 days any change in the following by filling out the Credential Status Change form or the Change in Test Menu form found on the LQA website.

- Name of medical test site
- Change of medical test site director
- Location of medical test site
- Tests, specialties, and subspecialties, and
- Test methodologies

Change of Ownership: Transfer or reassignment of a license is prohibited without the department's approval and must be initiated by the current owner sending a written notice to the department 30 days prior to transfer.

- The current owner of the medical test site must notify the department, in writing, at least 30 days before the change and must provide the following information:
  - o Name, address, and federal tax ID of the medical test site; and
  - o Full name, address, and location of the current owner and prospective new owner; and
  - o The date of the proposed change of ownership.
- The prospective new owner must submit the following information at least 30 days before the change of ownership by filling out a new medical test site application and checking box the change of ownership at the top of the first page:
  - o New name and federal tax ID number of the medical test site; and
  - o Changes in technical personnel and supervisors; and
  - o Any changes in tests, specialties, and subspecialties; and
  - o Other information as requested by the department.

The owner of an accredited license must notify the department, in writing, within 30 days of the medical test site having its **accreditation denied or terminated** by the

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Inside This Issue

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	

Minimum Method Validation Process - Moderate Complexity Testing

by Susan Walker, Department of Health/LQA

Validation of new instruments must be performed before reporting patient results. This validation must be performed at the facility where the instrument is to be used. Here is a brief summary of the minimum validation requirements for moderate complexity testing.

Accuracy Check
- Analyze two levels of assayed control material 10 times each over several days.
- All control values should fall within the expected QC range.
- Calculate the average (mean) for each level. These values should be close to the midpoint of the range.

Precision Check
- Using a scientific calculator, calculate the standard deviation (SD) and the coefficient of variation (CV) from your accuracy check values above for each level.
- Calculate the %CV: %CV = SD/average (mean) x 100.
- Determine whether the CV meets the manufacturer's specifications for the test.

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Correlation Study with Patient Samples
Perform testing on at least 10 patient samples on your new instrument that span your reportable range (low range – mid range – high range) and compare these values with your old/current method or with your reference laboratory. The director must approve the agreement of the results based on the clinical expectations and method accuracy/ precision claims.

Reportable Range Check
- Check the high and low values that represent your reportable range. You may use calibrators (run as patients) or a linearity set to do this. You may also use patient specimens that have been tested by a reference method or proficiency testing specimens for this check.
- Analyze, in duplicate, reference or linearity materials that reflect the minimum and the upper limits.
- Compare the values. The director must approve the agreement of the results, based on clinical expectations. These must be used to set the lowest limit and upper limit for reporting patient values.

Reference Range Check
The manufacturers usually provide this information. The reference range should be provided with the patient test results. Have your director review and approve the results. Enure they are appropriate for your patient population. If the reference range is different from your old method, you must notify your providers of the change.

Calibration
Follow the manufacturer's instructions for the calibration of the instrument if required for your instrument.

If your instrument is to use a whole blood fingerstick specimen, please call your surveyor for additional suggestions for completing your validation.

The minimized instrument validation process information has been placed on the LQA website under Supplemental Materials for your convenience.

MTS Notification Requirements, cont'd from page 1

accreditation organization or voluntarily dropping its accreditation status. A new application must be submitted if the medical test site is going to continue testing.

The owner must notify the department, in writing, within 30 days of any **convictions of fraud and abuse, false billing, or kickbacks** under state or federal law.

If medical test sites follow these simple notification schedules, they will be in compliance with the notification requirements of the Department of Health, Laboratory Quality Assurance program.

These notifications are required by Statutory Authority: RCW 70.42.005.

Mosquito Season in Washington

by Kathy Lofy, MD, Department of Health/State Health Officer

It is now mosquito season in Washington. Not only a nuisance, mosquitoes can pose a serious health threat to people. More than 40 different mosquito species are found in Washington. Some are vectors for diseases, such as West Nile virus, western equine encephalitis, and St. Louis encephalitis. Mosquitoes in several Washington counties have recently tested positive for West Nile virus. We don't have any reported human cases of West Nile virus disease yet this season.

The best ways to protect yourself and your family against mosquitoes and the diseases they carry are to avoid mosquito bites and to not give mosquitoes a home. See our website for more information.

Zika has been in the news lately. We have had 22 cases of Zika virus reported in Washington as of August 5, 2016. For up-to-date numbers of confirmed Zika cases in Washington, check here.

All Zika cases reported so far in Washington have been among travelers to areas outside the U.S. where Zika transmission is ongoing. The mosquitoes that are known vectors for Zika virus, *Aedes aegypti* and *Aedes albopictus*, aren't found in Washington.

The above websites are updated with new information as it occurs so check the websites periodically to find updated information.

23rd Annual Clinical Lab Conference

What?
The 23rd Annual Clinical Laboratory Conference

When?
Monday, November 14, 2016

Where?
Foster Links Golf Course
Tukwila, WA

Plan to attend.
Mark your calendars now!!!

Calendar of Events

Training Classes:

2016 Northwest Medical Laboratory Symposium
October 12-15 Portland

23rd Annual Clinical Laboratory Conference
November 14 Tukwila

2017 ASCLS-WA Spring Meeting
April 27-28, 2017 Kennewick

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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For persons with disabilities, this document is available upon request in other formats. To submit a request, please call 1-800-525-0127 (TTY/TDD 1-800-833-6388).

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