

Proposal Subject:	Saxitoxin (PSP) ELISA Kit
Specific NSSP Guide Reference:	Section IV. Guidance Documents, Chapter II Growing Areas, .11 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods Section II. Model Ordinance Chapter III. Laboratory @.02 Methods C. Biotoxin
Text of Proposal/ Requested Action	See attached ISSC Method Application Faster, easier, and/or more reliable methods are needed to satisfy the needs of the regulatory community and shellfish industry. The proposed ELISA method is a fast and easy to perform method with ready to use reagents i.e. analyst only needs to extract shellfish sample or dilute water sample before analysis. The proposed ELISA also provides a quantitative and/or semi-quantitative screening for shellfish extracts and/or water samples. This assay is part of Abraxis platform for marine toxin testing and complements the company's other offering for NSP, DSP, and ASP testing. The proposed ELISA can be used on-site (boat, dock) or established analytical laboratories.
Public Health Significance:	
Cost Information (if available):	As low as \$15 per sample.
Action by 2009 LMRC	Recommended no action on Proposal 09-107. Rationale: Insufficient data.
Action by 2009 Task Force I	Recommends adoption of Laboratory Methods Review Committee recommendation on Proposal 09-107.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 09-107 with the following comments and recommendations for ISSC consideration. The Laboratory Methods Review Committee determined that Proposal 09-107 was accompanied by insufficient data necessary for the Committee to make a determination regarding the efficacy of the proposed Saxitoxin test method for use under the NSSP. As a result the General Assembly voted "No Action" on the proposed analytical method. It has been FDA's observation and experience that the proposed ELISA method for Saxitoxins presents itself as a reliable screening method to supplement existing NSSP tools for managing Paralytic Shellfish Poisoning (PSP). Therefore, FDA recommends the Conference pursue submission of additional data from Abraxis, LLC via the Proposal submission process to advance a thorough examination of this method for Saxitoxin screening.
Action by ISSC Executive Board March 2010	The Executive Office will send a letter to the submitter of Proposal 09-107 to resubmit Proposal 09-107 Saxitoxin (PSP) Elisa Kit with additional information.
Action by 2011 Task Force I	Recommended adoption of Proposal 09-107 as an emerging method.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 09-107.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 09-107.

Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended no action on Proposal 09-107. Rationale - Action by the committee was not necessary. Requested additional action on this proposal was addressed by Proposal 13-109
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 09-107
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 09-107.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 09-107.