Proposal Subject:	Real ASP (Domoic Acid) Test Kit
Specific NSSP Guide Reference:	Section IV Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests, Table 4 - Marine Biotoxin Test Methods
Text of Proposal/ Requested Action	We request review of the validation study submission for the Reveal ASP (domoic acid) test kit and consideration of the method for approval as a Type IV marine biotoxin screening method for qualitative determination of domoic acid in shellfish. Add Reveal ASP (domoic acid) test to list of approved Type III and Type IV marine biotoxin methods.
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. 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.
Cost Information (if available):	Approximately $17.00 per test.
Action by 2011 LMRC	Recommended Proposal 11-107 be referred to the appropriate committee as determined by the Conference Chairman and further recommends the following guidance on the data needed from the submitter: • Analysis of samples with naturally incurred residues over a range of toxin concentrations. • Evaluate extraction recovery by comparison with HPLC. • Additional replicates of spiked samples of shellfish species. Eliminate theoretical data regarding dose response curve.
Action by 2011 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendations on Proposal 11-107.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 11-107.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-107.
Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended no action on Proposal 11-107. Rationale: This proposal is resolved by action on Proposal 13-112.
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 11-107
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 11-107.

Action by FDA
May 5, 2014

Concurred with Conference action on Proposal 11-107.