# Coast to Coast PCR Technologies: California and New Jersey's State Perspectives

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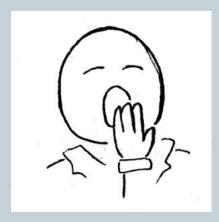




# **Molecular Testing**







Molecular testing methods are widely used and accepted





## qPCR for Recreational Water Monitoring

qPCR detection of enterococcus





# Legislative Changes

Senate Bill 1395 (Passed September 2014)

"Authorize the department (CDPH) to allow a local health officer to use specified polymerase chain reaction testing methods published by the United States Environmental Protection Agency or approved as an alternative test procedure pursuant to federal law to determine the level of enterococci bacteria as a single test based on a single indicator at one or more beach locations"

July 2015 CDPH project funded to support Senate Bill 1395 mandate





# Regulatory Changes

- All methods approved for drinking water testing requires a National approval process.
- States need the US EPA to approve methods for molecular testing in order to be able to offer drinking water certification for any federally required testing.
- States can develop method approvals nondrinking water testing unless the state regulations prohibit such changes.





## qPCR for Recreational Water Monitoring

#### Over a decade of performance analysis

Multiple published methods

#### **US EPA Methods**

**1609.1** Enterococci in Water by TaqMan® Quantitative Polymerase Chain Reaction (qPCR) with Internal Amplification Control (IAC) Assay (April 2015)

**1611.1** Enterococci in Water by TaqMan® Quantitative Polymerase Chain Reaction (qPCR) (April 2015)





## qPCR for Recreational Water Monitoring

#### Over a decade of performance analysis

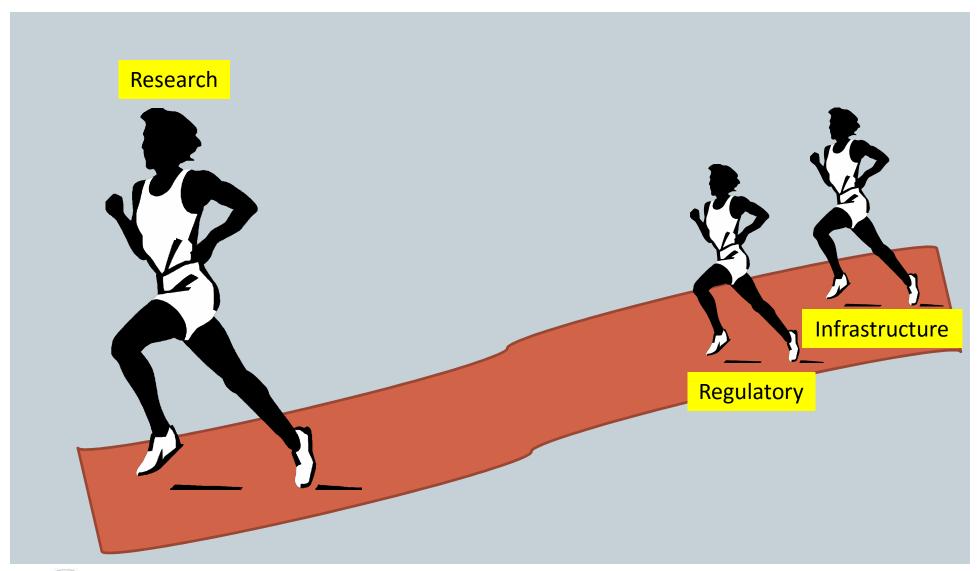
- Multiple published methods
- Numerous sites evaluated
- Training provided



Are we ready to use qPCR yet?











### Regulatory Needs: California and New Jersey

- Molecular water quality standards
  - Numeric standards

California and New Jersey Single Sample Standard

"104 enterococcus bacteria per 100 milliliters"

Culture-based metrics: CFU and MPN

Molecular-based metrics





### Regulatory Needs: California and New Jersey

- Molecular water quality standards
  - Numeric standards
  - Standardized calculation





### Regulatory Needs: California and New Jersey

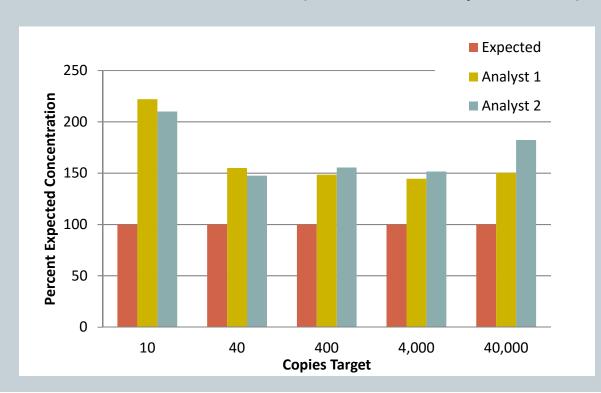
- Laboratory certification
  - Lab setup
  - Training
  - Documentation
  - Performance standards





## Infrastructure Needs

- Standardized reagents
  - DNA standards (2 8,000 copies / uL)



2 copies / uL  $\approx$  1.8 fg /uL





### Infrastructure Needs

- Standardized reagents
  - DNA standards
  - Bacterial standards
- Competency assessment
  - Training
  - On going performance





# Steps Being Taken in California

- Guidance material
  - EPA method companion
  - Bench sheets
  - Checklists
  - Documentation guides
  - Site performance criteria
  - Developing expertise

#### Remove Variables

"suggest"
"encourage"
"recommended"





# Steps Being Taken in New Jersey

- Method Comparison Study
- OQA continues to develop and provide guidance on the development of qPCR at the laboratories
- Draft development of method checklists for the approved methods in existence for future use
- Ongoing research for the development of a laboratory certification program for qPCR





# In-house Method Beta Testing

CDPH partnered with East Bay Regional Parks to get water samples for enterococcus testing



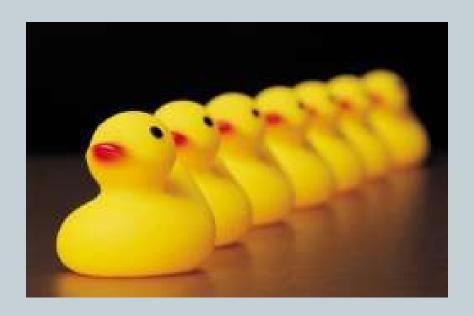
- Year long project
- Compare qPCR to two culture based methods
- Evaluating US EPA method 1609.1 and 1611.1





### Where is California Now

#### Getting our ducks in a row



#### **Getting your ducks in a row**

means to complete one's preparations; to *get* organized so that you are ready for the next step





# New Jersey Projects with qPCR

- Method Comparison Study in Ocean Waters for Enterococci (US EPA Region 2)
- Research in the Barnegat Bay to investigate Jellyfish (Montclair University)
- Monitoring of shellfish tissue for Vibrio for NJ programs (NJDEP Leeds Point Laboratory)





# New Jersey Projects with qPCR

#### **Sea Nettles in Barnegat Bay New Jersey:**

- http://nj.gov/dep/dsr/barnegat/finalreport-year1/
- http://nj.gov/dep/dsr/barnegat/final-reports/sea-nettles-year2.pdf
- <a href="http://nj.gov/dep/dsr/barnegat/final-reports/sea-nettles-year3.pdfsea-nettles-year1.pdf">http://nj.gov/dep/dsr/barnegat/final-reports/sea-nettles-year3.pdfsea-nettles-year1.pdf</a>





# Thank you

Please be involved in the conversation

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