**Vibrio vulnificus** Isolated in Washington Oysters

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Each summer, the Washington State Department of Health Office of Shellfish and Water Protection (OSWP) harvests oysters from Washington waters to conduct routine monitoring for pathogenic *Vibrio* sp. with laboratory testing performed by the Washington State Public Health Laboratories (WA PHL). In August 2013, the WA PHL detected *Vibrio vulnificus* (*Vv*) from oyster samples both by PCR and by culture. This finding is a first for WA PHL, though reports of isolation of *Vv* in Washington have been described in the past, including in a sediment sample from Washington described by the FDA in 1987(1) and oyster samples collected by FDA at the retail level in 2007(2). Additionally, during the summer of 2013, the FDA isolated what appears to be *Vv* in oyster samples from Washington collected for a research study on harvest practices and *Vibrio parahaemolyticus* (*Vp*) levels. FDA is still in the process of confirming that the suspected *Vv* colonies it isolated in culture are indeed *Vv*.

Three confirmed *Vv* isolates from oysters tested at WA PHL were sent to both FDA and CDC for verification and additional characterization. Both agencies verified all three isolates as *Vv* using a *Vv*-specific PCR assay. Using 16S rRNA and virulence correlated gene (vcg) genotyping analysis, the WA PHL isolates were compared to known virulent and nonvirulent strains of *Vv*. FDA determined the WA PHL *Vv* isolates fall within less virulent genotypes of *Vv*.

*Vv* can cause more severe illness than *Vp*, particularly in immunocompromised persons. To date, the department’s Communicable Disease Epidemiology (CDE) has not had any illness reports of people acquiring *Vv* infections in association with either consuming Washington oysters or exposure to Washington waters. Prior *Vv* infections among Washington residents have been associated with travel to the Gulf Coast states. However, the establishment of detectable levels of *Vv* in Washington oysters presents the possibility that illnesses from *Vv* may occur locally in the continued on page 3

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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
- Intestinal Parasites
- Wellness

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Individual Quality Control Plan (IQCP) for Nonwaived Testing

The Centers for Medicare and Medicaid Services (CMS) are implementing IQCP as a new quality control option based on risk management for Clinical Laboratory Improvement Amendments (CLIA) laboratories performing nonwaived testing. IQCP will provide laboratories with flexibility in customizing Quality Control (QC) policies and procedures based on the test systems in use and the unique aspects of each laboratory.

The Medical Test Site (MTS) program in Washington will also follow the CMS IQCP recommendations.

IQCP is voluntary, but if laboratories choose to not implement IQCP, they will need to achieve compliance by performing two levels of external (QC) material each day of patient testing. Testing that meets the default of two levels of external QC does not necessarily need to be included in your IQC plan. The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained to ensure the quality of laboratory services provided, and to identify failures in quality as they occur.

An IQCP Education and Transition Period will allow laboratories an opportunity to learn about IQCP and to implement their chosen QC policies and procedures. The IQCP Education and Transition Period will begin on January 1, 2014, and end on December 31, 2015.

Laboratories will have three acceptable QC options during the IQCP Education and Transition Period:
1. Follow the MTS/CLIA QC regulatory requirements as written which is two levels of external QC each day of testing.
2. Continue to follow the Equivalent Quality Control (EQC) procedures as described in the current Interpretive Guidelines.
3. Implement IQCP.

At the end of the education and transition period, EQC will no longer be an acceptable option to meet MTS/CLIA QC requirements and will be removed. Therefore, it’s important that laboratories understand that on this date, only two options will remain to meet MTS/CLIA QC compliance.

1. Follow the MTS/CLIA QC default of two levels of external QC each day of testing or
2. Implement IQCP, as applicable.

During the education and transition period, MTS surveyors will be instructed not to cite QC deficiencies relevant to IQCP. At the end of this period, laboratories will receive deficiency citations if they aren’t in compliance with one of the two options outlined in the previous paragraph.

Laboratories that receive CLIA certification by virtue of accreditation by a CMS-approved accrediting organization (AO) should continue to follow the requirements of their AO.

Laboratories can find IQCP educational materials at the CLIA website.
future. Therefore, we advise that you inform healthcare providers in your institutions about the possibility of $Vv$ acquired in Washington. Should a potential case of $Vv$ be reported to you, please notify CDE promptly.

Providers should be aware that $Vv$ may be present in Washington waters and oysters, and that if they suspect a clinical illness with $Vv$ they should notify the clinical microbiology laboratory to which they are submitting specimens for culture workup. Notifying the clinical lab will help ensure that it is performing appropriate review of colonies to look for $Vv$, as some colonies may grow differently than $Vp$ on certain selective media. Most $Vv$ (~85 percent) will grow as green colonies on TCBS (Thiosulfate Citrate Bile Salts Sucrose) agar; however, the three isolates tested by WA PHL during the 2013 season were sucrose positive. Sucrose-fermenting $Vv$ will grow as yellow colonies on TCBS. It is important to familiarize yourself with typical and atypical growth characteristics of different $Vibrio sp$. All isolates within the family Vibrionaceae (including $Vibrio parahaemolyticus$, $V. vulnificus$, $V. cholerae$, $V. mimicus$, $V. alginolyticus V. fluvialis$, and $Grimontia hollisae$) are required to be submitted to the WA PHL.

OSWP and WA PHL will continue to monitor any further developments related to $Vv$ in the environment. Surveillance for potential emerging $Vv$ illnesses will require your continued vigilance when performing wound and stool cultures during peak Vibrio season (May-September) in Washington State.

Additional information regarding $Vv$ infections can be found at these website at these DOH and CDC websites.


Approved PT Providers

Amer. Acad. of Family Physicians  (800) 274-7911
Amer. Assoc. of Bioanalysts  (800) 234-5315
American Proficiency Institute  (800) 333-0958
ASIM Medical Lab Evaluation  (800) 338-2746
California Thoracic Society  (714) 730-1944
College of American Pathologists/EXCEL  
(800) 323-4040
WSLH  (800) 462-5261

For answers to your PT questions, go to the LQA website or call Leonard Kargacin at (253) 395-6747.

Calendar of Events

Training Classes:

2014 Northwest Medical Laboratory Symposium  
October 1-4  Portland, OR

21st Annual Clinical Laboratory Conference  
November 2014  Tukwila

2014 ASCLS-WA Spring Meeting  
April 24-26  Spokane

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.

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).