

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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Biennial Review of IQCP Implementation in Washington State for DOH Surveyed Laboratories

by Honora Estes, Department of Health/LQA

On January 1, 2016, the Centers for Medicare and Medicaid Services (CMS) implemented Individualized Quality Control Plan (IQCP), a quality control (QC) model based on risk management. The model provides laboratories the flexibility in customizing quality control procedures based on the test systems in use and on each laboratory's unique aspects. IQCP is voluntary, but otherwise laboratories can comply by performing the minimum standard of testing two external levels of QC each day of patient testing.

Before IQCP implementation, Laboratory Quality Assurance (LQA) surveyors provided training and an IQCP handout during routine laboratory surveys. This training included a review of the test systems where IQCP would apply and an explanation of the three essential components of an IQCP: risk assessment, quality control plan, and quality assessment. Additionally, LQA included a written statement about IQCP in survey letters that provided the due date for IQCP and listed the applicable test systems used at the laboratory.

In order to assess regulatory compliance since IQCP implementation, LQA tracked IQCP data for qualifying testing systems during routine on-site surveys. Based on the data collected, 93 percent of laboratories in Washington comply with state and federal IQCP requirements by either implementing an IQCP or opting-out of writing an IQCP by performing two levels of control daily. LQA surveyors reviewed IQCPs to make sure that the IQCPs met minimum manufacturer and regulatory requirements. In total, 46 IQCP deficiencies were cited representing 5 percent of the total deficiencies cited at routine surveys during the first biennium of IQCP implementation.

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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	

Washington State Department of Health Updates to Surveillance of Antibiotic Resistant Organisms—Effective Immediately

Antibiotic resistance is a growing threat. High-profile resistant organisms that have recently been in the news include mobile colistin resistance (*mcr-1-4*), *Candida auris* and highly drug-resistant *Neisseria gonorrhoeae*. Since the Washington State Department of Health Public Health Laboratories (PHL) became the western regional lab in the Center for Disease Control’s Antibiotic Resistance Laboratory Network (ARLN), our state multidrug-resistant organism (MDRO) surveillance and advanced resistance testing capabilities have expanded.

MDRO surveillance serves several different purposes. We are interested in tracking the prevalence of certain types of resistance, such as carbapenem-resistant (CR) *Acinetobacter* and CR-*Pseudomonas*. In addition, we seek to identify carbapenemases in carbapenem-resistant Gram-negative bacteria in order to implement infection prevention interventions in a timely manner. Similarly, it is important to know whether mobile colistin resistance (*mcr*) or *Candida auris* have been introduced in Washington so we can respond promptly to prevent transmission.

Isolates submitted to PHL ARLN by clinical labs undergo identification, resistance and mechanism testing, and, for some isolates, whole genome sequencing (WGS). If necessary, isolates are sent to CDC for additional testing and banking.

Some MDRO surveillance is statewide, whereas other isolates are requested only from sentinel labs that have volunteered to participate in this effort. Lab directors of sentinel labs were contacted and recruited and have a formal agreement and submission plan in place specifying which organisms to submit and how many. Lab staff members should be knowledgeable about what their lab should submit to PHL.

All Washington labs should submit the following isolate-types to PHL:

- All carbapenem-resistant *E. coli*, *Klebsiella species*, and *Enterobacter species*
- All *Candida auris*
- All carbapenem-resistant *Acinetobacter species*

In addition to submitting the isolate-types above, sentinel labs should also submit one or more of the following isolate-types to PHL:

- Carbapenem-resistant *Pseudomonas species* (all, or only a subset, depending on volume).
- All *Candida species*, EXCEPT *albicans*, *parapsilosis*, *dubliniensis*, *lusitaniae*, *tropicalis*, and *krusei*. (For *C. glabrata*, submit all isolates, or only a subset, depending on volume.)
- *E. coli* and *Klebsiella pneumoniae* resistant to third-generation cephalosporins (all isolates, or only a subset, depending on volume).
- All genera of Carbapenem-resistant Enterobacteriaceae (time-limited January 1, 2018 - April 30, 2018).

Table 1 on page 4 summarizes species and resistance criteria for submission of isolates for MDRO surveillance.

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Website access:

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[Public Health Laboratories](#)

Biennial Review of IQCP Implementation, cont'd from page 1

IQCP Statistics between IQCP Implementation and November 2017

Total laboratories eligible for IQCP – 258

- Laboratories opting-out of IQCP and performing two levels of external control daily – 63 (24 percent)
- Laboratories with IQCPs written – 178 (69 percent)
- Laboratories without IQCP as required – 17 (7 percent)

Total IQCP deficiencies – 46

- Quantitative Test Systems 246-338-090(4) – 18
- Qualitative Test Systems 246-338-090(5) – 21
- Coagulation IQCP Test System 246-338-090(9)(c)(iii) – 2
- Microbiology IQCP Test Systems 246-338-090(9)(f)(vi)(A) – 5

Part of the assessment process involves the on-going review at specific intervals of how your IQCP is working for your laboratory. DOH surveyors will review this at your routine surveys, so your IQCP is a living document that may require changes and updates. Documents to consider for assessment review may include, but are not limited to:

- QC review
- Proficiency testing records (scores, testing failures, trends)
- Patient result review
- Specimen rejection logs
- Turnaround time reports
- Records of preventive measures, corrective actions, and follow-up
- Personnel competency records

For additional IQCP information please see the following websites:

[CDC IQCP link](#)

[CMS IQCP information page](#)

Updates to Surveillance Antibiotic Resistant Organisms—Effective Immediately, cont'd from page 2

We offer the following brief summary of MDRO surveillance.

- Quarterly [CR-organism surveillance reports](#) are posted on the DOH website. These reports include CRE, CR-*Acinetobacter* and CR-*Pseudomonas*.
- As of December 2017, *Candida auris* has not been reported in Washington State. See CDC's "[Tracking Candida auris.](#)"
- In 2016, retrospective testing of surveillance isolates identified a *Salmonella* isolate with mcr-3. The isolate was collected in 2008 and the illness was associated with travel in Asia. As of December 2017, no other mcr isolates have been reported in Washington. See CDC's "[Tracking the mcr gene.](#)"

Detailed submission and testing information for each organism is available on the PHL [Microbiology Laboratory Test Menu](#).

The ARLN will cover shipping costs associated with MDRO submission. Contact Kelly Kauber at 206-418-5589 or [e-mail](#) for pre-paid labels.

We sincerely thank laboratories for their diligence in reporting and submitting antibiotic resistant organisms to public health. The Healthcare Associated Infections Program is available for consultation on any aspect of MDRO surveillance and infection prevention or questions about ARLN. Please contact Kelly Kauber at 206-418-5589 or by [e-mail](#) with questions or comments.

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Table 1. Species, Resistance Criteria, and Submitters for Washington State MDRO Surveillance

Family/Genus	Antibiotic Resistance Criteria	Submitters
CR-Enterobacteriaceae: <i>E. coli</i> <i>Klebsiella spp.</i> <i>Enterobacter spp.</i>	Resistant to ≥ 1 carbapenem: Minimum inhibitory concentrations ≥ 4 mcg/ml for meropenem, imipenem, and doripenem, and ≥ 2 mcg/ml for ertapenem OR Kirby-Bauer zone of inhibition diameter ≤ 19 mm for meropenem, imipenem, and doripenem, and ≤ 18 mm for ertapenem	All state labs
<i>CR-Acinetobacter spp.</i>	Resistant to ≥ 1 carbapenem: Minimum inhibitory concentration ≥ 8 $\mu\text{g/mL}$ for any carbapenem OR Kirby-Bauer zone of inhibition diameter ≤ 14 mm for doripenem and meropenem, and ≤ 18 mm for imipenem	All state labs
<i>Candida auris</i>	None	All state labs
CR- <i>Pseudomonas species</i> *	Resistant to ≥ 1 carbapenem: Minimum inhibitory concentration ≥ 8 $\mu\text{g/mL}$ for any carbapenem OR Kirby-Bauer zone of inhibition diameter ≤ 15 mm for any carbapenem	Sentinel labs
All <i>Candida spp.</i> * EXCEPT <i>albicans</i> , <i>parapsilosis</i> , <i>dubliniensis</i> , <i>lusitaniae</i> , <i>tropicalis</i> , and <i>krusei</i>	None	Sentinel labs
ESBL <i>E. coli</i> and <i>Klebsiella pneumoniae</i> *	Resistant to ≥ 1 third-generation cephalosporin Minimum inhibitory concentration ≥ 4 $\mu\text{g/mL}$ for cefotaxime and ceftriaxone, and ≥ 16 $\mu\text{g/mL}$ for ceftazidime OR Kirby-Bauer zone of inhibition diameter ≤ 22 mm for cefotaxime, ≤ 19 for ceftriaxone, and ≤ 17 for ceftazidime	Sentinel labs
All genera of CR-Enterobacteriaceae	Resistant to ≥ 1 carbapenem: Minimum inhibitory concentrations ≥ 4 mcg/ml for meropenem, imipenem, and doripenem, and ≥ 2 mcg/ml for ertapenem OR Kirby-Bauer zone of inhibition diameter ≤ 19 mm for meropenem, imipenem, and doripenem, and ≤ 18 mm for ertapenem Note: For Enterobacteriaceae that are intrinsically resistant to imipenem (e.g., <i>Providencia</i> , <i>Proteus</i> , and <i>Morganella spp.</i>), the carbapenems, meropenem, doripenem and ertapenem should be used to determine if the isolate meets the definition.	Sentinel labs, time limited January 1-April 30, 2018

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:

[2018 ASCLS-WA Spring Meeting](#)

April 26-27 Renton

[2018 Northwest Medical Laboratory Symposium](#)

October 24-27 Portland, OR

[25th Annual Clinical Laboratory Conference](#)

November 2018 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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