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| **Proposal Subject:** | Reveal 2.0 DSP |
| **Specific NSSP Guide Reference:** | NSSP Section IV. Guidance Documents Chapter II. Growing Areas<br>.11 Approved NSSP Laboratory Tests |
| **Text of Proposal/ Requested Action** | We request review of the validation study submission for the Reveal 2.0 DSP (okadaic acid group) test kit and consideration of the method for approval as a screening method for qualitative determination of okadaic acid group in shellfish. Add Reveal DSP to Section IV. Guidance Documents, Chapter II. Growing Areas, .11 Approved NSSP Laboratory Tests. |
| **Public Health Significance:** | Toxins that cause diarrhetic shellfish poisoning (DSP) include the okadaic acid (OA) group of toxins [1, 2] OA is produced by marine dinoflagellates such as *Dinophysis*, and has structural analogues referred to as the dinophysistoxins (DTXs). The U.S. Food and Drug Administration action limits are 160 ppb OA equivalents (OA, DTX1, DTX2, DTX3) in shellfish.<br><br>LC-MS/MS methods [3] have been accepted as quantitative reference methods in many parts of the world. Assays facilitating more rapid determination of OA toxins with simplified procedures are needed by the shellfish industry and regulatory authorities.<br><br>[1] J. Sobel and J. Painter (2005), Illness caused by Marine Biotoxins. Clin. Infect. Dis. 4, 1290.<br><br>[2] Van Dolah, Frances M. (2000), Marine algal toxins: origins, health effects, and their increased occurrence. *Environmental health perspectives* 108. Suppl 1, 133**.**<br><br>[3]Community Reference Laboratory for Marine Biotoxins (CRLMB)., Agencia Española de Seguridad Alimentaria y Nutrición (AESAN). (2009). EU Harmonised Standard Operating Procedure for determination of OA-Group Toxins by LC-MS/MS. Version 1. |
| **Cost Information (if available):** | Approximately $17.00 per test. Reader based assay – approximate cost of Reader $1995. |
| **Action by 2013 Laboratory Method and Quality Assurance Review Committee** | Recommended Proposal 13-113 be referred to an appropriate committee as determined by the Conference Chairman and await data to determine if the method is fit for purpose within the NSSP. |
| **Action by 2013 Task Force I** | Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-113. |
| **Action by 2013 General Assembly** | Adopted recommendation of 2013 Task Force I on Proposal 13-113. |
| **Action by FDA May 5, 2014** | Concurred with Conference action on Proposal 13-113. |
| **NOTE:** | Click here for Proposal 13-113 Supporting Documentation |