

COMPLETION NOTICE

SA ¶4(i) Evaluate the suitability of individual combinations of indicators and methods for different CWA programs (P18)

Summary of the Study

This study was conducted to evaluate the strengths and weaknesses of both rapid and culture indicator/method combinations to method performance criteria and their appropriateness for different Clean Water Act programs. EPA identified and prioritized key concerns related to indicator/method performance and identified eight performance criteria: (1) limit of detection; (2) sensitivity; (3) specificity; (4) precision; (5) percent false positives and false negatives; (6) ability to differentiate fecal sources; (7) performance in different waterbody types; and (8) indicator/illness health relationship established. The indicator/methods evaluated were methods that showed a correlation to health in the freshwater and/or marine water epidemiological studies conducted by EPA under the National Epidemiological and Environmental Assessment of Recreational (NEEAR) Water Study or used to support the development of the 1986 ambient water quality criteria. Four methods (*Enterococcus* quantitative polymerase chain reaction (qPCR), *Bacteroidales* qPCR, EPA Method 1600 and EPA Method 1603) were quantitatively evaluated with respect to the performance criteria. EPA evaluated the performance criteria based on published literature for the various indicator/method combinations.

Additionally, qPCR and culture methods were evaluated qualitatively with respect to several method attributes/considerations for implementation purposes, and how well each method works for each Clean Water Act program. QPCR methods were evaluated relative to culture methods on the following evaluation criteria that were important to the CWA programs: (1) ease of use, (2) low cost, (3) time to results, (4) allowance for use of historical data for model development, (5) ability to demonstrate effectiveness of treatment from source to beach, (6) count/signal associated with human health risk pathogens, and (7) precision/accuracy.

Summary of Findings

The quantitative evaluation of performance criteria revealed:

	<i>Enterococcus</i> 23S qPCR (diluted crude extract)	<i>Bacteroidales</i> 16S qPCR (diluted crude extract)	Method 1600	Method 1603
50% Limit of detection in CCE[CSE]	65 [904]	99 [1,380]	Not reported	Not reported
False positives	0%,19%	0%	6%	6%
False negatives	1.1-4.5%, 2%	1.1-4.5%, 2%	6.5%	5%
Specificity	100%	100%	Not reported	Not reported

- A new or revised wastewater test method may not be necessary because existing culture methods approved for wastewater may be sufficient.
- The qualitative evaluation of the culture and QPCR methods indicates that a rapid method is important only for Beach Program monitoring and notification.

This study has been completed as of December 15, 2010.