

Molecular Assessment Program: MAP

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NBS Molecular Assessment Program (MAP)

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

- In-depth review of molecular-based Newborn Screening Assays
 - Peer-based review
 - Non-regulatory!

Why MAP was Developed

- ❑ **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

What Constitutes a High Complexity Test

- ❑ Specialized Knowledge
- ❑ Training and Experience
- ❑ Reagents and Materials Preparation
- ❑ Characteristics of Operational Steps
- ❑ Calibration, Quality Control, and PT Materials
- ❑ Test System Troubleshooting
- ❑ Interpretation and Judgment

Three point scale for each criteria – most molecular 18-21 points

Why MAP was Developed

- ❑ Molecular tests have different quality management requirements
 - DNA extraction
 - PCR amplification common step
 - Cross contamination risks
 - Types of positive and negative controls



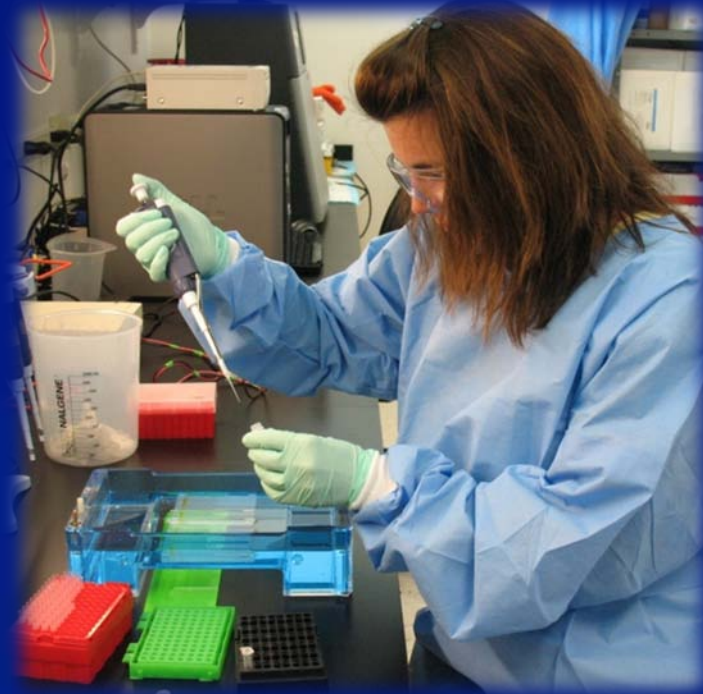
Goals of MAP

□ NBS Laboratory Support

- Provide molecular testing-specific assistance for NBS laboratories implementing molecular testing
- Guidance for laboratories that are expanding NBS molecular testing
- Mechanism to communicate best practices and strategies for continual laboratory assay quality improvement

What is the Benefit for NBS Programs?

- ❑ Consider how to fit molecular testing into a screening program
- ❑ Balanced approach:
 - Application needs
 - Available resources



What is the Benefit for NBS Programs?

- ❑ 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



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)

Professional Guidelines

- ❑ American College of Medical Genetics (ACMG)
 - ❑ Standards and Guidelines for Clinical Genetics Laboratories
 - General Standards and Guidelines
 - Clinical Biochemical Genetics
 - Clinical Molecular Genetics
 - ❑ Disease/Phenotypic-Specific Standards and Guidelines

www.acmg.net – publications



Professional Guidelines

- ❑ **Clinical and Laboratory Standards Institute (CLSI)**
 - ❑ MM01-A2: Molecular Diagnostic Methods for Genetic Diseases
 - ❑ MM13-A: Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods
 - ❑ MM14-A: Proficiency Testing (External Quality Assessment) for Molecular Methods
 - ❑ MM17-A: Verification and Validation of Multiplex Nucleic Acid Assays
 - ❑ MM19-P: Establishing Molecular Testing in Clinical Laboratory Environments



Professional Guidelines

■ College of American Pathologists



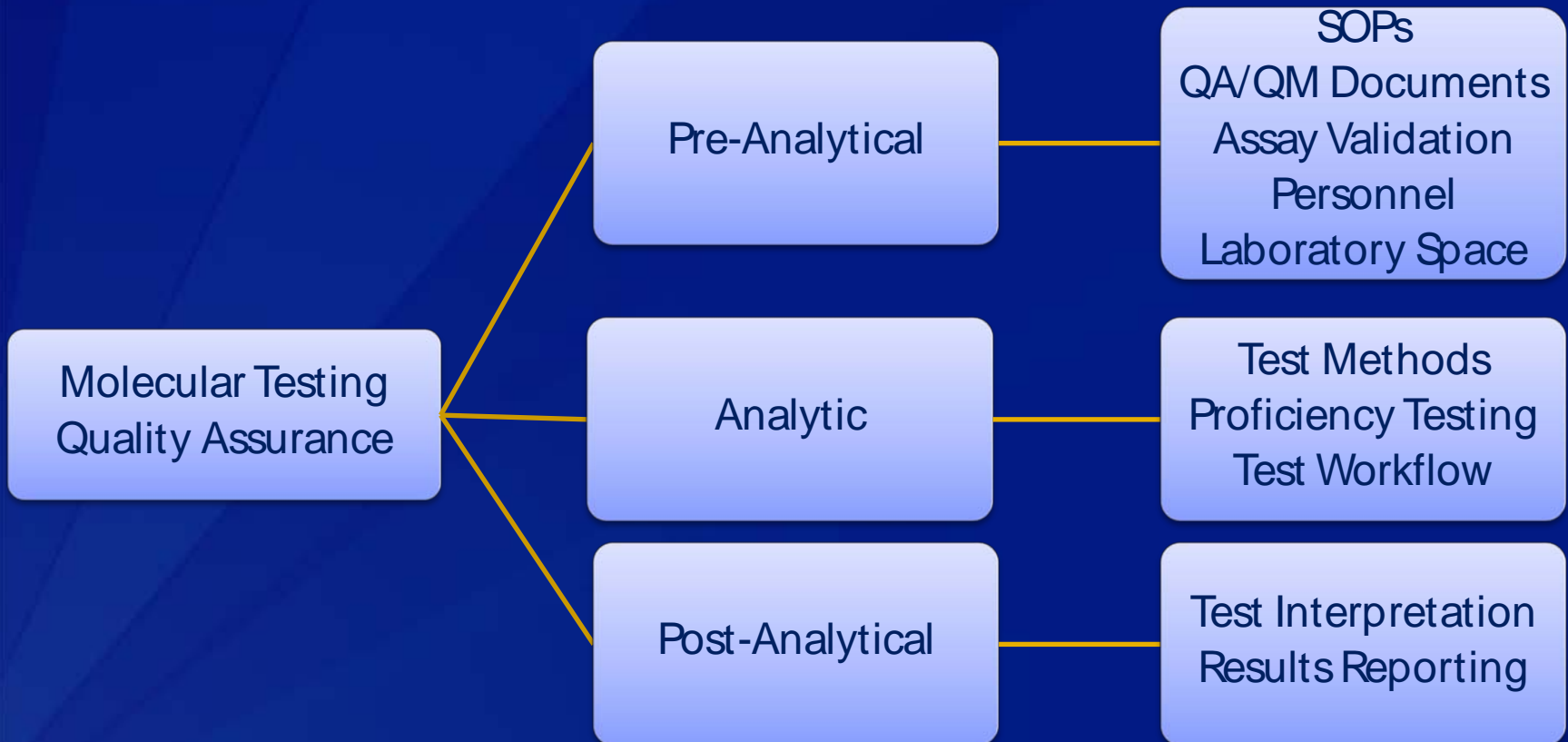
- Molecular Pathology Accreditation Checklist
- CAP Learning Portal
- Archived webinars and presentations



MAP: Molecular Assessment Program

Phase of Testing

Components



MAP Timeline



MAP Site Visit Agenda

- ❑ **Two – Three Weeks Prior to Site Visit**
 - Discuss what is the goal for the site visit
 - Molecular assay SOPs for review
 - Quality Assurance/Management (QA/QM) documents for review

- ❑ **Day Prior to Site Visit**
 - Team discusses SOPs and documents to prepare for site visit
 - Dinner with hosting laboratory program

MAP Site Visit Agenda

□ Day 1: Morning

- Meet with laboratory members for review of NBS program and current molecular testing activities and future molecular plans
- Program expectations for site visit
- Laboratory observation of molecular procedures

□ Day 1: Afternoon

- SOPs
- Laboratory and molecular-specific QA/QM plans
- Assay validation
- Molecular assay results reports

MAP Site Visit Agenda

□ Day 2: Morning

- Exit discussion with laboratory members
- Observations and recommendations
- Feedback to MAP team



Exit discussions usually finish before noon

Additional time can be allocated for specific topics

MAP Site Visits

- ❑ **Wisconsin State Hygiene Laboratory**
 - July 2011 – NY and WA
- ❑ **Wadsworth Center New York Newborn Screening Program**
 - August 2011- MI and TX
- ❑ **State of Washington DOH Newborn Screening Laboratories**
 - September 2011 – TX and WI
- ❑ **Michigan Department of Community Health, Bureau of Laboratories – (Joint MAP and SCID)**
 - February 2012 – TX and WA

Lessons Learned from MAP 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



Program Testimonials

The opportunity for a constructive review of our newborn screening program was invaluable...The objective was simply to help us validate what we were doing well and to suggest ways we might improve.

- Mike Glass, WA



We came away from the interaction with the assurance that we were doing certain things well as well as things to improve on. This type of friendly inspection will without doubt better prepare us for future inspections by our regulatory agency.

- Heather Wood, MI

How to Participate in MAP

- ❑ Information for program application available through APHL and CDC's NSMBB
- ❑ MAP visits can be scheduled late 2012 and onward



State Partners

NBS Molecular Network Steering Committee

MAP Host Programs

Gary Hoffman (WI)

Mei Baker (WI)

Michele Caganna (NY)

Carlos A. Saavedra-Matiz (NY)

Michael Glass (WA)

Tim Davis (WA)

Kevin Cavanaugh (MI)

APHL

Elizabeth Jones

Jelili Ojodu

MAP Site-Visit Teams

Heather Wood (MI)

Colleen Stevens (NY)

Rachel Lee (TX)

Tim Davis (WA)

Mei Baker (WI)

CDC

Christopher Greene

Suzanne Cordovado

Stanimila Nikolova

Carla Cuthbert