Proposal Subject:	Reveal 2.0 ASP
Specific NSSP Guide Reference:	NSSP Guide Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	We request review of the validation study submission for the Reveal 2.0 ASP (domoic acid) test kit and consideration of the method for approval as a screening method for qualitative determination of domoic acid in shellfish. Add Reveal ASP to Section IV. Guidance Documents, Chapter II. Growing Areas, .11 Approved NSSP Laboratory Tests.
Public Health Significance:	Amnesic shellfish poisoning is caused by the toxin domoic acid, produced by phytoplankton of the genus Pseudonitzschia. It is associated with eating contaminated oysters, clams, mussels, and other shellfish [1,2]. There have been numerous outbreaks of ASP, and there is evidence that the occurrence of the phytoplankton responsible for ASP is widespread. Current methods for detection of domoic acid consist primarily of instrumental chemistry methods, which are laborious and time-consuming. Methods for rapid screening for domoic acid, in field and laboratory settings, are needed and will assist the industry and public health authorities in responding to this health concern. The Reveal ASP test is a lateral flow immunoassay designed for qualitative determination of domoic acid in shellfish at levels of 10 ppm (mg/kg) and above. The test uses minimal equipment and simple reagents, does not require specialized training, and can provide results in 20 minutes from sample receipt, including sample preparation. 1] J. Sobel and J. Painter (2005), Illness caused by Marine Biotoxins. Clin. Infect. Dis. 4, 1290. [2] Van Dolah, Frances M. (2000), Marine algal toxins: origins, health effects, and their increased occurrence. *Environmental health perspectives* 108. Suppl 1, 133.
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 adoption of this method as a Limited Use Method for the purpose of screening and precautionary closure for ASP and direct the Executive Office send a letter to the submitter requesting additional information as provided by the Laboratory Method Review and Quality Assurance Committee.
Action by 2013 Task Force I	Recommended adoption of the Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-112 and recommended that the Conference be made aware the submitter of Proposal 13-112 is looking for samples to be used in testing.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-112.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-112.
NOTE:	Click here for Proposal 13-112 Supporting Documentation