Newborn Screening Molecular Resources: NBS Molecular Network and CDC's Molecular Quality Improvement Program

Suzanne Cordovado, Ph.D.

Team Lead, Molecular Quality Improvement Program

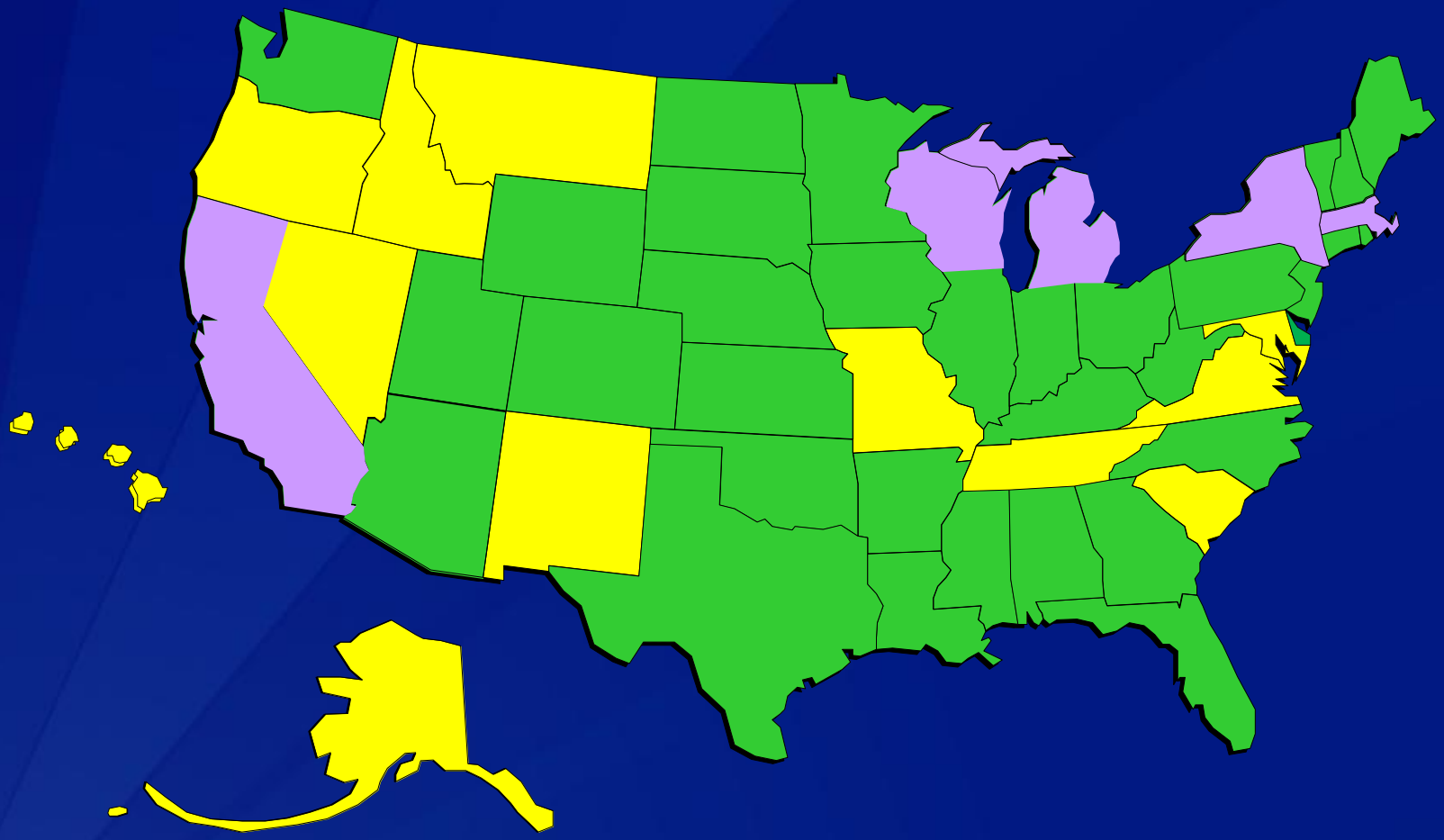
Newborn Screening and Molecular Biology Branch,

Division of Laboratory Sciences

NCEH, CDC

9th November 2011

NBS Molecular Testing Status



39 programs offer a secondary molecular test (86% of babies born/year)

5 states offer a primary molecular test (25% of babies born/year)

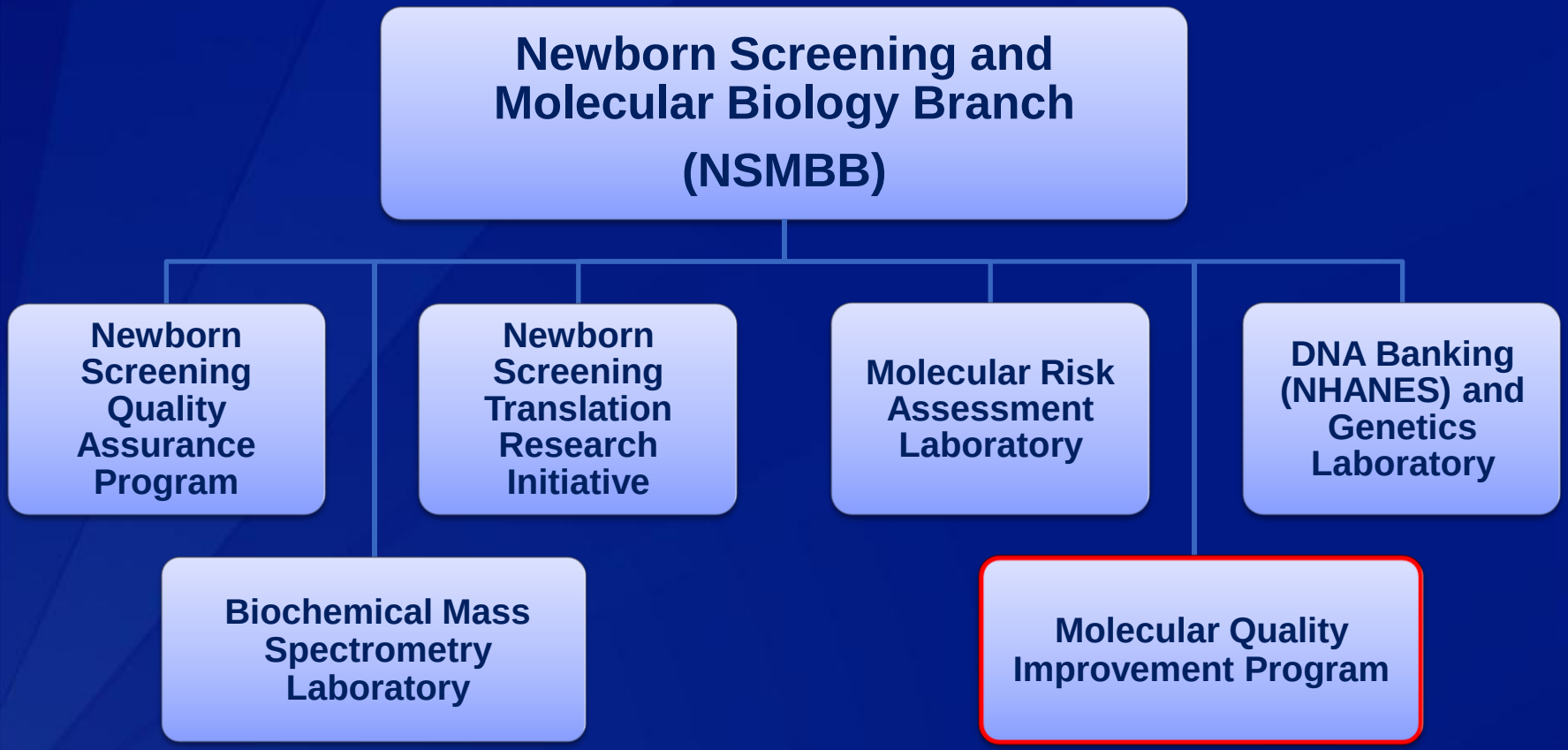
Mandate from Congress: Provide Quality Assurance Materials for NBS Laboratories

NSMBB shall provide for:

- Quality assurance activities for laboratories involved in screening newborns and children for heritable disorders
- Appropriate quality control and other performance test materials to evaluate the performance of new screening tools

Newborn Screening Saves Lives Act of 2008

CDC's Newborn Screening and Molecular Biology Branch: Team Organization



Molecular Quality Improvement Program

Mission:
Work with public health laboratories to detect newborn disorders with molecular methods, and provide a public health forum to exchange molecular practices, quality improvements and educational resources to enhance laboratory performance.

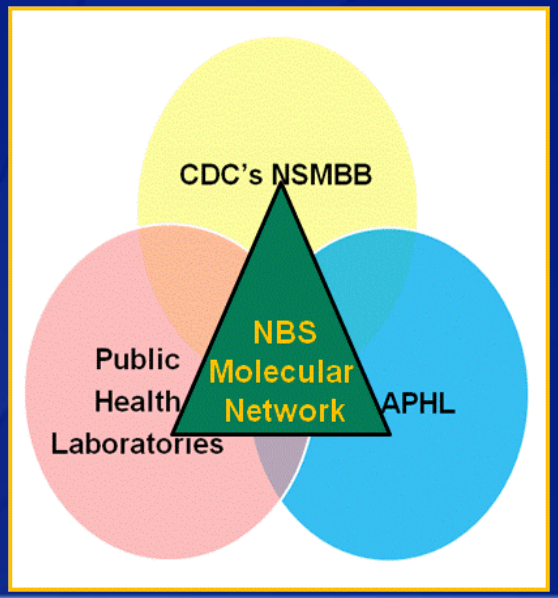
- **Second tier and primary molecular methods are now being used by a number of newborn screening laboratories**
- **Molecular screening brings new and different technologies into the NBS laboratory creating a need for newborn screening laboratory resources**
  - **NBS Molecular Network and Steering Committee**

NBS Molecular Network

Public health partners working synergistically to enhance newborn screening with molecular tests

Steering Committee Members:

Mei Baker	Mike Glass
Stan Berberich	Rachel Lee
Michele Caggana	Fred Lorey
Kevin Cavanagh	Mark McCann



- **Goal 1:** Plan strategies to enhance communication, education and dissemination of molecular laboratory practices and resources
- **Goal 2:** Define collaborative projects to fill gaps in molecular NBS
- **Goal 3:** Prioritize newborn screening disorders for which a molecular test could enhance the primary test's sensitivity or specificity

Activities and Priorities for 2011

- Creation of a NBS molecular laboratory resource website
- Implementation of NBS Molecular Assessment Program (MAP)
- Quality assurance research to identify and develop molecular methods for the DBS matrix
  - Performance Evaluation of DBS DNA Extraction Methods in PCR Based Newborn Screening Assays

Activities and Priorities for 2011 cont.

- Laboratory created QC materials for CF NBS testing
- Molecular characterization of quality assurance materials (e.g. cystic fibrosis and hemoglobinopathies)
- Development of molecular test for CAH
- Education/Training: CDC and APHL sponsored Molecular Training Workshop
  - June 28th–30th in Atlanta, GA at the CDC laboratory

Molecular Quality Improvement Program Team Members

Suzanne Cordovado	**Team Lead**	**SCordovado@cdc.gov**
Christopher Greene	**MAP Coordinator**	**CGreene@cdc.gov**
Laura Hancock	**Research Specialist**	**LHancock@cdc.gov**
Miyono Hendrix	**Research Specialist**	**MHendrix@cdc.gov**
Stanimila Nikolova	**Research Specialist**	**SNikolova@cdc.gov**
Daniel Turner	**ORISE Fellow**	**DTurner@cdc.gov**
Carla Cuthbert	**NSMBB Branch Chief**	**CCuthbert@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 Web: www.cdc.gov