

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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New Resources for Clinical Lab Reporting

The Washington State Department of Health (DOH) is proud to introduce our new Clinical Laboratory Reporting webpage and the new and improved Laboratory Reporting Poster. We have been working to create a one-stop resource for notifiable condition reporting issues affecting clinical laboratories. We are happy to report the new webpage and poster are available for your reference.

Please take a moment to review these new resources and consider your laboratory's notifiable condition reporting processes.

Clinical Laboratory Reporting Webpage

The [Clinical Laboratory Reporting webpage](#) includes:

- Links to the Washington Administrative Code laboratory reporting requirements
- Tips for understanding the what, where, when, with what, and how of notifiable condition result reporting
- Links to view answers to frequently asked reporting questions, including:
 - Are borderline, indeterminate and equivocal results notifiable to public health?
 - Should laboratories report any IgG results?
 - What information should be included in notifiable condition reports to public health?
- Links to view previous DOH reporting guidance com-

munications (emails, letters, and Elaborations newsletter articles)

Laboratory Reporting Poster

The new Laboratory Reporting Poster (linked on the new Reporting webpage) and [here](#) is re-organized for easier reference and now also includes local health jurisdiction contact information. For optimal viewing, please print in color on 11 by 17-inch paper.

Questions or Suggestions? Let Us Know!

Thank you for all of your work that supports the provision of exceptional patient care in our state, and for partnering with public health in creating a safer and healthier Washington. If you have any questions about notifiable condition reporting for your laboratory or suggestions for the website, please contact Dr. Scott Lindquist by [e-mail](#) or 206-418-5406.

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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	

FDA: Reporting Device-Related Adverse Events

by Susan Walker, Department of Health/LQA

An important part of the Food and Drug Administration (FDA) program for regulating medical devices is surveillance of problems with FDA-approved devices after they enter the marketplace. The FDA surveillance process ensures safety and timely identification of problems.

When the FDA identifies problems, it works with manufacturers to take necessary action to protect the public's health. Examples of FDA actions include educational tools such as publications, public health notices, workshops, joint communications with CDC -- MMWR reports, and enforcement tools such as recalls, directed inspections, and labeling changes.

Required reporting of adverse events that result in serious patient injury or death: The FDA requires manufacturers, importers, and health care professionals in hospitals

and outpatient diagnostic facilities to report adverse events as follows:

- **Death:** File the report with both the FDA and the device manufacturer.
- **Serious patient injury:** File the report with the manufacturer only, unless the manufacturer is unknown. If the manufacturer is unknown, file it with the FDA.
- File [FDA Form 3500A](#) or an electronic equivalent no later than 10 working days from the time personnel become aware of the event.

***Note:** The Washington State Department of Health requires certain facilities to report certain adverse events to its [Adverse Events Reporting](#) program, including those related to devices.

The FDA defines serious patient injury as one that

- is life threatening; or
- results in permanent impairment of a body function or permanent damage to a body structure; or
- necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Note: Inaccurate test results produced by an in-vitro diagnostic device (IVD) and reported to the health care professional may lead to medical situations that fall under the definition of serious injury. These are reportable adverse events.

Voluntary reporting of other adverse events: The FDA requires manufacturers to report when a device fails to perform as intended and there is a chance of death or serious injury because there may be a recurrence of the malfunction. The FDA encourages health care professionals in hospitals and outpatient diagnostic facilities to:

- report device malfunctions to manufacturers. Malfunctions may relate to any aspect of a test including hardware, labeling, reagents, calibration, or user error that may be related to faulty instrument instructions or design.
- submit voluntary reports of device malfunctions and patient injuries that do not qualify as serious injuries by using [FDA Form 3500A](#).
- submit voluntary reports of adverse events noted in the

continued on page 3

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Website access:

[Department of Health](#)
[Laboratory Quality Assurance](#)
[Public Health Laboratories](#)

FDA: Reporting Device-Related Adverse Events, cont'd from page 2

course of clinical care, not events that occur in the course of clinical trial or other studies. You can find instructions on how to submit a voluntary report on the [FDA website](#).

Laboratory policies: The clinical laboratory should have written procedures for

- the identification and evaluation of adverse patient events,
- the timely submission of required medical device reports, and
- compliance with record-keeping requirements.

Laboratories that are part of a larger organization (e.g., hospital laboratories) should:

- document participation in the overall institutional medical device reporting (MDR) process.
- educate personnel in the FDA MDR requirements.
- submit an annual report of device-related deaths and serious injuries to FDA if any such event was reported during the previous year. Annual reports must be submitted on [FDA Form 3419](#) or an electronic equivalent by January 1 of each year. The laboratory or institution must keep records of MDR reports for two years.

Zika, Dengue, and Chikungunya Testing Added at WAPHL

by Brian Hiatt, WAPHL Microbiology Director

We are pleased to announce that testing for Zika, dengue, and chikungunya at the Washington State Public Health Laboratories (WAPHL) began on January 17, 2017. The WAPHL performs real-time polymerase chain reaction (rRT-PCR) for Zika, dengue, and chikungunya as well as the InBios enzyme-linked immunosorbent assay (ELISA) for Zika. Samples not requiring the plaque reduction neutralization test (PRNT) will have an average turnaround time of 14 days. Results will be faxed directly to the submitter and Local Health Jurisdiction upon test completion. Specimens that require PRNT will still be sent to CDC.

Important change: To facilitate timely and accurate specimen submission, the laboratory has developed a new [Zika submission form](#) that should accompany the specimen(s). The form must be filled out completely to ensure specimen acceptability. The [new submission form](#) is found on the Department of Health website as well as the Public Health Lab [Microbiology Test Menu](#).

The process for collecting clinical and exposure information, and criteria for testing through public health, remains unchanged. Please continue to fax or secure email your completed intake forms for approved patients.

Please let us know if you have any questions through this [email link](#) or calling 206-418-5500.

Approved PT Providers

[Amer. Acad. of Family Physicians](#) (800) 274-7911

[Amer. Assoc. of Bioanalysts](#) (800) 234-5315

[American Proficiency Institute](#) (800) 333-0958

[ACP Medical Lab Evaluation](#) (800) 338-2746

[California Thoracic Society](#) (415) 536-0287

[College of American Pathologists/EXCEL](#)
(800) 323-4040

[WSLH](#) (800) 462-5261

For answers to your PT questions, go to the [LQA web-site](#) or call Veronica Bush at (253) 395-6782.

Calendar of Events

Training Classes:

[2017 ASCLS-WA Spring Meeting](#)

April 27-28 Kennewick

[2017 Northwest Medical Laboratory Symposium](#)

October 18-21 Lynnwood

[24th Annual Clinical Laboratory Conference](#)

November 13 Tukwila

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).