

# Molecular Assessment Program: MAP

**Christopher N. Greene, PhD**  
**Newborn Screening and Molecular Biology Branch,**  
**Division of Laboratory Sciences**  
**NCEH, CDC**

Wednesday, November 9<sup>th</sup>, 2011

# **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**

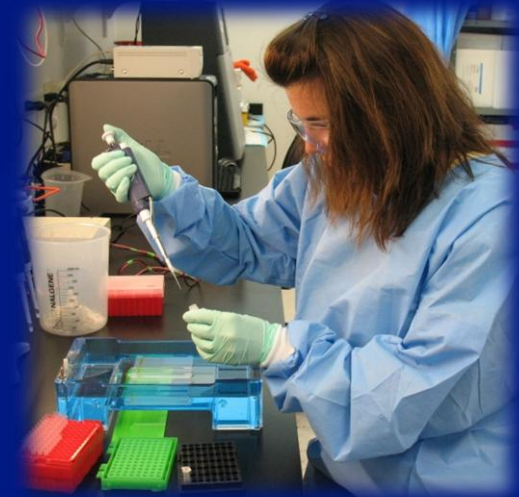
## **□ Goal of MAP – To support laboratories**

- **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



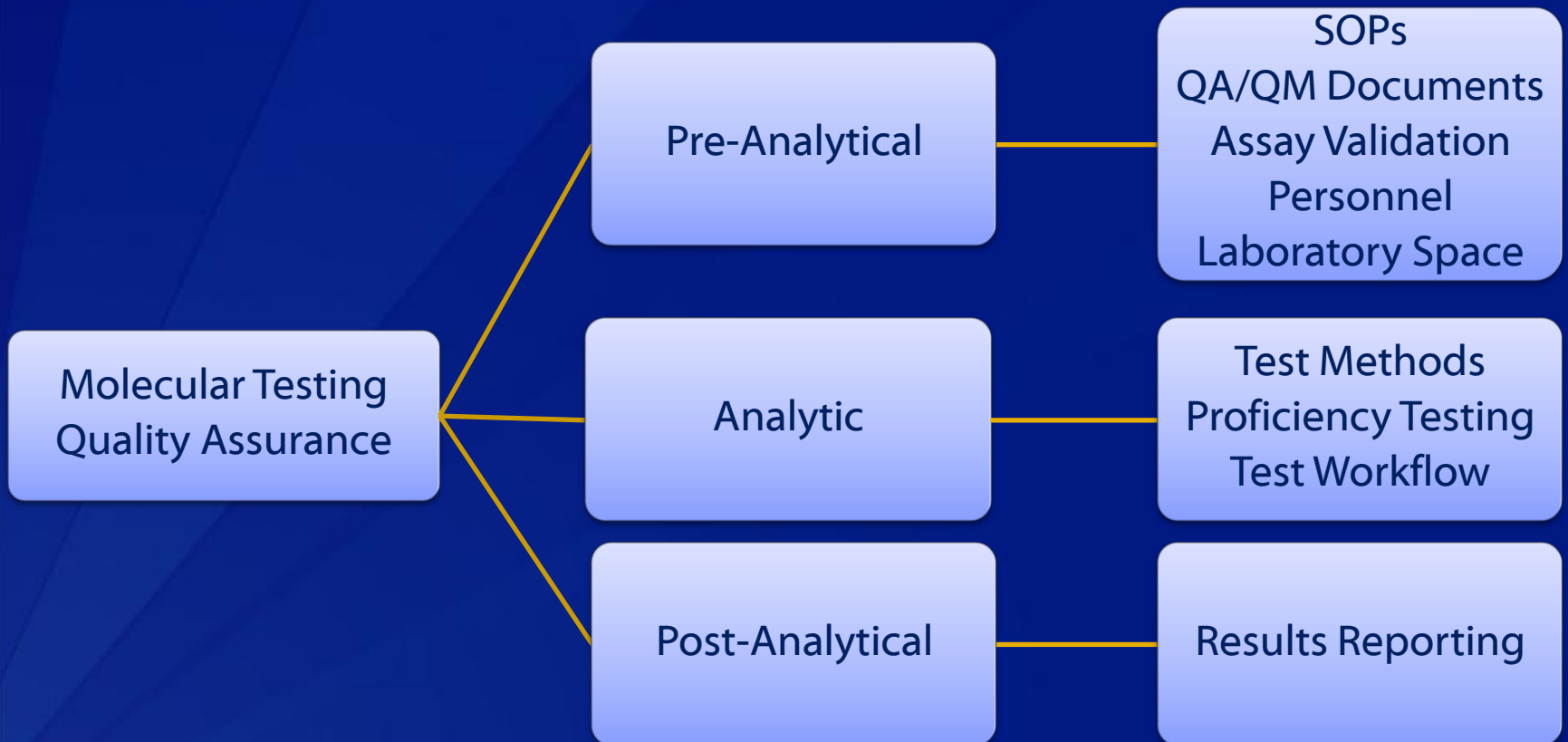
# Basis for MAP Evaluations

- ❑ **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

## Components



# Development of MAP

- ❑ **Molecular Network Steering Committee**

- ❑ **Three pilot site visits**

- **Wisconsin State Hygiene Laboratory**

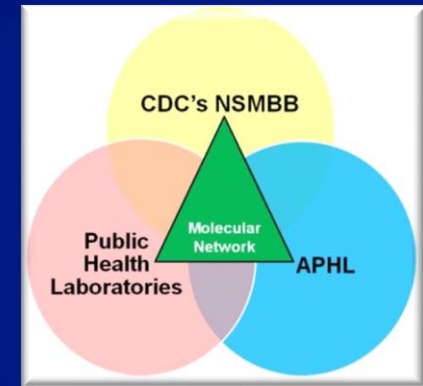
- Colleen Stevens (NY) & Tim Davis (WA)

- **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





# 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



## **State Partners**

**NBS Molecular Network Steering Committee**

**MAP Pilot Host Programs**

**Gary Hoffman (WI)**

**Mei Baker (WI)**

**Michele Caganna (NY)**

**Carlos A. Saavedra-Matiz (NY)**

**Michael Glass (WA)**

**Tim Davis (WA)**

## **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**

# Speaker Contact Information

MQIP	Suzanne Cordovado	SCordovado@cdc.gov
Website	Laura Hancock	LHancock@cdc.gov
MAP	Christopher Greene	CGreene@cdc.gov

**For more information please contact Centers for Disease Control and Prevention**

1600 Clifton Road NE, Atlanta, GA 30333  
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348  
E-mail: [cdcinfo@cdc.gov](mailto:cdcinfo@cdc.gov) Web: [www.cdc.gov](http://www.cdc.gov)

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.

