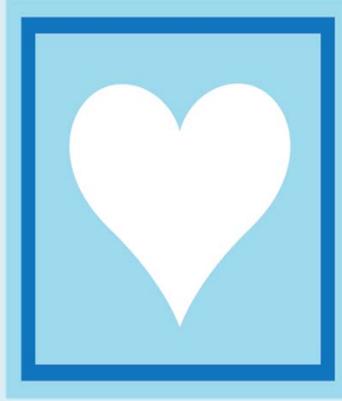


50  
YEARS



MICHIGAN  
Newborn  
Screening

1965 - 2015



# Overview of Newborn Screening- Laboratory and Follow-up



Harry Hawkins, Section Manager  
Newborn Screening Laboratory

Lois Turbett, Nurse Consultant  
Newborn Screening Follow-up



# Newborn Screening (NBS)

- Mandated by Michigan law
  - Parents may opt out
- Funded by purchase of the newborn screening card, not by tax dollars
  - \$125.36 first sample
  - \$117.29 repeat sample
- Operated by the Bureau of Laboratories and Bureau of Disease Control, Prevention and Epidemiology



# Newborn Screening (NBS)

- 112,790 babies screened in 2014
- 259 diagnosed with one of the disorders (preliminary)
  - One infant out of 435 screened
- 5,711 babies identified by NBS through December 31, 2014



# Babies Diagnosed through NBS in 2014

- Cystic fibrosis (27)
- Endocrine (95)
  - Congenital hypothyroidism (84)
  - Congenital adrenal hyperplasia (11)
- Hemoglobinopathies (52)
- Metabolic disorders (70)
- Primary immunodeficiencies (15)



# Three Components of NBS

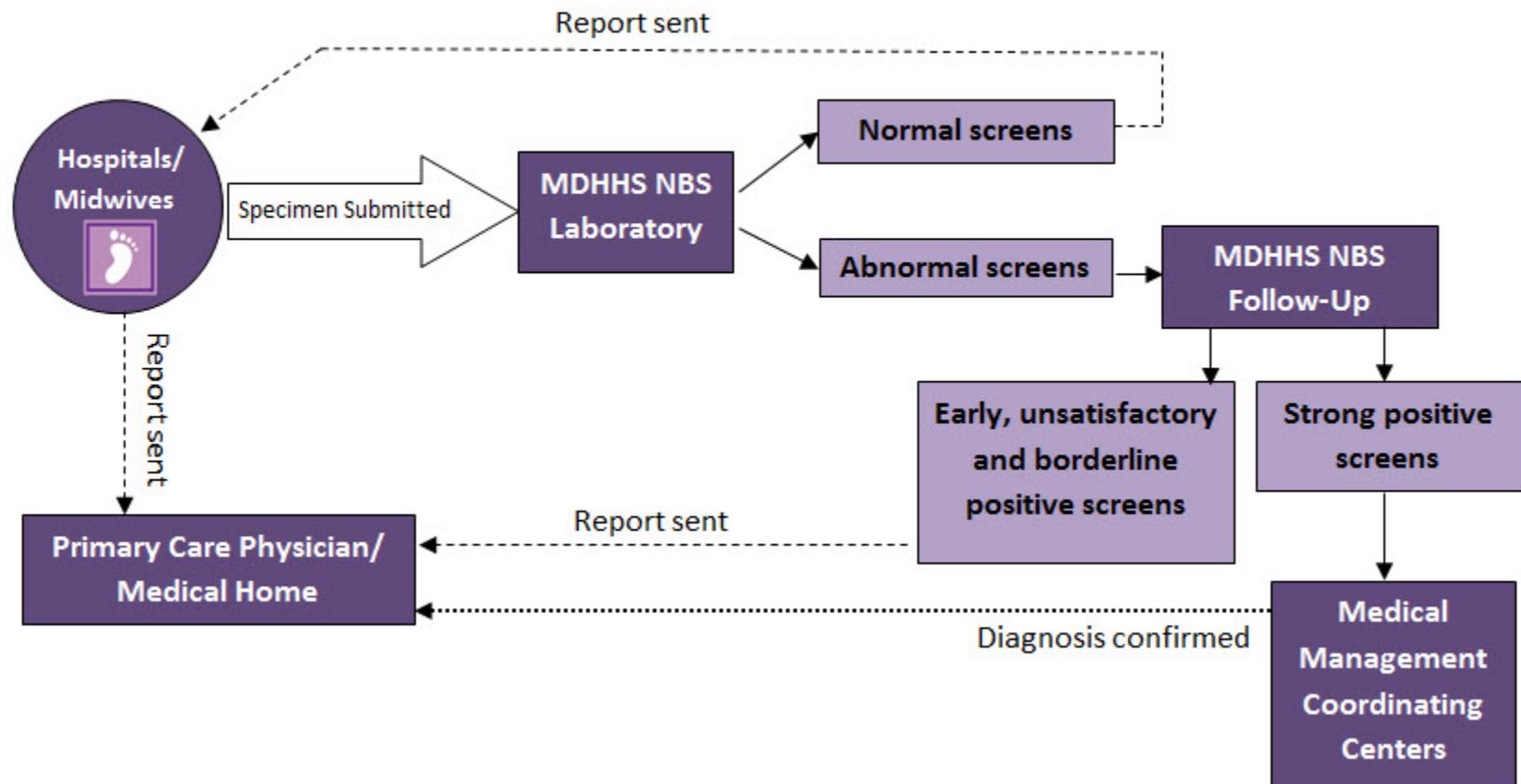
- Bloodspot collection on filter paper
  - 24-30 hours
- Hearing screening (point of care)
  - Early Hearing Detection and Intervention
- Critical congenital heart disease (CCHD) screening (point of care)
  - Pulse oximetry screening at approximately 24 hours



# Bloodspot Screening and Follow-up System



## Michigan's Blood Spot Screening and Follow-up System





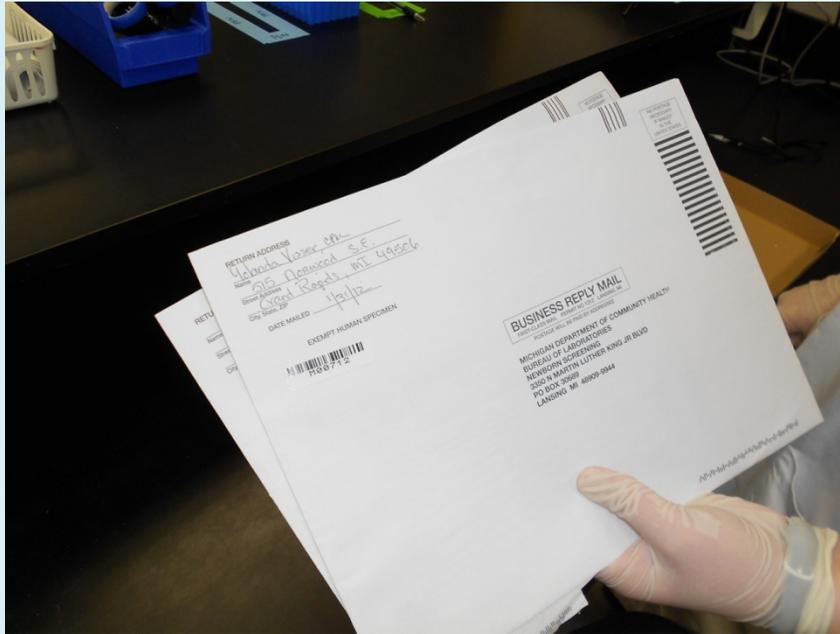
NBS blood spot samples are delivered here





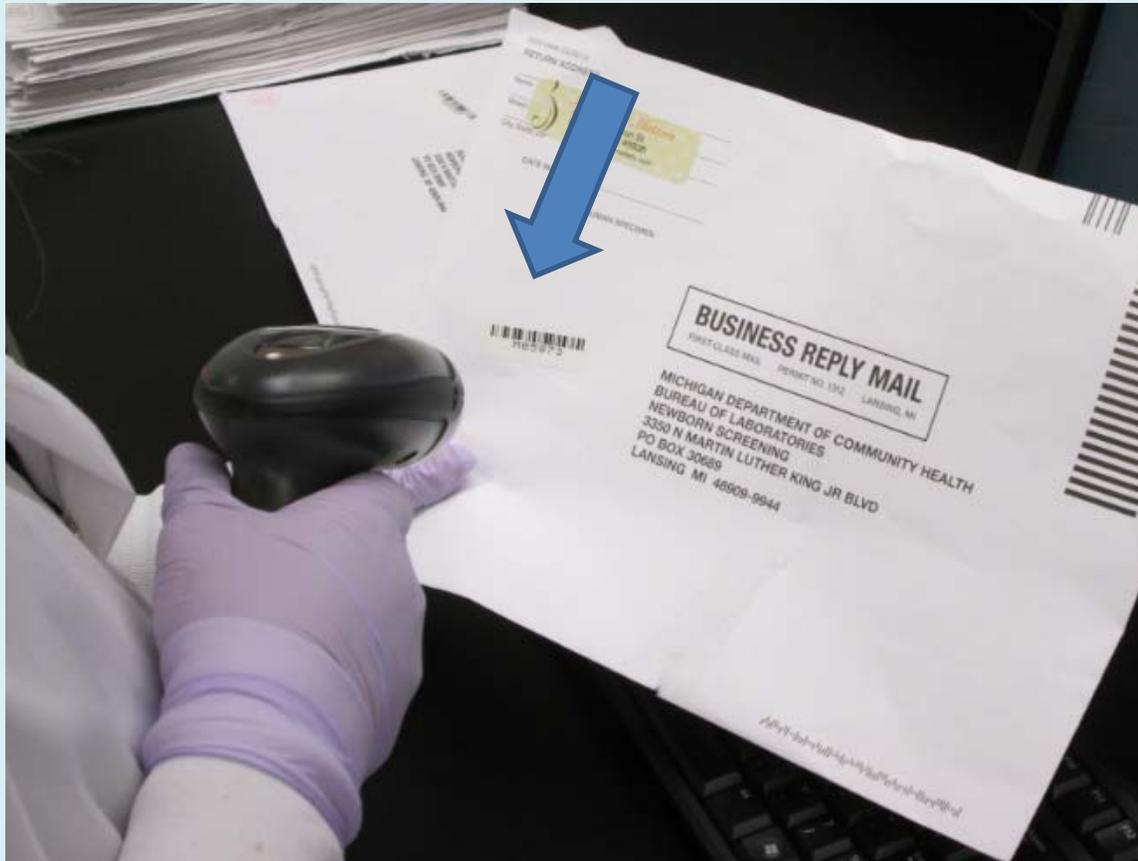
Specimens are received early in the morning from the NBS contract couriers (hospitals) and by US mail or UPS (homebirth midwives)





Approximately 350 -700 NBS specimens are processed each day





Each envelope has a unique barcode



LAST NAME  
 BIRTH DATE  
 SPECIMEN DATE  
 MEDICAL RECORD #  
 TYPE OF COLLECTION:  Heel Stick  Capillary Tube  Line Draw (control, other)

BIRTH TIME (Military) BIRTH WT (gms) FIRST NAME  
 COLLECTION TIME (Military) Collected By:  NICU or SPECIAL CARE?  ANY RBC TRANSFUSION?  SINGLE BIRTH  MULTIPLE BIRTH  BIRTH ORDER  
 NO  YES  NO  YES  NO  YES  NO  YES  NO  YES

GENDER: MALE  FEMALE  ANTIBIOTICS?  NO  YES  
 TRANS START TIME (Military)

MOTHER: LAST NAME, ADDRESS, CITY, MEDICAL RECORD #  
 PROVIDER: LAST NAME, PHONE, ADDRESS, CITY, SUBMITTER NAME, FAX, BIRTH DATE, STATE, ZIP, PHONE

HEPATITIS B SURFACE ANTIGEN (HBsAg) TEST DATE:  POSITIVE  NEGATIVE  
 RACE:  WHITE  BLACK  AMERICAN INDIAN  ASIAN/PACIFIC ISLAND  ARAB DESCENT  MULTI-RACIAL  
 OTHER FEEDING:  BREAST  MLK-BASE  SOY  NONE

1901011  
 MDCH USE ONLY  
 EXPIRES: 2017-07

Each page of the NBS card (kit) has the same unique number and barcode



HEARING SCREENING RESULTS

1901011

Hearing Results:  
Detach this sheet before blood collection. Enter results.

The NBS software links the card to the envelope



The image shows a screenshot of a software application window titled "Demographic Information". The window contains several sections for data entry:

- Accession Number:** A dropdown menu with "HELLC" selected.
- Card Type - BPHM:** A dropdown menu.
- Spec Type - IRM:** A dropdown menu.
- Current Version:** ".117".
- Baby Section:** Fields for Baby's Last Name, First Name, Gender (M/F), Birth Date, Birth Date Type, Birth Wt (kg), Wts Gest, Multi Birth (Y/N), Birth Order A/B/C, Antibiotics (Y/N), Cell Date, Time, Age At Collection, NICU (Y/N/35), Transfused (Y/N), Transfused Date, Time, Medical Record Number, TPH (Y/N), Hispanic (Y/N), and Ethnicity (White/Black/Asian/East/Hispanic).
- Mother Section:** Fields for Mother's Last Name, First Name, Research Consent, Consent Change, Address, City/State, Phone, Medical Rec #, Birth, Hospital, and Hep (Y/N).
- Physician Section:** Fields for Physician, Phone, and Fax.
- Submitter / Hospital Section:** Fields for Hospital Code, Submitter, and Birth Hospital.
- Unsat Section:** A field for Unsat Reason.

Demographic information is entered manually

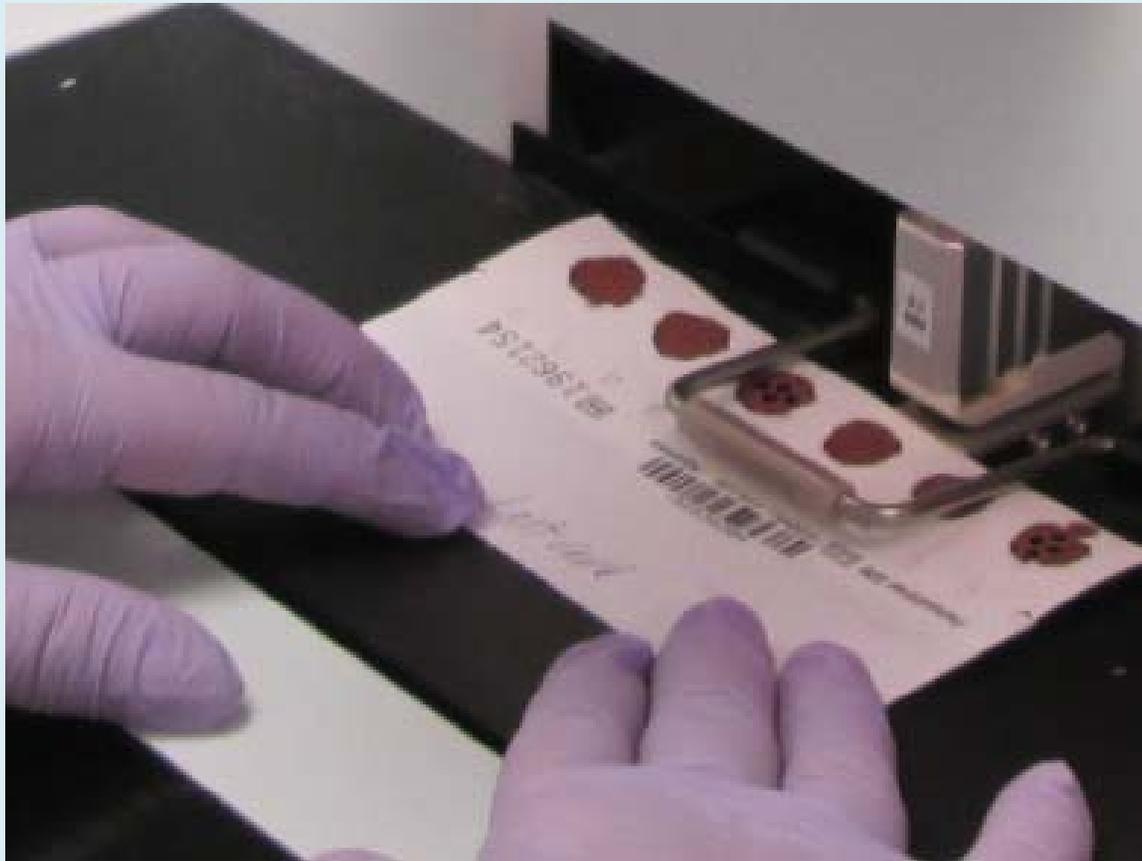
In the near future, this information will be sent electronically from the hospital to NBS via HL7 messaging.





Every specimen is examined for quality





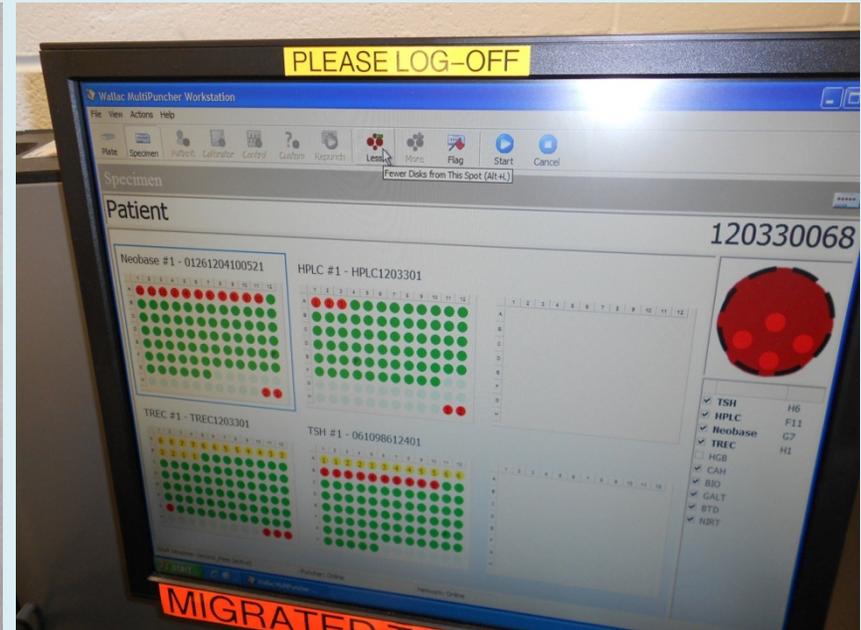
Cards are punched for testing





Two punchers fill plates with a total of 8 punches for the initial tests

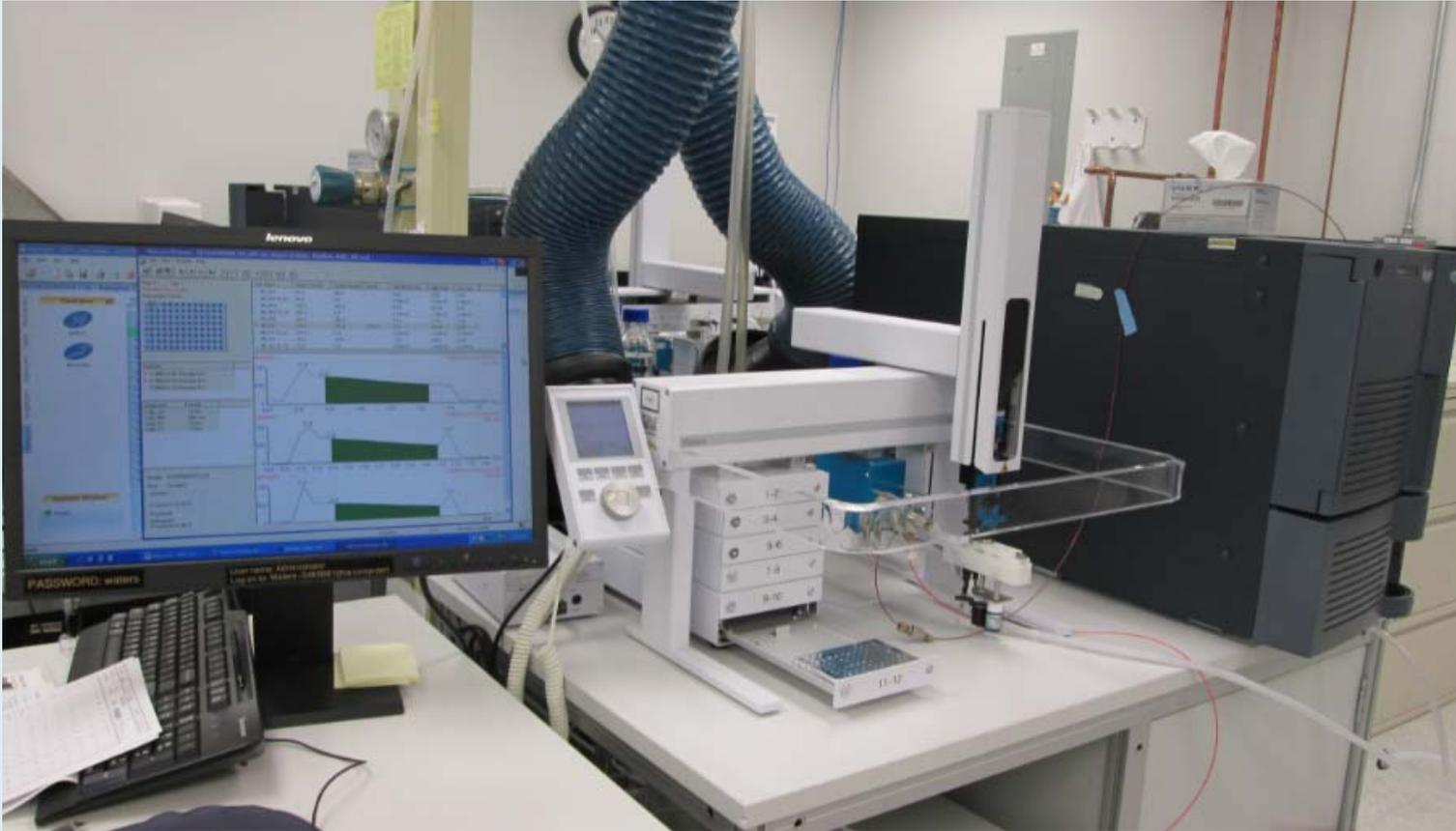




The NBS software maintains positive identification by keeping track of where each punch is located in each microtiter plate.



# Mass Spectrometry



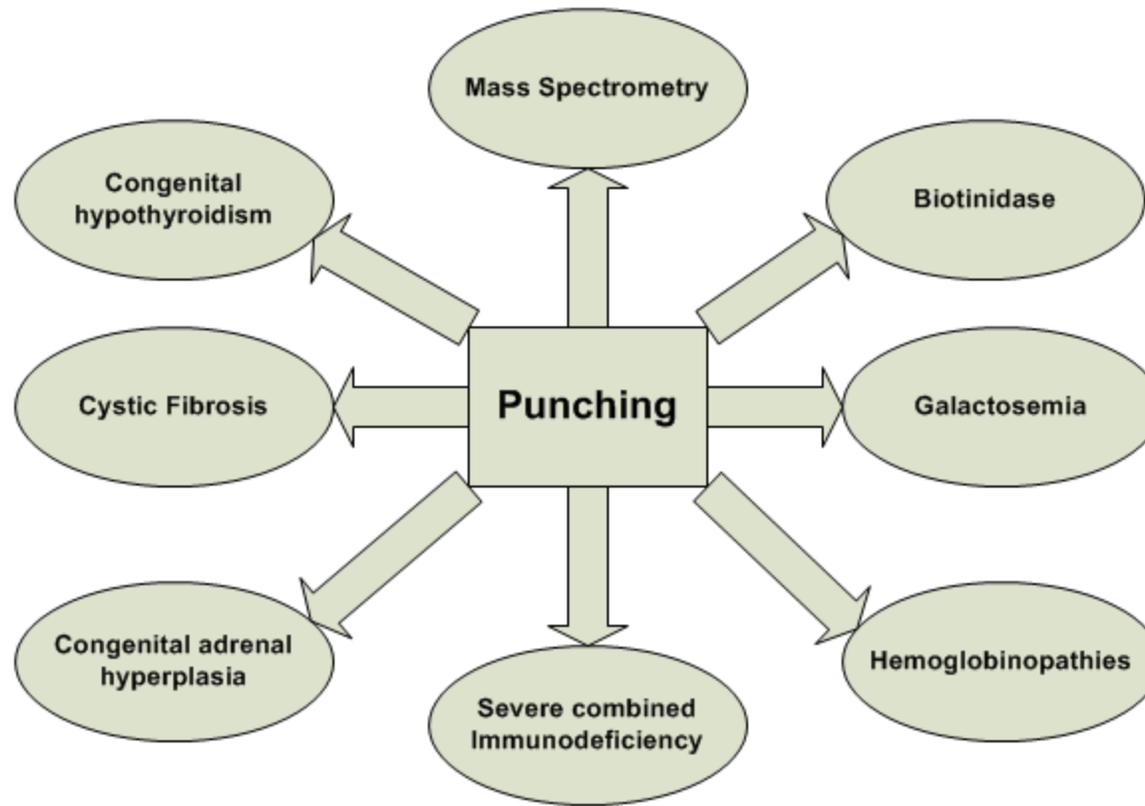
Multiplex detection of 41 metabolic disorders





Each day's specimen cards are stored in one bin





Specimens go to 8 areas when punching is completed





Scientists review all test results





This cutter separates one spot that is stored in Lansing for future use by the parent





The remaining four to five spots are sent to the Michigan Neonatal Biobank for permanent storage





# Michigan BioTrust for Health

- Michigan blood spots
  - Coded to remove identifying information
  - Stored at Michigan Neonatal Biobank
    - Archived (July 1984-April 30, 2010), *opt-out*
    - Consented (May 1, 2010-present day), *opt-in*
  - Approximately 5 million samples
  - Spot stored at MDHHS for use by parent
- Review/approval process for research use



# Michigan BioTrust for Health

The image shows the back of the brochure, which is a consent form. At the top left is the Michigan BioTrust for Health logo. To the right is a box for "Baby Name" and a box for "Admin. Use Only". Below these is a box for "Affix Label Here if Desired" with the instruction "Mark Parent Decision, Collect Signature, Return to MDCH". The main text explains that blood spots are stored indefinitely and can be used for health research. It asks the parent to choose "Yes" or "No" regarding the use of blood spots for health research. Below the choices are two columns: "Yes, my baby's blood spots may be used for health research." and "No, my baby's blood spots may not be used for health research." Each has a checkbox. Below the "Yes" column is the text "This applies to all blood spots collected for newborn screening." and below the "No" column is "There is no penalty for saying no." At the bottom, there are lines for "Parent Signature" and "Date". A barcode is on the right side with the number "4707801". A QR code is on the left side with the number "38371". At the bottom center, it says "MI Dept of Community Health Laboratory Copy".

[www.michigan.gov/biotrust](http://www.michigan.gov/biotrust)



# Michigan BioTrust for Health- Second Quarter 2015

- 86% of BioTrust consent forms returned completed
- Total number screened
  - ~68% consented yes
    - May be released for approved research
  - ~18% refusal on record
    - Blood **not** released for research
  - ~14% no BioTrust decision on record
    - Blood **not** released for research



# Testing is Completed

- Normal results are faxed or mailed from the lab to the submitter (hospital or midwife)
- All other results are referred to NBS Follow-up
- NBS final reports are posted on Michigan Care Improvement Registry (MCIR)



# NBS Follow-up

- Inconclusive, early and borderline
  - Fax request for repeat screen to
    - hospital (if inpatient)
  - OR
  - primary care provider (if discharged)
- “Time outs” for follow-up scheduled in NBS follow-up database



# NBS Follow-up

- Strong positive (aka “out of range”)
  - Fax report to primary care provider
  - Fax report to medical management center; assure referral received
- Management center assumes follow-up of strong positive referral



# Medical Management Centers

- Newborn Screening and Coordinating Program for Cystic Fibrosis (University of Michigan)
- Newborn Screening Endocrine Follow-up Program (University of Michigan)
- Sickle Cell Disease Association of America, Michigan Chapter
- Children's Hospital of Michigan Metabolic Clinic
- Children's Hospital of Michigan Coordinating Center for Primary Immunodeficiencies



# Pulse Oximetry Screening for Critical Congenital Heart Disease

- Detects low levels of oxygen before the baby has any symptoms
- Screen as close to 24 hours of life as possible, or prior to discharge
- Probe placed on baby's right hand and either foot while baby is awake, comfortable, and quiet



# CCHD Reporting

- Hospitals submit individual data by one of three ways
  - eReports
  - File Transfer Protocol (FTP)
  - Health Level-7 (HL7)



# Benefits of Reporting Individual CCHD Results

- Identify babies with missed bloodspot screens through linking with the NBS database
- Ability to determine if hospitals are following the CCHD screening protocol properly
- Assess the effectiveness of screening for various CCHDs
- Public health surveillance of CCHD occurrence and treatment



# Quality Assurance Measures

- Missed screens
- NBS advisory committees
- Performance metrics for hospitals



# Missed Screens

- NBS database linked to vital records weekly to look for missing bloodspot screens
  - Follow-up staff will contact birth hospital to determine why a screen is missing
  - If an out of hospital birth, follow-up staff mails a letter to the parents informing them of the missed screen
- Quarterly reports are received from vital records; birth attendant contacted



# NBS Advisory Committees

- Continuous improvement of testing and interpretation of screening results
- Expert advice on follow-up and treatment protocols
- Evaluation and recommendations for addition of disorders



# Hospital Performance Metrics

January – June 2015

- <2% screens collected >36 hours after birth
  - 81% of units met
- <1% screens are unsatisfactory
  - 44% of units met
- >90% of screens arrive in state lab by the appropriate day
  - 47% of units met
- >95% of birth certificates have NBS card number recorded
  - 82% of units met
- >90% of screens have a completed BioTrust consent form
  - 44% of units met
- >90% of screens have pulse oximetry screening results reported
  - 42% of units met



# Hospital Performance Metrics

January – June 2015

- 7 hospitals met all the goals:
  - Beaumont Hospital – Troy
  - Dickinson County Healthcare System
  - Holland Hospital
  - McLaren Port Huron
  - Mid-Michigan Medical Center – Midland
  - Spectrum Health Gerber Memorial
  - Spectrum Health Zeeland Hospital



# Beaumont Hospital - Troy



- Diane Moskal, NBS Coordinator
- Robert Kelly, Laboratory



# [www.michigan.gov/newbornscreening](http://www.michigan.gov/newbornscreening)

- List of disorders screened
- General information for families
- Annual reports
- Newsletters and announcements
- Hospital and homebirth guides
- Contact information for medical management centers
- Online ordering of cards and supplies

