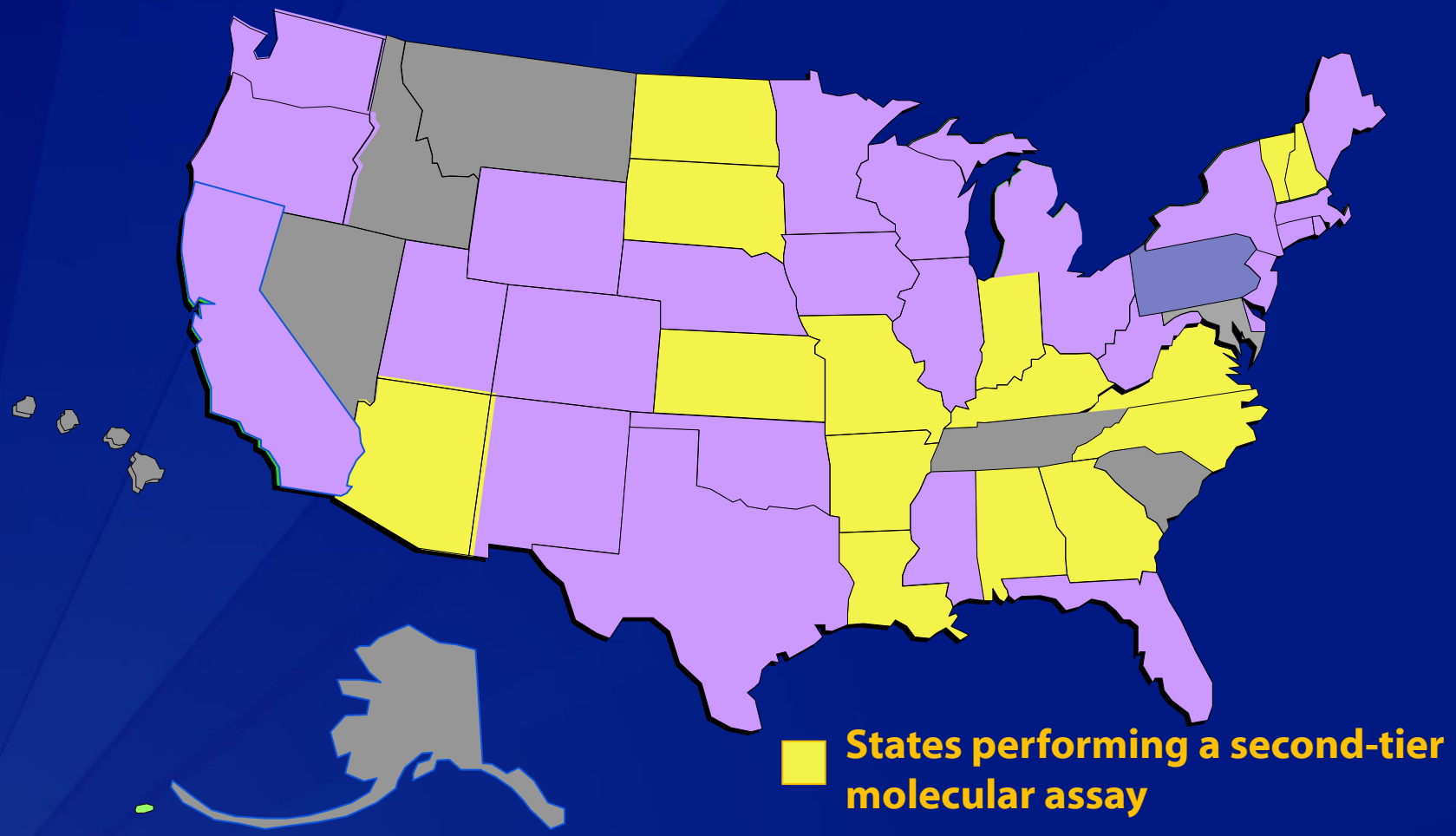
NBS Molecular Resources Website

2015 NBS Molecular Training Workshop

Laura Hancock, M.S.
Molecular Quality Improvement Program
Newborn Screening and Molecular Biology Branch,
Division of Laboratory Sciences
NCEH, CDC

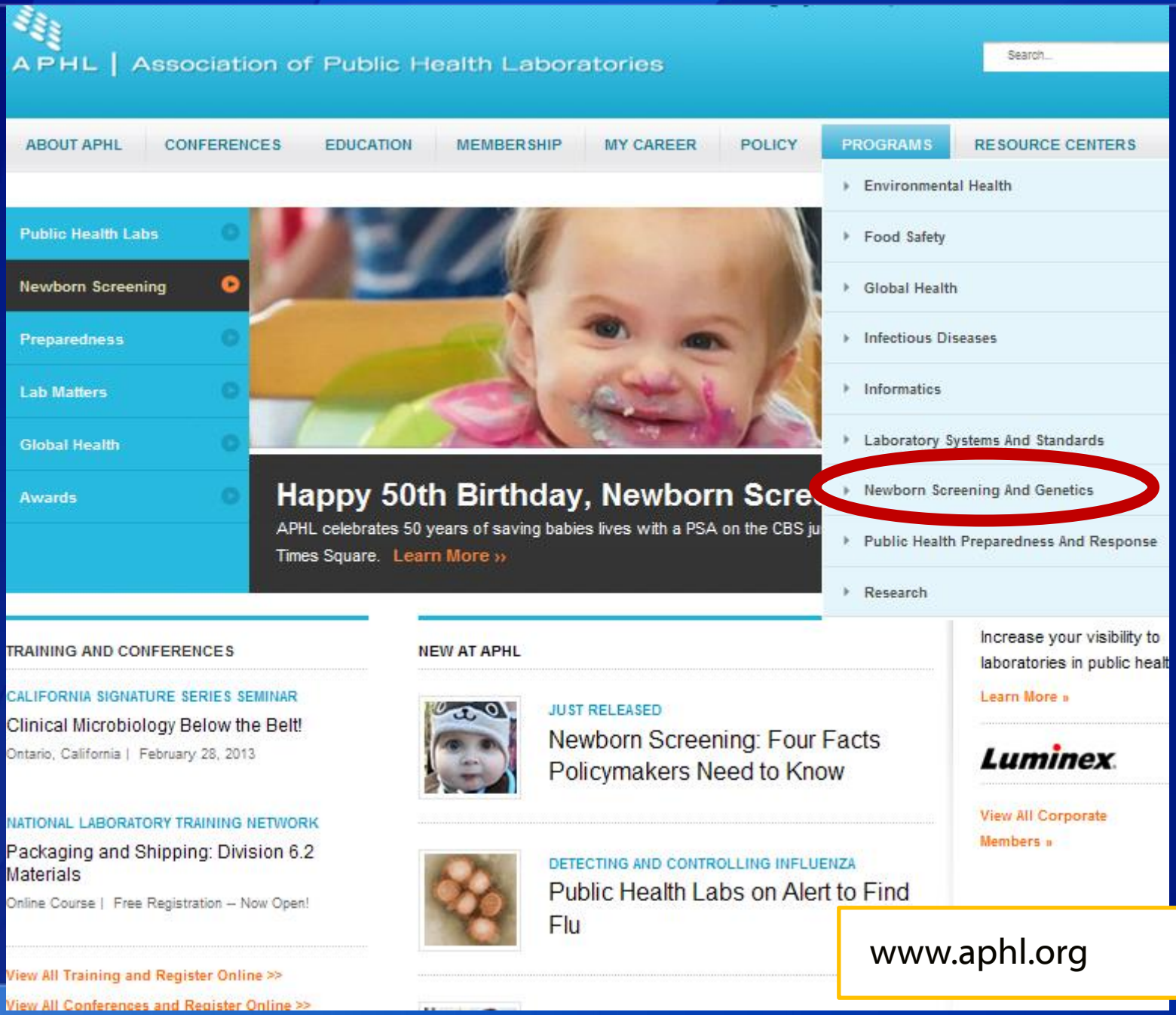
National Center for Environmental Health
Centers for Disease Control and Prevention

State of Molecular Screening in 2015



NBS Molecular Resources Website Resources Available

- Find liquid handling options by viewing detailed summaries of instruments used by other NBS programs
- Research Molecular Assays by reviewing detailed summaries of assays used by other NBS programs
- Access the Molecular Assessment Program (MAP) site visit checklist and request a MAP visit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- Public Health Preparedness and Response

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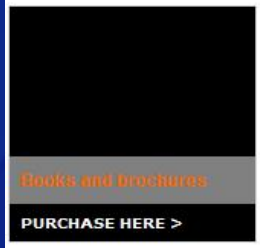

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CONTACT

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Director of Newborn Screening and Genetics
240.485.2772
jelili.ojodu@aphl.org

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Buy Books, Brochures

Buy Shirts

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Newborn Screening and Genetics

Resources

Content for newborn screening laboratory staff, parents and providers

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Quality Improvement for Newborn Screening Laboratorians

HEALTHCARE PROVIDERS

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Items for Parents and Families

CONTACT

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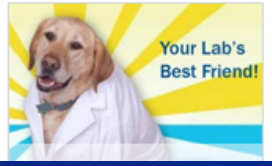

Newborn Screening and Genetics

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AUTOMATION METHODS

Find the Liquid Handling Instrument that Fits Your Needs:

Liquid Handling Options

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Questions to Ask When Purchasing a Liquid Handler

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View State NBS Laboratory Assays

QUALITY IMPROVEMENT

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Newborn Screening and Genetics

Liquid Handling Options

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When exploring automation commonly used in molecular newborn screening, there are two levels of automation: highly automated, in which the technician has little to no intervention until the method set up is complete; and semi-automated, which is a combination between the manual and the automated levels. In a semi-automated method, the technician will often use instruments on the front end of a method to assist adding reagents. All other steps are completed manually.

Semi-Automated

- Used when processing a small (<500) to medium (>500) daily number of specimens
- Used for adding reagents directly into plate wells
- Does not work when mixing is required
- Instrument used to assist technician with addition of reagents, however other instruments are often used to complete the method
- No specialty positions on deck available (instrument cannot include barcode readers, heated peltier, plate shakers or plate hotels)
- Cannot be used for selective choosing of specimens (aspirating or dispensing to one specimen at a time, i.e. "cherry picking")
- Technician must be present while instrument(s) is running
- Small footprint
- Cheaper than highly-automated instruments

Highly-Automated

- Used when processing a medium to large daily number of specimens
- Used for adding reagents directly into plate, washing specimens, mixing specimens, and removing buffers from specimens
- Level of automation is flexible. Methods can be written to any level of user assistance; from zero user assistance needed, technician can walk away upon starting the method; or partial assistance with one or more step(s) completed with technician assistance
- Many specialty positions available. Common positions found in NBS labs include: barcode readers, heated peltier, plate shakers and plate/tip hotels
- Medium to large footprint
- More expensive than semi-automated instruments

CONTACT

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Research Biologist, Newborn Screening & Molecular Biology Branch - CDC
lfn2@cdc.gov

Title	Robotic one 8 channel liquid handler	Robotic 96-channel Liquid Handler	Robotic one 8-channel and 96-channel Liquid Handler
Photo	 *Picture Courtesy of the Michigan Department of Community Health*	 *Picture Courtesy of the Georgia Department of Public Health*	 *Picture Courtesy of New York State Department of Health - Wadsworth Center*
Mode Of Operation	Aspirates & dispenses or multi-dispenses between 1 and 8 channels at a time.	Simultaneously aspirates & dispenses and multi-dispenses up to 96-channels at a time.	Instrument has two dispensing mechanisms. One that aspirates & dispenses between 1- and 8-channels at a time. The other arm simultaneously aspirates & dispenses and multi-dispenses up to 96-channels at a time.
DNA Extraction	Used when extracting one plate at a time. Used when method includes 1 wash of DBS punches. Please note that this can be used when multiple washes are needed. However many NBS labs currently use a vacuum apparatus to remove wash buffer and leave punches in well, therefore increasing the amount of time a laboratorian must interact with the method. Please note that vacuum is a separate instrument, and is not attached to liquid handler. Used for addition of elution solution.	Used when extracting 1 to 4 plates at a time. Used when method includes 1 or more washes of DBS punches. NBS labs currently have methods that effectively remove the wash buffer and leave the DBS punches in the wells. Used for addition of elution solution.	Used when extracting 1 to 8 plates at a time. Used with 96 head arm when method includes 1 or more washes of DBS punches. NBS labs currently have methods that effectively remove the wash buffer and leave the DBS punches in the wells. Used with 1- to 8-channel head for addition of elution solution.
PCR Set-Up	Used for addition of PCR master mix. Use for addition of DNA to PCR plate.	Used for addition of PCR master mix on instrument with the selective tip head. Used for addition of PCR master mix on instruments that only have the ability to simultaneously aspirate 96-wells at a time, however this is often an expensive reagent and a large excess volume must be added to the instrument to fill the 96-well reservoirs.	Used with 1 to 8 head for addition of PCR master mix on instrument with the selective tip head. Used with 96 head arm for addition of DNA to PCR plate.

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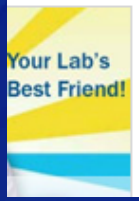

Newborn Screening and Genetics

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Molecular Resources

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AUTOMATION METHODS

Find the Liquid Handling Instrument that Fits Your Needs:

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Automation Methods

Newborn screening programs across the country have implemented automation for molecular assays into their screening protocols. Select a method below to view automation techniques used in US laboratories or to upload your own.

- DNA Extraction Method
- PCR Set-Up Method
- On-Card Assay Method

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Newborn screening programs across the country have implemented automation for molecular assays into their screening protocols. Select a method below to view automation techniques used in US laboratories or to upload your own.

- DNA Extraction Method

State	Contact	# Samples (Busiest Day)	Dispensing Instrument
Minnesota	Berta Wa[illegible]an	350	Non-robotic 8 channel reagent dispenser
Massachusetts	Jacalyn Thompson	1100	Manual
Michigan	Heather Wood	1200	Robotic 1-8 channel liquid handler

Add New DNA Extraction Method

- PCR Set-Up Method
- On-Card Assay Method

Questions to Ask When Purchasing a Liquid Handler

MOLECULAR METHODS

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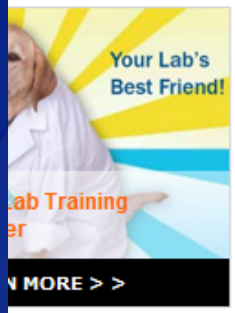

Complete the form below to submit your response

For drop down choices, select existing option or type in your answer.

State:	Minnesota		
Contact:	Berta Warman	Alt Contact:	Carrie Wolf
Contact Email:	berta.warman@state.mn.us	Alt Email:	carrie.wolf@state.mn.us
Contact Phone:	651.201.4836	Alt Phone:	651.201.5458
Number of Samples on Busiest Day:	350		
Number of Samples per Year:	70,000		
Dispensing Instrument Used:	Non-robotic 8 channel reagent dispenser		
Instrument 1 Model (Manufacturer):	Viafill (Integra)		
Aspirating Instrument Used:	VP 177A-1 aspiration manifold (V7P Scientific, INC)		
Instrument 2 Model (Manufacturer):	N/A		
Type of DNA Extraction:			
Assay:	CF and SCID		

Manage Close

Assay:	CP and SCID
How Many Technicians are Needed to Run this Instrument Each Day?	1
Plate Used for Extraction:	96 well, unskirted PCR plate, v bottom
Size of Punch Extracted:	3.2 mm
Number of Washes for Extraction:	3
If Washes are Heated, What Temperature?:	N/A
Extra Volume of Wash Added to Reservoir to Assure Accurate Pipetting:	N/A
Describe Wash 1:	1. 150µl of Purificartion solution 1 (Qiagen) is added to each well containing a DBS using the Viafill. 2. Plate is
Describe Wash 2 (if applicable):	1. 150µl of Purification solution 1 is added to each well containing a DBS using the Viafill. 2. Plate is shake for 15 min. on the Vortemp 56 shaking-incubator at room
Describe Wash 3 (if applicable):	1. 150µl of Elution solution 2 (Qiagen) is added to each well containing a DBS using the Viafill. 2. Plate is shake for 15 min. on the Vortemp 56 shaking-incubator at room

Describe Wash 4 (if applicable):	N/A
Average Number of Spots Lost During Wash Removal:	0.01%
Detail How Liquid is Removed During Wash to Leave Spot:	with an 96 well aspiration manifold
Elution Volume:	25ul
Describe Elution:	Elution solution 2 (Qiagen) is added, plate is sealed with thermal sealing foil and placed in the Vortemp 56 shaking-incubator @ 900rpm for 30 minutes at 99.5oC.
Level of Automation:	Semi-automated
Describe User Intervention Step(s) (if applicable):	Apply and remove adhesive film. Transfer plates from one instrument to the other. Press "start" on each instrument.
Smallest Volume Pipetted:	25 ul
Largest Volume Pipetted:	150 ul
List Speciality Positions Used:	N/A
Number of Plates Extracted at Same Time:	2-5

Number of Plates Extracted in 1 Day:	
Is Sample Tracking Required?:	No
Number of Tips Used per Sample:	Non
Are Tips Re-used?:	N/A
Describe How Tips are Used? (One tip per sample, multiple tips per sample, tips used for multiple samples):	N/A
Are Speciality Tips Used?:	No
Time it Takes to Complete Method:	90 minutes (60 minutes in liquid handler, aspirator and RT incubation and 30 mi
How Many Positions on the Deck are Used During Method:	N/A
Important Method Logistics/Hints:	N/A

Important Method Logistics/Hints:	N/A
Describe Other Instruments Used:	Shaker incubator (Vortemp 56)
List Other Methods (Molecular and Non-molecular) that Use this Instrument:	N/A
List of Labware that is Commonly Used with this Method:	Viafill: tubing cassettes (one per solution); Aspirator Manifold: vacuum pump, vacuum trap bottles, tubing
Limitations of Instrument for this Method:	

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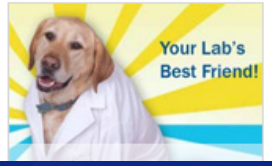

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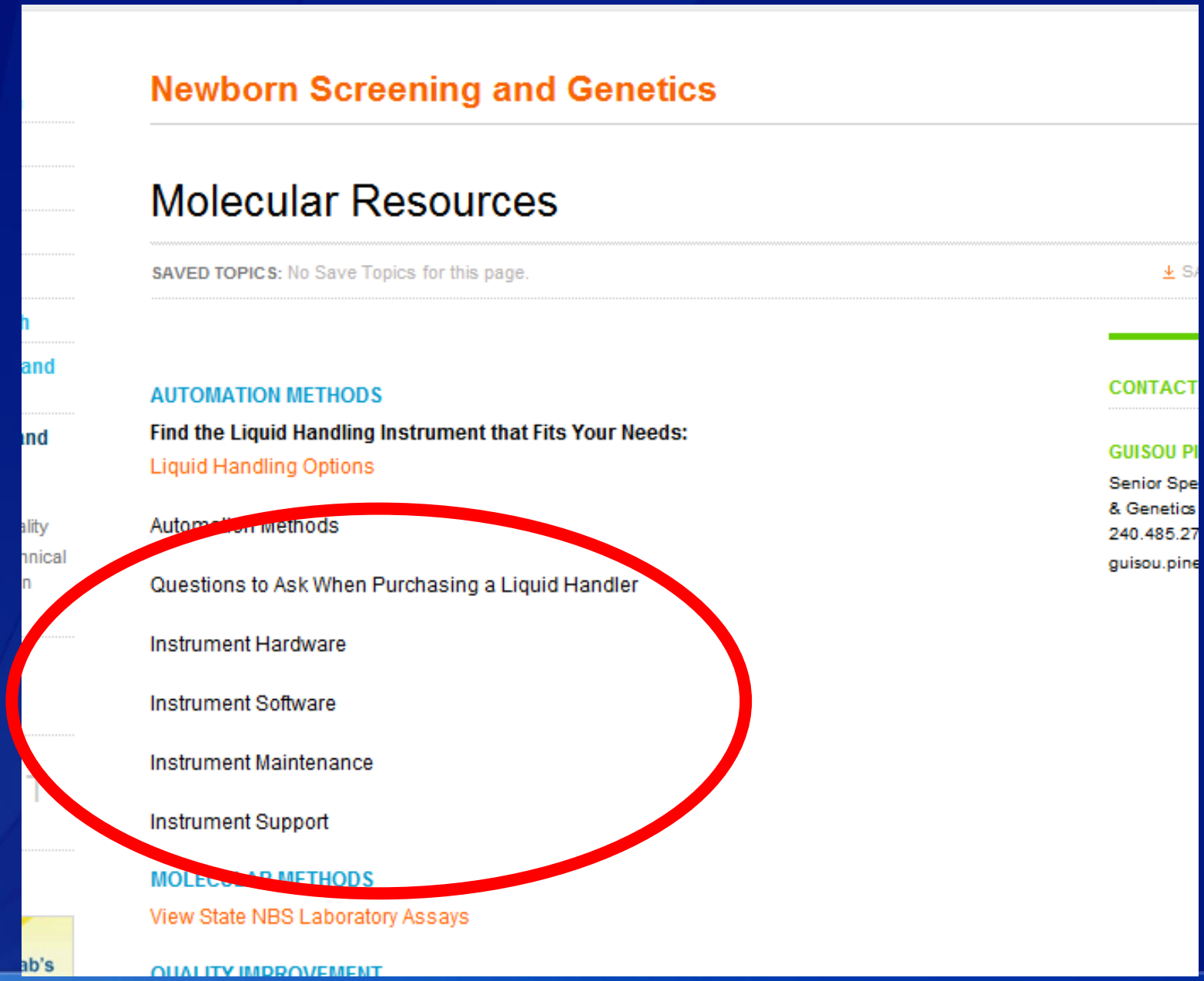
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Instrument Maintenance
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Questions to Ask When Purchasing a Liquid Handler

Instrument Hardware

1. How much space will this instrument take up? Will existing benches need to be modified (widened, pulled away from the wall, extended)?
2. What types of specialty additions can be incorporated?
    1. Plate shaker
    2. Barcode reader
    3. Heating unit
3. How many plates/tips can I fit on the deck?
4. Can the instrument track samples?
5. Is the labware (plates, reservoirs, tips) I plan to use compatible? If not, are there adaptors that can be used?
6. What is the cost of the recommended labware? Are there other options for needed labware (other brands) or does it have to be from the same company as the instrument?
7. Can low reagent volumes be accurately pipetted? What are the accuracy and precision rates?
8. What is the dead volume when pipetting my lowest volume needed from my desired reservoir? Are there other reservoirs available that would decrease my dead volume that would also work for my needs?
9. Approximately how long does it take to dispense reagent to a 384 well plate? Into a 96 well plate? From different sources (reservoirs, plates, tubes)
10. Can the instrument be used for non-molecular cross purposes?
11. Can the instrument be connected to the intranet?
12. Do I have a mechanism to purchase this instrument?
13. Do I have a mechanism to purchase consumables (tips, plates, reservoirs)?
14. Where can I see this instrument in action with a method similar to what I have planned?
15. Can I demo the instrument?
16. Does our specimen throughput or backup requirements necessitate instrument redundancy (purchase of more than one of the same instrument)?

Instrument Software

1. How much control does the user have over the labware descriptions, including plates and tips? (Example – if you need the tip to enter a plate at the side of a well, instead of the middle – can the end user adjust this?) Can the user define their own labware specifications or is that done by the manufacturer?
2. What level of programing is required?
3. Is the software user-friendly?
4. Do we have a person currently in our lab who can manage/maintain the more technical

Instrument Maintenance

1. What is covered by the warranty at time of purchase and what options there are when warranty need to be renewed?
2. Is this instrument maintenance covered under the contract agreement with my lab?
3. Recommendations on how often the instrument has to be shut down (daily, over the weekend, monthly).
4. What is the required instrument maintenance (daily, weekly, monthly, annually)?

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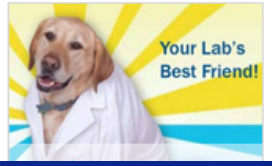

Newborn Screening and Genetics

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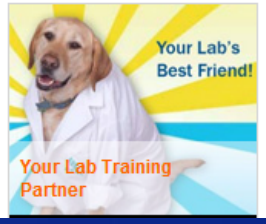

Newborn Screening and Genetics

State NBS Molecular Assays

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Newborn screening programs around the country are in various stages of implementing molecular assays into their screening protocols. Select a disorder to learn about the different molecular methods currently in use in a NBS laboratory.

Please select disorder of interest:

- Cystic Fibrosis
- Galactosemia
- Hemoglobinopathies
- Krabbe
- Medium Chain Acyl CoA Dehydrogenase (MCAD)
- Maple Syrup Urine Disease (MSUD)
- Severe Combined Immunodeficiency Disorder (SCID)

Enter Your Assay

Thank you for assisting us to create an accurate summary of all NBS molecular assays currently in use. Please fill out a form for each assay performed by your laboratory. For assistance in completing the form, please contact Laura Hancock, Research Scientist, Newborn Screening and Molecular Biology Branch, CDC at lfn2@cdc.gov.

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LAURA HANCOCK, MS
Research Biologist, Newborn Screening & Molecular Biology Branch - CDC
lfn2@cdc.gov

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- Cystic Fibrosis

STATE	CONTACT PERSON	LABORATORY ASSAY	TIER
Iowa	Mike Ramirez	Hologic InPlex	Second
California	George Helmer	Luminex xMAP	Second
California	George Helmer	DNA Sequencing	Second
Michigan	Kelly TenEyck, M.S.	Hologic InPlex	Second
Minnesota	Amy Hietala	Luminex xMAP	Second
Massachusetts	Anne Marie Comeau, PhD	Luminex xMAP	Second
New York	Dr. Michele Caggana	Hologic InPlex	Second
New York	Dr. Michele Caggana	Polyacrylamide Gel Electrophoresis	Second
Texas	Rachel Lee	Hologic InPlex	Second
Washington	Tim Davis	Fluorescent Probe Mutation Detection (i.e. TaqMan)	Second
Wisconsin	Mei Baker	Hologic InPlex	Second
Virginia	Thomas Hickey, Ph.D.	Luminex xTAG 39	Second
Colorado	Jeana Foster	Luminex xTAG 39	Second

- Galactosemia
- Hemoglobinopathies
- Krabbe

Molecular Assay Description Form

State:	Massachusetts		
Program Website:	http://www.umassmed.edu/nbs/index.aspx		
Contact Person:	Anne Marie Comeau, PhD	Alt Contact:	jacalyn.thompson@umassmed.edu
Contact Email:	anne.comeau@umassmed.edu	Alt Email:	jacalyn.thompson@umassmed.edu
Contact Phone:	617-983-6300	Alt Phone:	617-983-6300
Condition:	Cystic Fibrosis		
Laboratory Assay:	Luminex xMAP		
Tier:	Second		
Please indicate the method of DNA extraction used in your laboratory:	Qiagen Generation method using in-house prepared wash solution as a substitute for Solution 1, and Solution :		

Extraction Duration (hrs):	1.25	Assay Duration Excluding Extraction (hrs):	5-6 hrs. Duration consists of 4 sets of ...
Mutations or Targets Screened:	Exon3: G85E, 394delTT; Exon4 :Y122X, R117H; Intron4: 621+1G>T*; Intron5: 711+1G>T*; Exon7: R347H, R347P*, R334W*, 1078delT*; Exon9:A455E*,5/7/9T; Exon10: deltaI507*,deltaF508*,V520F,F508C,I507V,I506V; Intron 10: 1717-1G>A*; Exon11: A559T , G542X*,G551D*, R553X*, R560T*, S549N, S549R (T>G); Exon12: 1898+1G>A*, Intron12: 1898+5G>T; Exon13: 2307insA, 2183AA>G , 2184delA*; Intron14b: 2789+5G>A*; Intron16: 3120+1G>A*; Exon17b: M1101K, Y1092X (C>A), Y1092X (C>G); Exon19: R1162X*, S1255X (19), 3659delC*; Intron19: 3849+10kbC>T*; Exon20: S1255X (20), 3876delA, 3905insT, W1282X*; Exon21: N1303K*. * indicates that mutation is on ACMG carrier screening panel.		
Assay Description:	The objective is to test a specific set of DNA sequences in the Cystic Fibrosis transmembrane conductance regulator (CFTR) gene simultaneously in order to detect and identify each as containing specific mutations, variants or wild-type sequence. The xTag® Cystic Fibrosis 39 v2 accomplishes this objective using multiplex Polymerase Chain Reaction (PCR) and multiplex Allele Specific Primer Extension (ASPE) with Luminex Molecular Diagnostic's (Luminex Corp) proprietary Universal Tag sorting system on the Luminex® analyzer		
Assay Limitations:	1. the assay will only identify the listed mutations and their respective wild-type sequences; it will not identify other mutations or deletions. 1a. Other mutations can be added, but only through a "laboratory developed test", which would be run independently. 2. the assay is dependent upon hybridization of primers and probes thus has the typical limitations related to such assays. 3 Though the technology has a wide range of flexibility in choice of alleles to be assayed, as an FDA-approved kit, there are limitations to this flexibility. Specifically, all mutations and polymorphisms are tested and software drives the reporting of the test results. Version 2 appears to be more limited than version 1 per FDA requirement (under		

Instruments Used for this Assay	Assay Platform/Instrumentation and Manufacturer: Luminex 39+4 assay/Luminex 100/200 Reader System
Instruments Used for this Assay - Liquid Handling Robotics Instruments:	Liquid Handling Robotics Instrumentation and Manufacturer: Biomek 3000 for transfer of DNA eluate from 96-well plate to PCR tubes (optional)
Population Frequency for Disorder Within Your State:	The frequency of cystic fibrosis (excluding CRMS and CRD) in the Massachusetts population is about 1 in 380...
Important Assay Logistics /Hints Not Described Above (i.e. If multiple assays are used for this disorder, describe how each is used)	The Luminex TDAS software included in the kit is excellent for quality control monitoring. This is the same platform that we use for Laboratory-Developed tests for GALT and MCADD.

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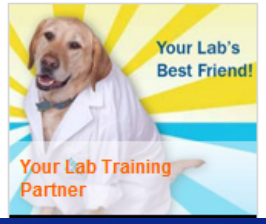

Newborn Screening and Genetics

State NBS Molecular Assays

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Newborn screening programs around the country are in various stages of implementing molecular assays into their screening protocols. Select a disorder to learn about the different molecular methods currently in use in a NBS laboratory.

Please select disorder of interest:

- Cystic Fibrosis
- Galactosemia
- Hemoglobinopathies
- Krabbe
- Medium Chain Acyl CoA Dehydrogenase (MCAD)
- Maple Syrup Urine Disease (MSUD)
- Severe Combined Immunodeficiency Disorder (SCID)

Enter Your Assay

Thank you for assisting us to create an accurate summary of all NBS molecular assays currently in use. Please fill out a form for each assay performed by your laboratory. For assistance in completing the form, please contact Laura Hancock, Research Scientist, Newborn Screening and Molecular Biology Branch, CDC at lfn2@cdc.gov.

CONTACT

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LAURA HANCOCK, MS
Research Biologist, Newborn Screening & Molecular Biology Branch - CDC
lfn2@cdc.gov

State NBS Molecular Assays

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STATE	CONTACT PERSON	LABORATORY ASSAY	TIER
California	George Helmer	Real Time qPCR	First
Michigan	Heather D Wood, M.S.	Real Time qPCR	First
Massachusetts	Anne Marie Comeau, PhD	Real Time qPCR	First
New York	Dr. Michele Caggana	Real Time qPCR	First
Texas	Rachel Lee	Real Time qPCR	First
Wisconsin	Mei Baker	Real Time qPCR	First
Colorado	Mark Dymerski	Real Time qPCR	First
Minnesota	Amy Hietala	Real Time qPCR	First
Washington	Tim Davis	Real Time qPCR	First

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Molecular Assay Description Form

State:	New York		
Program Website:	http://www.wadsworth.org/newborn/index.html		
Contact Person:	Dr. Michele Caggana	Alt Contact:	Dr. Carlos Saavedra or Jason Isabelle
Contact Email:	mxc08@health.state.ny.us	Alt Email:	cas28@health.state.ny.us or jti02@he...
Contact Phone:	518-473-3854	Alt Phone:	518-486-1641 or 518-474-3853
Condition:	SCID		
Laboratory Assay:	Real Time qPCR		
Tier:	First		
Please indicate the method of DNA extraction used in your laboratory:	In house wash/alkaline lysis/boil method (automated)		

Extraction Duration (hrs):	~ 2.5 hrs / 384 samples	Assay Duration Excluding Extraction (hrs):	48 hrs (including retests)
Mutations or Targets Screened:	TREC and RNaseP target screened for in every newborn.		
Assay Description:	Immune function and T-cell counts are difficult to illicit directly from a dried blood spot. In this case, a substitute marker is used to make this determination. During normal T-cell development in the thymus, a short section of DNA is excised from the T-cell receptor gene. The ends of this linear sequence are ligated together to form a circular DNA episome. This circular piece of DNA is deemed a T-cell receptor excision circle or TREC. A lack or very low number of these TRECs is indicative of a severe T-cell lymphopenia such as that seen in SCID. TREC quantities from a dried blood spot are measured by a quantitative real-time PCR assay that utilizes TaqMan® Chemistry. Specimens with low TREC values are repunched and retested in duplicate. An average of the 2 values is reported.		
Assay Limitations:	Deletions/mutations in primer or probe sequence would limit assay efficiency.		
Instruments Used for this Assay	Assay Platform/Instrumentation and Manufacturer: ABI 7900HT Sequence Detection System.		

Instruments Used for this Assay - Liquid Handling Robotics Instruments:	Liquid Handling Robotics Instrumentation and Manufacturer: Beckman Biomek NXp / INHECO Shaking peltier devices / Thermo Scientific Cytomat Hotel.
Population Frequency for Disorder Within Your State:	1:44,000
Important Assay Logistics /Hints Not Described Above (i.e. If multiple assays are used for this disorder, describe how each is used)	RNaseP and TREC are multiplexed. Due to liquid handler/peltier unit limitations, a modified version of the DNA extraction method was adapted. Separate rooms house preparation of assay solutions, DNA extractions, and reaction runs.

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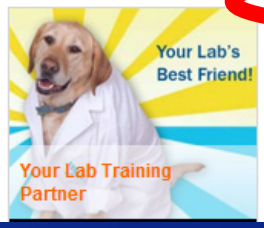

Newborn Screening and Genetics

State NBS Molecular Assays

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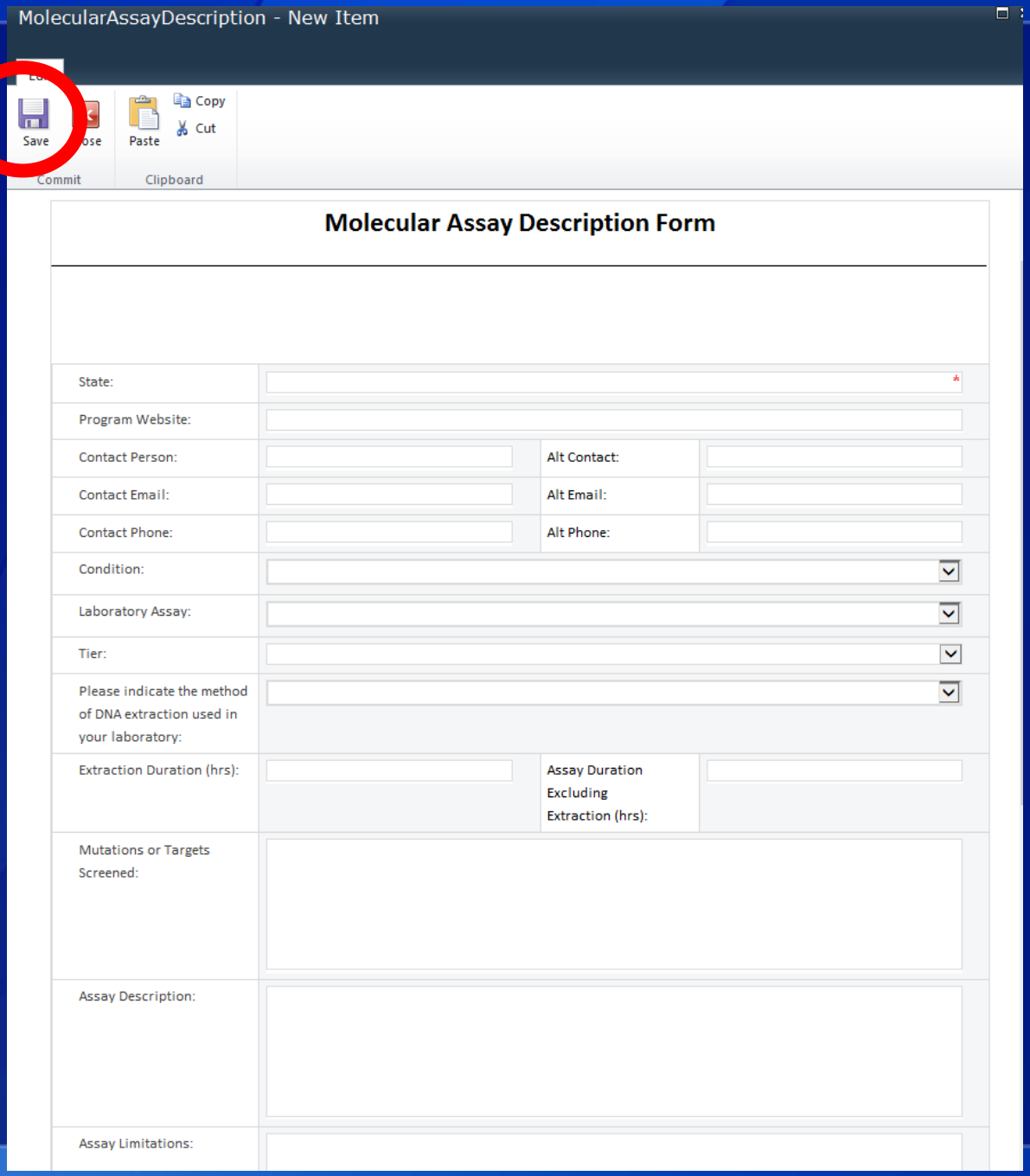
MolecularAssayDescription - New Item
Save
Paste
Copy
Cut
Commit
Clipboard
Molecular Assay Description Form
State:
Program Website:
Contact Person:
Alt Contact:
Contact Email:
Alt Email:
Contact Phone:
Alt Phone:
Condition:
Laboratory Assay:
Tier:
Please indicate the method of DNA extraction used in your laboratory:
Extraction Duration (hrs):
Assay Duration Excluding Extraction (hrs):
Mutations or Targets Screened:
Assay Description:
Assay Limitations:

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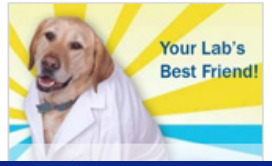

Newborn Screening and Genetics

Molecular Resources

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Find the Liquid Handling Instrument that Fits Your Needs:
Liquid Handling Options

Automation Methods

Questions to Ask When Purchasing a Liquid Handler

MOLECULAR METHODS

View State NBS Laboratories

QUALITY IMPROVEMENT

Molecular Assessment Program (MAP)

Some content is restricted access; if you have trouble accessing content but believe you should have access, please reach out to your newborn screening program staff contact of choice.

CONTACT

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Newborn Screening and Genetics

Molecular Assessment Program

Improve the quality of your state's Newborn Screening molecular program with a CDC/APHL Molecular Assessment Program (MAP) visit.

SAVED TOPICS: Laboratory Systems and Standards, Newborn Screening, Quality Systems

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The CDC's Newborn Screening and Molecular Biology Branch, in cooperation with APHL, offers onsite visits designed to assess the quality of a state newborn screening molecular program. The MAP visits are tailored to the specific needs of the newborn screening program with guidance in evaluating ongoing or soon to be implemented molecular testing procedures. The MAP team of CDC and state public health laboratory scientists work with laboratory personnel to assess of all molecular testing procedures.

Read MAP Testimonials

Get Started

Review MAP Checklist

Review MAP Visit Timeline

Request a MAP Visit

After the MAP visit, the laboratory director receives a summary report and any resources related to specific molecular testing issues that were discussed during the visit. Findings from MAP assessments inform the CDC's Newborn Screening and Molecular Biology Branch's efforts to support newborn screening laboratories.

Follow-Up

Rate your MAP Visit

CONTACT

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CHRISTOPHER GREENE, PHD

Research Scientist
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CDC - Newborn Screening Quality Assurance Program

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RELATED CONTENT

CDC - Newborn Screening Quality Assurance Program

The Molecular Assessment Program (MAP): Evaluation of Newborn Screening Molecular Testing

Newborn screening (NBS) is the process of testing infants for serious developmental, metabolic, and genetic disorders. The Health and Human Services (HHS) Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) lists 31 core disorders that are recommended to be included in every NBS program in the United States. These core conditions share criteria including that they are prevalent in the U.S. population; can be screened for using a simple, robust test; and a treatment or intervention exists if the disorder is detected early. The majority of screening for these disorders is through a biochemical test. The recommended inclusion of cystic fibrosis (CF) to the core panel of disorders in the mid-2000s resulted in the first wide-spread use of a molecular test in NBS to increase the sensitivity and specificity of biochemical screening results. In addition to CF, several programs adopted second-tier molecular tests for disorders including galactosemia, MCAD, PKU, and CAH. In 2010, the SACHDNC added Severe Combined Immunodeficiency (SCID) to the core screening panel. This disorder signified the first time a molecular assay was used as a primary screening test. The inclusion of SCID will require the expansion of molecular testing activities in NBS programs. Despite the increased use of molecular testing, there are still several public health programs that have yet to introduce molecular testing into their NBS programs.

As NBS laboratories introduce molecular assays into their routine testing, it is imperative that the specific concerns related to molecular testing are addressed to ensure the quality of test performance and laboratory practice. Molecular testing requires specific guidelines that are not covered by CLIA. In response to this, the Newborn Screening Molecular Subcommittee developed a pilot initiative, the Molecular Assessment Program (MAP). MAP will involve the public health laboratory personnel working together with the NSMBB molecular quality improvement program to provide quality management guidance for molecular testing in NBS

3A: Unidirectional Workflow

3A.1: Does the laboratory have clearly defined pre-PCR and post-PCR laboratory spaces?

N/A ☐ YES ☐ NO ☐

Comments:

3A.2: Are pre-PCR and post-PCR laboratory spaces physically separated in different rooms?

N/A ☐ YES ☐ NO ☐

Comments:

3A.3: If pre-PCR and post-PCR areas are in the same room, does the laboratory utilize enclosed dead-air boxes to minimize contamination?

N/A ☐ YES ☐ NO ☐

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Newborn Screening and Genetics

Molecular Assessment Program

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SAVED TOPICS: Laboratory Systems and Standards, Newborn Screening, Quality Systems

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Follow-Up

Rate your MAP Visit

CONTACT

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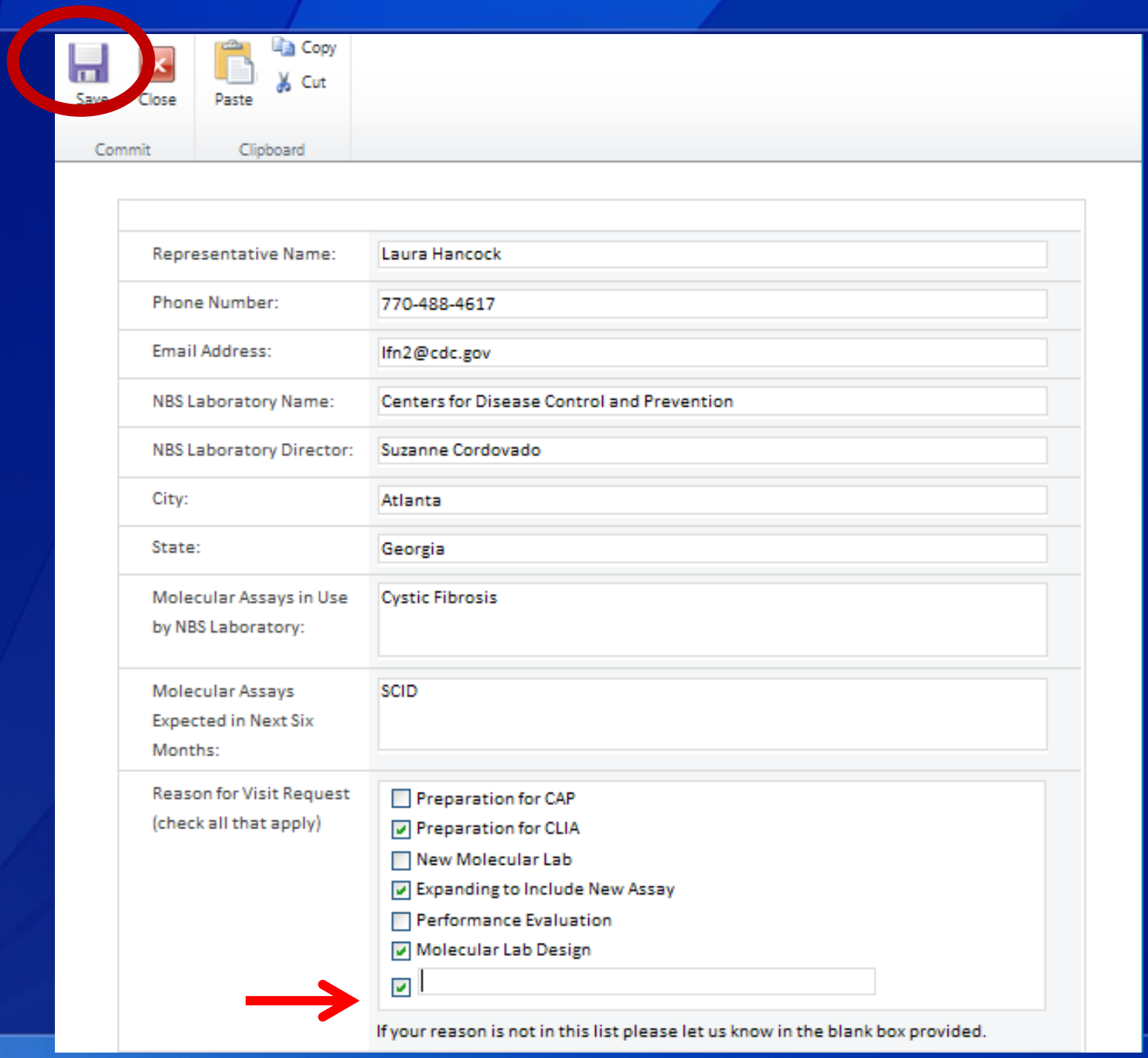
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Representative Name:
Laura Hancock
Phone Number:
770-488-4617
Email Address:
lfn2@cdc.gov
NBS Laboratory Name:
Centers for Disease Control and Prevention
NBS Laboratory Director:
Suzanne Cordovado
City:
Atlanta
State:
Georgia
Molecular Assays in Use by NBS Laboratory:
Cystic Fibrosis
Molecular Assays Expected in Next Six Months:
SCID
Reason for Visit Request (check all that apply)
Preparation for CAP
Preparation for CLIA
New Molecular Lab
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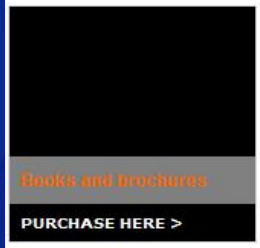

Newborn Screening and Genetics

APHL strengthens the role of public health laboratories in genetics testing and newborn screening science and practice.

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Babies' and Families' Video Stories

CONTACT

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Director of Newborn Screening and Genetics
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jelili.ojodu@aphl.org

ITEMS FOR PURCHASE

Buy Books, Brochures

Buy Shirts

Conferences, Workshops and Webinars

APHL regularly hosts small conferences, workshops and trainings concerning newborn screening.

Tandem Mass Spectrometry Laboratory Workshop

Applications are now open for the upcoming course, "Newborn Screening by Tandem Mass Spectrometry (MS/MS): A Hands-On Course in Understanding Laboratory Issues and Interpreting Test Results," The course is a five-day intensive workshop and is co-sponsored by the Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC). The course will be held at the Newborn Screening and Molecular Biology Branch Laboratories at CDC in Atlanta, GA on April 20-24, 2015. The course will feature MS/MS hands-on exercises designed to enhance understanding of the didactic portions of the workshop. The exercises will cover routine MS/MS newborn screening tests as well as second tier testing using MS/MS methods applicable to the modern newborn screening system.

Apply today. Applicants must be logged into their APHL accounts in order to apply. Accounts are easy to create and are free of charge. Don't have an account? Click here. Have an account but forgot your password? Click here. Applications will be open until close of business on Friday, February 20, 2015.

Free CEs for Laboratory and Health Professionals Involved in Biochemical Genetic Testing

Laboratory professionals working in biochemical genetic testing or newborn screening laboratories who are looking for CE opportunities are encouraged to read the 2012 MMWR Recommendation and Reports: Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders and take a post-test to document knowledge gained and earn CEs. The document can be used to prepare for an upcoming accreditation or laboratory certification inspection, strengthen a laboratory's quality improvement program, and assist in developing a competency testing plan for staff. For more information, go to www.cdc.gov/TCEOnline and search for course number "WB2010."

Molecular Training Materials

2013 APHL Molecular Training Workshop
2013 APHL Molecular Resources Website Webinar
2009 APHL Molecular Testing Webinar

CONTACT

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PAST CONFERENCES

2014 Newborn Screening and Genetics Testing Symposium
Anaheim, CA

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NewSTEPs Educational Resources

NewSTEPs Quality Practice Resources

What Can You Do?

- Request access to the NBS Molecular Resources Website from APHL
- Describe your liquid handling solutions for DNA Extraction, PCR Set up or the On-Card Assay Method
- Fill out Molecular Assay Description forms to describe your molecular assays

NBS Molecular Resources Website

To add program members: Guisou Pineyro
guisou.pineyro@aphl.org

Scientific questions and suggestions: Laura Hancock
Lhancock@cdc.gov

Molecular Assessment Program: Christopher Greene
Cgreene@cdc.gov

Molecular Subcommittee Questions: Michele Caggana
mxc08@health.state.ny.us

NBS Molecular Subcommittee:
Michele Caggana (NY) – Chairperson
Fred Lorey (CA)
Stan Berberich (IA)
Mark McCann (MN)
Rachel Lee (TX)
Mike Glass (WA)
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Carla Cuthbert

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
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National Center for Environmental Health
U.S. Centers for Disease Control and Prevention