

Volume XXIII Issue 3 May/June 2023

Updates from Laboratory Quality Assurance

The Medical Test Site Program is responsible for ensuring that the public receives accurate and reliable clinical laboratory test results by monitoring and evaluating medical test sites (MTS) for compliance with the minimal standards of quality assurance under Chapter 70.42 RCW and Chapter 246-338 WAC. This is accomplished by providing technical assistance and performing on-site surveys and investigations of laboratories in the state.

Staff Updates

The Medical Test Site Program staff has been restructured and we have hired new personnel to better serve the needs of laboratories in Washington. Most notably, the Medical Test Site Survey and Program Manager role has been divided into two positions: the Facilities Program Manager for Medical Test Sites and the Medical Test Sites Survey & Investigation Manager. What do each of these roles do? See page 3.

Surveyors and support staff are also available to answer your questions.

Mathica (Math) Brithold Festers Weshing

- Mathias (Matt) Reinbold Eastern Washington surveyor
- Bradford (Logan) Beltz Western Washington surveyor
- Mandy Tabarestani Western Washington surveyor
- LQA@doh.wa.gov Our email is monitored by Dayane Gomez, Health Services Consultant I for Medical Test Sites. Please direct questions to our inbox and your question will be directed to the appropriate personnel for response.

MTS Licensing Updates

- Licensing fees for Medical Test Sites increased on April 1, 2023. The new fees are listed in Chapter 246-338-990 WAC.
- Medical test site licenses expire every odd year on June 30th. Renewal notices were mailed in continued on page 2

Practice Guidelines

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

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
Group B Streptococcus
Hepatitis
HIV
Urinalysis
Infectious Diarrhea
STD
Thyroid
Tuberculosis
Urinalysis
Wellness

Intestinal Parasites

Inside This Issue

- 1-3 Updates from Laboratory Quality Assurance
 - 4 Calendar of Events

Updates from Laboratory Quality Assurance

April 2023 to all labs holding an active license. If you have not yet received your renewal notice and wish to renew your license, contact hsqafc@doh.wa.gov as soon as possible.

Post-COVID Public Health Emergency (PHE) Updates

- CMS published memo QSO-23-15-CLIA which provides updates on the status of temporary enforcement discretions and other flexibilities utilized during the COVID-19 PHE. Although Washington is a CLIA-exempt state, requirements for medical test sites in Washington must be equal to, or more stringent than, CMS rules and policies. Therefore, the standards described in the memo will be implemented by the Office of Laboratory Quality Assurance (LQA).
- The federal COVID-19 PHE declaration ended on May 11, 2023. Section 18115 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act granted CMS authority to implement regulations requiring laboratories to report SARS-CoV-2 test results during the PHE. Because CMS only had authority to require reporting during the PHE, the federal requirement that all licensed laboratories report SARS-CoV-2 test results ended on May 11, 2023. However, the Washington State Board of Health (Board) has the authority under RCW 43.20.050 to adopt rules for the prevention and control of infectious and non-infectious dis-

ELABORATIONS is a free bi-monthly publication of the Washington State Department of Health (DOH) Public Health Laboratories (PHL) and Office of Laboratory Quality Assurance (LQA).

Secretary, DOH: Umair A. Shah, MD, MPH Acting Health Officer: Scott Lindquist, MD Director, PHL: Romesh Gautom, PhD Program Manager, LQA: Jessica Holloway

Editor: Chuck Talburt Circulation: Chuck Talburt

Comments, letters to the editor, information for publication, and requests for subscription can be directed to:

> ELABORATIONS 1610 NE 150th St Shoreline, WA 98155

e-mail address: chuck.talburt@doh.wa.gov

NOTE: Letters to the editor may be published unless specified otherwise by the author.

Website access:

Department of Health Laboratory Quality Assurance Public Health Laboratories

- eases. The purpose of chapter 246-101 WAC, Notifiable Conditions, is to provide critical information to public health authorities to aid them in protecting and improving public health through prevention and control of disease. The Board adopted revisions to chapter 246-101 WAC in March 2021. Of the many revisions, COVID-19 was designated as a notifiable condition on a permanent basis (see 246-101-201 WAC). The revisions went into effect January 1, 2023.
- We encourage you to carefully review the guidance and share this information widely with your network(s). Questions related to the guidance should be sent to LQA@doh.wa.gov.

continued on page 3

Division of Health Systems Quality Assurance (HSQA)

Provides oversight of Washington's health care delivery system

Office of Community Health System (OCHS)

Supports DOH's mission to protect public health and safety through regulation, education and partnership.

Facilities Program Manager

- Technical assistance for licensing and policy
- Rulemaking and legislation
- Program management, including coordination, communication, and process improvement
- Oversight of regulatory and enforcement input and decisions
- Relationship management, including building, maintain and strengthening relationships with external partners
- Monitoring of MTS Proficiency Testing

Jessica Holloway

<u>Jessica.Holloway@doh.wa.gov</u>

Office of Health Systems Oversight (OHSO)

Supports DOH's mission to protect public health and safety by ensuring timely inspections of facilities and complaint responses.

Survey & Investigation Manager

- Manages the statewide Medical Test Site survey program
- Administers the CLIA program as part of the Federal exemption granted to the state
- Assures compliance with Federal and state laws and regulations by overseeing inspection of, and investigation of complaints against clinical laboratories
- Recommends enforcement actions
- Directly supervises the inspection and investigation staff for Medical Test Sites

Contact Information

Lori Eschenbacher

Lori.Eschenbacher@doh.wa.gov

Calendar of Events

Training Classes:

2023 Northwest Laboratory Symposium (NWMLS)

October (date TBA) Virtual

2023 30th Annual Clinical Laboratory Conference

November (date TBA)

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.



ELABORATIONS

Washington State Department of Health 1610 NE 150th St Shoreline, WA 98155

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).