

One Year Experience for the Newborn Screening Molecular Assessment Program (MAP)

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Quality Improvement Cycle



NBS Molecular Assessment Program (MAP)

- ❑ **Evaluation of molecular newborn screening programs**
 - **Invited site visit of molecular biologists from:**
 - **CDC's Newborn Screening and Molecular Biology Branch**
 - **State Public Health Newborn Screening Programs**
 - **Representatives from Association of Public Health Laboratories**
- ❑ **Support for newborn screening laboratories**
 - **Non-regulatory review of molecular testing activities**
 - **Guidance for expansion of NBS molecular testing**
 - **Provided at no cost to participating programs**

Why MAP was Developed

- ❑ **Gaps in current regulatory guidelines**
 - **No CLIA genetic testing specialty**
 - **Complexity with molecular testing especially using dried blood spots does not fit standard framework**
 - **“Regulatory rigidity” may constrain new technologies**

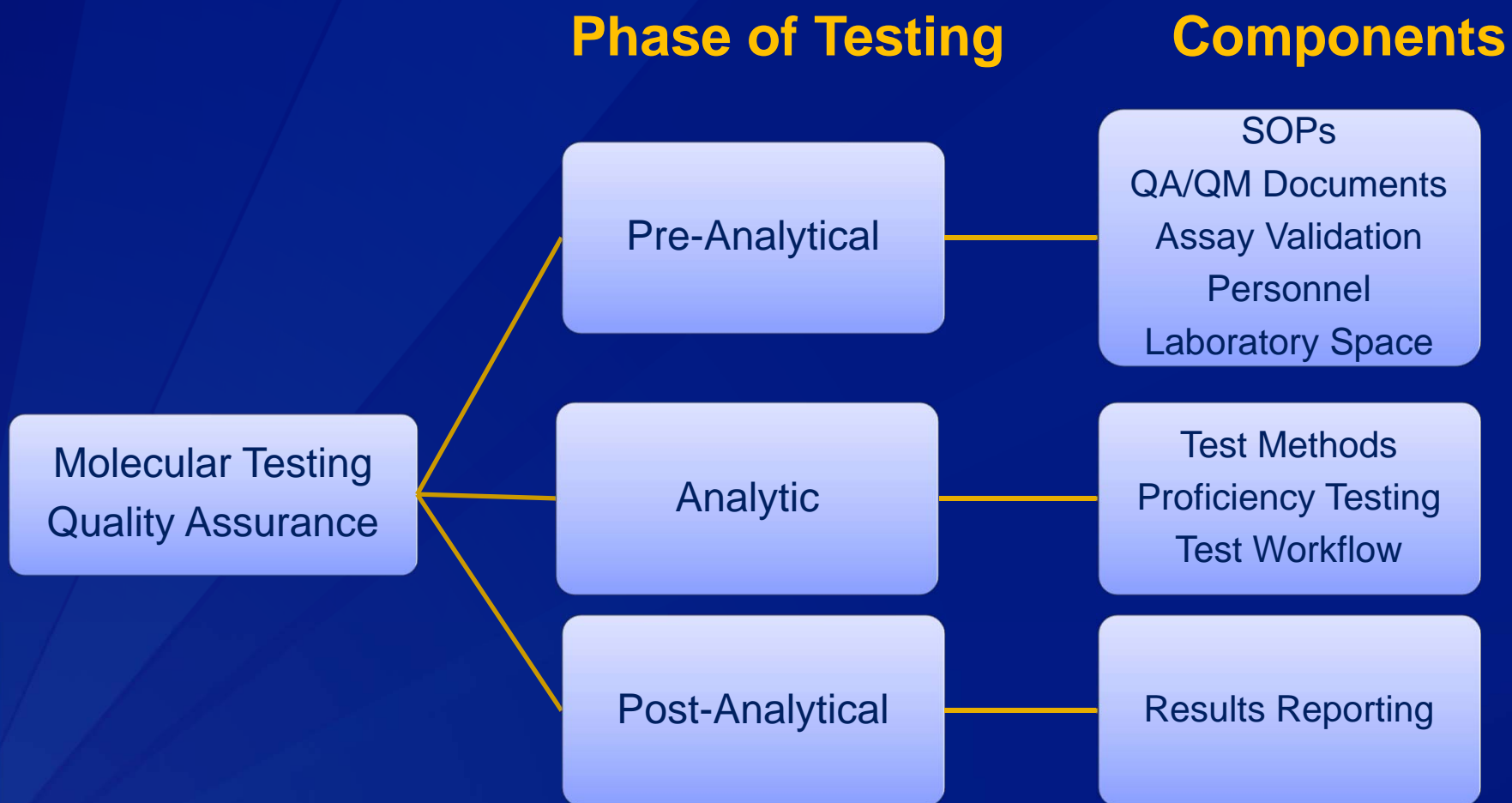
- ❑ **Molecular tests have different quality management requirements**
 - ❑ **Molecular is still relatively new for many programs**
 - ❑ **Hiring of new staff is limited**



Basis for 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)**

Assessment Components



Overview of MAP Site Visits

□ Pre-visit

- Review of written SOP and quality assurance manuals

□ Visit Day 1

- Overview of program and molecular activities
- Assessment of molecular workspace and workflow
- Review of quality assurance, validation documents and molecular reporting

□ Visit Day 2

- Exit discussion with program members

□ Post-visit

- Written report for program's use

MAP Activity

□ 2011 Pilot Site Visits

- Wisconsin
- New York State
- Washington State

□ Program Site Visits

- Michigan - 2012
- Texas - 2012
- Florida - 2013
- Minnesota - 2013
- Virginia - June 2013

□ Program Partners

- APHL
- Wisconsin
- New York State
- Washington State
- Michigan
- Texas

Cited Reasons for Site Visits

- ❑ Overall evaluation of molecular activities
- ❑ Suggestions for improving workflow efficiency
- ❑ Optimizing the utilization of existing workspace(s)
- ❑ Planning for implementing new assays
- ❑ Preparation for inspections

Benefit for NBS Programs

- **Approaches to incorporate molecular into screening programs**

- Application needs
- Available resources



- **MAP teams offer a range of molecular NBS expertise**

- Provide alternate strategies for molecular screening
- Best-practices and ideas for what has worked for other programs

Results from Visits

- ❑ Harmonization of SOPs
- ❑ Definition of molecular QA processes
- ❑ Modification to workflow
- ❑ Opportunities for program collaborations

Future Directions of MAP

- ❑ **Component of NSMBB's continual quality improvement mandate**

- ❑ **Resources for NBS molecular testing community**
 - Molecular screening best practices
 - Examples and templates for APHL molecular screening website

- ❑ **Feedback to CDC**
 - QC materials for molecular testing
 - Training needs for APHL-sponsored molecular workshops

For More Information on MAP

For questions about MAP:
Christopher Greene
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For access to the NBS
Molecular Resources
Website:
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The screenshot displays the APHL website interface. At the top, the APHL logo and name are visible, along with navigation links for Sign In, My APHL, Create an Account, Media Center, and Contact Us. A search bar is located on the right. Below the header, a navigation menu includes ABOUT APHL, CONFERENCES, EDUCATION, MEMBERSHIP, MY CAREER, POLICY, PROGRAMS, and RESOURCE CENTERS. The main content area features a sidebar on the left with a list of categories: Environmental Health, Food Safety, Global Health, Infectious Diseases, Informatics, Laboratory Systems and Standards, Newborn Screening and Genetics (highlighted), Public Health Preparedness and Response, and Research. The 'Newborn Screening and Genetics' category is expanded, showing sub-items like 50th Anniversary of Newborn Screening, Assuring Laboratory Quality, Baby's First Test, Genetic Testing, NBS Molecular Resources (highlighted), and Policy and Positions. The main content area is titled 'Newborn Screening Molecular Resources' and features a large image of newborn screening cards and a hand holding a baby's foot. Below the image, there are links for 'About Us', 'ONSITE LABORATORY VISITS Molecular Assessment Program (MAP)', and 'NBS MOLECULAR METHODS View Laboratory Assays Enter Your Assay'. A 'CONTACT' section on the right identifies JELILI OJODU, MPH as the Director of Newborn Screening and Genetics, with contact information: 240.486.2772 and jelili.ojodu@aphl.org. A 'RELATED CONTENT' section lists 'Newborn Screening Mainpage' and 'CDC - Newborn Screening Quality Assurance Program'. A 'CONFERENCE PROCEEDINGS' section mentions the '2011 Newborn Screening and Genetics Testing Symposium, San Diego, CA'. At the bottom left, there is a small image of a dog with the text 'Your Lab's Best Friend!'.

<http://www.aphl.org/aphlprograms/newborn-screening-and-genetics/molecular/pages/default.aspx>

Benefits of MAP from the States Perspective

- ❑ **“A constructive review of our newborn screening molecular program was invaluable... The objective was simply to help us validate what we were doing well and share the wide ranging experience of the team members to suggest ways we might improve”**
- Mike Glass, WA
- ❑ **“Came away from the interaction with the assurance that we were doing certain things well as well as a list of items to improve on”**
- Kelly TenEyck, MI
- ❑ **“Provided recommendations on the appropriate amount of QC required and advice to overcoming the barriers to acquiring rare QC materials”**
- Rachel Lee, Tx

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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.

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