TO: Nebraska Healthcare Providers, Laboratories, Emergency Medicine,

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RE: False-positive *Vibrio* and *Yersinia* results on **Culture-Independent Diagnostic Testing**

(CIDT)

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Nebraska is among several states that have recently observed an increase in sporadic *Vibrio* detections identified initially by CIDT, specifically the BioFire FilmArray Gastrointestinal Panel (GI panel).

From January 1 to August 31, 2018, the Nebraska Department of Health and Human Services (NDHHS) received 16 GI panel results where *Vibrio* and/or *Vibrio cholerae* were detected. All 16 specimens were sent to the Nebraska Public Health Laboratory (NPHL) for culture, and all were negative. This number represents a 400% increase in culture-negative, GI panel-positive ("detected") *Vibrios* compared to 2017 (16 vs. 4). Of the 16 individuals with GI panel-positive *Vibrio* results in 2018, 15 had known exposure information, 10 (67%) of which lacked exposure risk factors typically associated with *Vibrio* infection.

When CIDT results are not confirmed by culture and patients lack typical exposures normally associated with *Vibrio* infection, the utility of classifying them as "cases" is not clear. Additionally, BioFire recently released communication stating that the agar used in Cary Blair media was found to be sporadically contaminated with low levels of *Vibrio* nucleic acid due to the presence of *Vibrio* species in water where seaweed/algae is harvested to make the agar. Due to the sensitivity of molecular testing, this contamination can cause false-positive *Vibrio* results, including *Vibrio cholerae*, on the BioFire GI panel.

Because of these concerns, Nebraska and several neighboring states have decided to use new case definitions for vibriosis and cholera as follows:

- BioFire GI panel positive and culture positive = **Confirmed case**
- BioFire GI panel positive, culture negative, <u>AND</u> patient reports ≥1 exposure typically associated with *Vibrio* infection (e.g., shellfish or raw/undercooked seafood consumption, exposure to salt water, travel to an endemic area) = **Probable case**
- BioFire GI panel positive, culture negative, and no typical exposure reported = **Not a case**

Similar concerns exist for false-positive BioFire GI panel results for detections of *Yersinia enterocolitica*. However, since this organism is endemic in Nebraska, further assigning case status for

BioFire GI panel-positive, culture-negative results on the basis of exposure history is not feasible. Thus, we are not currently altering the case definition for yersiniosis.

Results from any CIDT should be used in conjunction with relevant clinical, epidemiologic, and supporting laboratory data, such as culture. Laboratory results that are incongruent with a patient's clinical picture, exposure history, or supporting laboratory data should be interpreted with caution.

Culture confirmation is necessary for organism recovery and to provide a complete epidemiologic picture. Laboratories should continue to send GI panel-detected *Vibrio* stools in Cary Blair or other maintenance media to NPHL for culture confirmation as specified in 173 NAC 1-007.03. Please refer to the NPHL Quick Shipping Guides for proper shipping requirements. For additional questions concerning shipment of these specimens, contact NPHL at 402-559-9444.

Additional information regarding the detection of *Vibrio* and *Yersinia* by the BioFire FilmArray GI Panel and other methods can be found in the following BioFire technical notes:

Technical Note - *Vibrio* detection by the FilmArray® Gastrointestinal (GI) Panel: http://www.online-ifu.com/ITIGI0239

Technical Note – *Yersinia enterocolitica* detection by the FilmArray® Gastrointestinal (GI) Panel: http://www.online-ifu.com/ITIGI0250