

VALIDATION CRITERIA

Ruggedness is the ability of a particular method to withstand relatively minor changes in analytical technique, reagents or environmental factors likely to arise in different test environments.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissue. Make every effort to use samples free of the target organism of interest. For each shellfish type of interest use a minimum of 10 – 12 animals. For each sample take two (2) aliquots of either the growing water sample or shellfish homogenate appropriately sized for your work. Spike both aliquots with a suitable concentration of the target organism of interest. Process both aliquots of the sample as usual to determine the method MPN. For the second aliquot of each sample, however, use a different batch or lot of culture media or test reagents as appropriate to process this aliquot. For growing waters, do ten (10) samples collected from a variety of growing waters. For shellfish do ten (10) samples for each shellfish tissue type of interest collected from a variety of growing areas, the same growing area harvested on different days or from different process lots. Use the same two batches or lots of culture media or test reagents as appropriate to process each sample such that “batch or lot 1” is used to process the first aliquot of each sample and “batch or lot 2” is used to process the second aliquot of each sample. Use a range of concentrations which spans the range of the method’s intended application to spike the sample aliquots. However both aliquots of the same sample must be spiked with the same concentration of the target organism. Process samples over a period of several days.

Data:

Sample type _____		
Sample	MPN “Batch or Lot 1”	MPN “Batch or Lot 2”
	Media or Reagents	Media or Reagents
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

For shellfish samples, repeat for each tissue type of interest.

DATA HANDLING

Ruggedness

In the day to day operations of the laboratory there will be changes in the batches/lots of culture media and/or test reagents used to process samples. Environmental factors are also likely to change over time. None of these factors, however, should adversely impact test results if the method as implemented is sufficiently rugged to be used routinely for regulatory monitoring.

Procedure: To determine whether the method as implemented is sufficiently rugged to withstand the types of changes anticipated to occur in routine use, a two-sided t-test at a significance level (α) of .05 will be used on the log transformed data to ascertain if results obtained using different culture media or test reagent batches/lots under slightly varying environmental conditions are significantly affected by such minor changes.

Data Summary:

Is there a significant difference between batch/lot 1 samples and batch/lot 2 samples Y/N