

**VALIDATION CRITERIA**

**Specificity** is the ability of a qualitative method to accurately determine the presence of the analyte/measurand/organism of interest in the sample. For qualitative methods the specificity of the method can be divided into four (4) zones, zone 1 where the response of the method is always negative; zones 2 and 3 where the response of the method consists of false positive (zone 2) and negative (zone 3) results; and zone 4 where the response of the method is always positive. To determine the specificity of the qualitative method as implemented, zones 1, 2, 3 and 4 are determined.

**Procedure:** This procedure is applicable for use with either growing waters or shellfish tissue. For each shellfish type of interest use a minimum of 10 – 12 animals. For each sample take ten (10) aliquots of either the growing water sample or shellfish homogenate appropriately sized for the work. Spike all ten (10) aliquots of each sample with the same concentration of the target analyte/measurand/organism of interest. Process all ten (10) aliquots for each sample as usual to determine whether the test response is positive or negative. Use a minimum of five (5) concentrations which span the range of the method's intended application to spike the samples. If spatial or geographic influences on method performance are suspected, follow the procedure above for all samples suspected of being so influenced.

**Data:**

Sample type _____		
Concentration	Positive/Negative results	Percent positive
1		
2		
3		
4		
5		
*n		

\*n is the last concentration tested

**Repeat for each shellfish tissue type of interest and/or samples suspected of being affected by spatial or geographic influences.**

**DATA HANDLING****Specificity**

To determine the specificity of the qualitative method, plot the response curve with percent positive results versus concentration. Calculate the concentration of target analyte/measurand/organism of interest at 5, 50 and 95% positive results. Concentrations of analyte/measurand/organism of interest which give positive results less than 5% of the time constitute zone 1 where the response of the method is always negative. Concentrations of analyte/measurand/organism of interest which give positive results between 5 and 50% of the time constitute zone 2 where the method results in false positives. The concentration of target analyte/measurand/organism of interest which gives positive results between 50 and 95% of the time constitute zone 3 where the method results in false negatives. Concentrations of target analyte/measurand /organism of interest which give positive results more than 95% of the time constitute zone 4 where the method results are always positive.

**Data Summary:**

Concentration of target analyte/measurand/organism of interest below which the results are always negative (zone 1)  
< \_\_\_\_\_

Range in concentration of target analyte/measurand/organism of interest where false positive results occur (zone 2)  
\_\_\_\_\_

Range in concentrations of target analyte/measurand/organism of interest where false negative results occur (zone 3)  
\_\_\_\_\_

Concentration of target analyte/measurand/organism of interest above which test results are always positive (zone 4)  
> \_\_\_\_\_