

Proposal Subject:	Male-specific Coliphage Method for Quahogs (<i>M. mercenaria</i>)
Specific NSSP Guide Reference:	NSSP Guide Section IV Guidance Documents Chapter II Growing Areas .11 Approved Limited Use Methods for Microbiological Testing
Text of Proposal/ Requested Action	<p>This submission presents the ‘Male-specific Coliphage method for Quahogs (<i>M. mercenaria</i>)’ for consideration as an approved limited use method for microbiological testing. At the 2009 ISSC, the ‘Modified Double Agar Overlay Method for Determining Male-specific Coliphage in Soft-shelled Clams and American Oysters’ was accepted as an approved limited use method for microbiological testing for re-opening growing areas after emergency closures due to sewage spills. SLV work with quahogs has demonstrated comparable performance characteristics as with soft-shelled clams and American oysters.</p> <p>The requested action is to include quahogs in the footnote for MSC along with soft-shelled clams and American oysters in NSSP Guide Section IV Guidance Documents Chapter II Growing Areas .11 Approved Limited Use Methods for Microbiological Testing.</p>
Public Health Significance:	<p>The MSC method for quahogs was used recently by the State of New Jersey to re-open growing areas after the devastating effects of Superstorm Sandy. Increasingly, enumeration of male-specific coliphage (MSC) in soft-shelled clams, American oysters, and quahogs is needed in the NSSP to assess <i>viral</i> contamination in molluscan shellfish harvested from growing areas where fecal coliform levels in both water quality and shellfish meats may be misleading. MSC is a specialized indicator of <i>viral</i> sewage contamination, which is substantially more meaningful than fecal coliform or <i>E. coli</i> in evaluating the safety of shellstock harvested from growing areas potentially impacted by treated and partially treated wastewater.</p>
Cost Information (if available):	<p>This method for the enumeration of male-specific coliphage in soft-shelled clams, American oysters, and quahogs is inexpensive, easy to perform, and rapid, providing results within 24 hours. The cost of laboratory glassware, plastic-ware, agars, and reagents is approximately \$25 per shellfish sample. In a well-equipped laboratory, the method requires 6 hours of time from initiating host to pouring plates. Hands on technician time to perform this test is significantly less on the order of 1-4 hours per test depending upon how many tests are done per day. The most expensive piece of equipment is a refrigerated centrifuge plus rotor, which costs approximately \$12,000. There are no special skill sets required beyond those required to operate a state-approved shellfish laboratory under the NSSP.</p>
Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended adoption of this method for use in detecting MSC in hard clams and direct the Executive Office to amend the table at Section IV. Chapter 2 @ .11 to add Quahogs to footnote #1
Action by 2013 Task Force I	Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-120.
Action by 2013 General Assembly	Adopted recommendation of Task Force I on Proposal 11-320.

**Action by FDA
May 5, 2014**

Concurred with Conference action on Proposal 13-120.