Molecular Assessment Program: MAP

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NBS Molecular Assessment Program (MAP)

What is MAP?
- Invited site visit of molecular biologists from:
  - CDC’s Newborn Screening and Molecular Biology Branch
  - State Public Health screening programs
  - Representatives from APHL

Goal of MAP – To support laboratories
- Provide molecular testing-specific assistance for NBS laboratories implementing molecular testing
- Guidance for laboratories that are expanding NBS molecular testing
What is the Benefit for NBS Programs?

- How to fit molecular testing into a screening program
  - Application needs
  - Available resources

- MAP teams represent a range of molecular NBS experts
  - Provide alternate approaches for molecular screening
  - Best-practices and ideas for what has worked for other programs
  - Help in planning for new molecular screening assays
Why MAP was Developed

- Molecular tests have different quality management requirements
  - DNA amplification and contamination risks
  - Types of positive and negative controls

- Gaps in current regulatory guidelines
  - No CLIA genetic testing specialty – CMS recommends use of general guidelines for high-complexity tests
  - Standard regulatory framework does not allow for complexity involved in molecular testing
  - Inflexible regulations may prevent use of new technologies
Basis for MAP Evaluations

- Assessment criteria modeled from multiple sources:
  - NNSGRC Performance Evaluation Assessment Scheme (PEAS)
  - CLIA regulations
  - Molecular Pathology Checklist (CAP)
  - Standards and Guidelines for Clinical Genetics Laboratories (ACMG)
  - Clinical Laboratory Standards of Practice (NYSDOH)
  - Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions (MMWR)
MAP: Molecular Assessment Program

Phase of Testing

- Pre-Analytical
- Analytic
- Post-Analytical

Components

- SOPs
- QA/QM Documents
- Assay Validation
- Personnel
- Laboratory Space
- Test Methods
- Proficiency Testing
- Test Workflow
- Results Reporting
Development of MAP

- Molecular Network Steering Committee
- Three pilot site visits
  - Wisconsin State Hygiene Laboratory
    - Colleen Stevens (NY) & Tim Davis (WA)
  - Wadsworth Center New York Newborn Screening Program
    - Heather Wood (MI) & Rachel Lee (TX)
  - State of Washington DOH Newborn Screening Laboratories
    - Rachel Lee (TX) & Mei Baker (WI)
MAP Timeline

- **Point of Contact with Laboratory**
- **Recruit Team Members**
- **Request SOPs**
- **Conference Call for Site Logistics**
- **Site Visit**
- **Draft Summary Report**
- **Final Summary Report**

2 Months Prior

2-3 Weeks Prior

2 Weeks Following

4 Weeks Following
Lessons Learned from Pilot Visits

- **Process must be flexible**
  - Every program is unique

- **Molecular-specific QA “Tips and Tricks”**
  - Numerous valid molecular procedures for a given disorder
  - Readily accessible knowledge base for molecular screening is needed

- **CDC and State Cooperation**
  - Provides a “pulse-point” of molecular needs and challenges
  - Opportunities for State-State and Federal-State collaboration
Benefits of MAP

- Continual Quality Improvement process for molecular screening
- Address specific concerns of programs
- Recommendations for additional program support
- Provide opportunities for collaboration between public health NBS programs
How to Participate in MAP

- NBS programs can request MAP visits starting in 2012
- Information for program application available through APHL and CDC’s NSMBB
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.