



**Michigan Department of Health and Human Services**  
**Newborn Screening**  
**Guide for Hospitals**  
**October 2016**

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# INTRODUCTION

Newborn screening (NBS) saves lives and protects the health of Michigan newborns. Since 1965, all Michigan newborns have been screened shortly after birth to determine if they are at risk for having rare but treatable genetic disorders. If untreated, these disorders can lead to illness, physical disability, mental retardation or death. Medication and changes in diet can help prevent most health problems caused by disorders detected by NBS.

Whether your role is as a primary care provider, neonatologist, pediatric or neonatal nurse practitioner, nurse clinician, nurse, laboratory professional, administrator or support staff member, you play an important role in NBS. Most primary care providers will, at some point, receive notice of an abnormal newborn screen. Neonatal Intensive Care Unit (NICU) staff members are much more likely to deal with abnormal NBS results. Nursery staff will be involved in the follow-up of abnormal results, collection of repeat specimens, and assurance that all infants in their units have documented NBS results. While the disorders included in the NBS panel are individually rare, approximately 250 Michigan newborns are identified with these disorders each year. The Newborn Screening Guide is intended to be a reference tool and contains background information, general guidance on common issues related to NBS and specific forms and contact information.

It is important to recognize that NBS, within the hospital setting, requires specific administrative guidelines to address Michigan Department of Health and Human Services (MDHHS) NBS Program specimen collection, handling and transit time procedures. **The appointment of a hospital NBS coordinator is necessary for quality assurance and ongoing coordination within your hospital and with the State's NBS program.** The coordinator may be a nurse manager, unit nurse, laboratory technician, clerk or secretary who will coordinate quality assurance activities within the hospital and between the hospital and the NBS program.

The hospital-based NBS program must include an internal, hospital NBS protocol. Specific information each hospital should include in the protocol are instructions/materials for:

- 1) Maintaining an inventory of NBS supplies, i.e. NBS cards, forms and educational materials.
- 2) Educating hospital nursery and NICU staff on the NBS specimen collection protocol.
- 3) Recording and entering the NBS card ("kit") number on the electronic birth certificate (EBC). Note that the NBS card ("kit") number is referred to as the "metabolic number" on the EBC.
- 4) Maintaining tracking logs on NBS specimen collection, courier pick-up and screening results.
- 5) Courier pick-up for delivery of NBS specimens to the MDHHS NBS Laboratory.
- 6) Ongoing education of hospital laboratory and nursery staff regarding the NBS process within the hospital and any NBS program changes.

This guide is updated quarterly, for the latest version, please visit: [www.michigan.gov/newbornscreening](http://www.michigan.gov/newbornscreening).

# OVERVIEW OF MICHIGAN NEWBORN SCREENING

## Dried Blood Spot Screening

Michigan is a leader in NBS and now screens for more than 50 disorders plus hearing loss. See [Appendix 9](#) for a complete list of disorders included in the NBS panel. Michigan law mandates NBS. If parents object to screening, it is suggested that the hospital request that parents sign a waiver stating that they were informed of the risk to their newborn if screening is declined and return the form to the NBS Program. See [Appendix 1](#) for NBS legislation and [Appendix 8](#) for a sample waiver form for parents who do not want their newborn to be screened. This form is just an example and each hospital should develop its own form in conjunction with the hospital legal department.

Before a newborn is discharged from the hospital, a blood specimen is collected on a NBS card purchased from the NBS program. A picture of the current NBS card is included in [Appendix 3](#).

Ideally, blood specimens should be collected at 24-30 hours of life and air dried for at least three hours. The hospital should send specimens to the NBS Laboratory daily. Specimens should be sent by courier within 24 hours of collection. Courier service (same day or overnight delivery to the state NBS Laboratory) is now in place in all hospitals. Laboratory testing is typically completed within one or two days of specimen receipt, and all NBS results are mailed/faxed to the hospital that submitted the specimen. The NBS Laboratory would like all hospitals to receive NBS results by fax in order to assure prompt receipt. See [Appendix 13](#). NBS Laboratory operations are Monday through Saturday, except for some state holidays.

The NBS program is unable to perform stat laboratory testing. If you are caring for a newborn who has been previously screened and subsequently develops an acute metabolic crisis, it is appropriate to contact the NBS program to obtain screening results. However, if a newborn is suspected of having a disorder that is included in the NBS panel, the newborn should be clinically evaluated rather than assume that screening results will be available with the rapidity required in an emergency situation. Sub-specialists are available for guidance in such circumstances (see contact information, page 24)

The NBS program will notify the health care provider (or NICU) identified on the specimen card if the specimen is:

- positive for a disorder
- unsatisfactory for testing
- early (obtained before 24 hours of life)

When a newborn screen is a strong positive for a disorder, the NBS program will contact the health care provider or NICU by fax. In addition, health care providers will be contacted by appropriate sub-specialists to arrange for confirmatory testing, diagnosis and treatment.

## **Hearing Screening**

Approximately 150 hearing impaired newborns are identified annually by newborn hearing screening in Michigan. NICU infants are at increased risk for hearing loss when compared to the general newborn population. Hearing screening of newborns who are premature, ill or have birth defects can be problematic due to confounding factors presented by their conditions and the treatment required. Michigan has instituted a mandated screening and reporting system for universal newborn hearing screening. The first goal of the hospital-based program is to screen all newborns no later than one month of age. Newborns who exhibit evidence of hearing loss should have a hearing assessment by an audiologist no later than three months of age and early intervention services no later than six months of age. Hearing screening should be completed no later than one month of age through either of the following methods: Otoacoustic Emissions (OAE) or Automated Auditory Brainstem Response (AABR). Each hospital should have a hearing screening protocol in place. When the Early Hearing Detection and Intervention (EHDI) program is informed about a newborn who does not pass the hearing screen, notification is sent to the primary care provider. Please contact EHDI to receive information on how to help ensure timely follow-up for newborns. See contact information (page 22).

## **Critical Congenital Heart Disease Screening**

Congenital heart defects are the most common group of birth defects, affecting 9 in 1000 newborns. Critical congenital heart diseases (CCHDs) are those requiring surgery or catheter intervention in the first year of life. CCHDs remain one of the most significant causes of infant death in the United States.

Effective April 1, 2014, the Michigan Department of Health and Human Services (MDHHS) has implemented statewide screening of all Michigan newborns for critical congenital heart disease using pulse oximetry prior to hospital discharge. The Newborn Screening Program and the CCHD Advisory Committee recommend that newborns be screened prior to hospital discharge, as close to 24 hours of age as possible, using the approved MDHHS CCHD Screening Algorithm.

More information about CCHD screening, data reporting and educational materials for healthcare providers and parents are available on the MDHHS CCHD website [www.michigan.gov/cchd](http://www.michigan.gov/cchd).

# NEWBORN SCREENING PRACTICE AND PROCEDURE

## Role of the Newborn Screening Coordinator

The hospital NBS coordinator plays a crucial role in assuring that the NBS process is both effective and efficient. The coordinator fulfills this role by: 1) knowing how the newborn nursery/NICU, hospital laboratory and mailroom interact in the NBS process; 2) assisting NBS program staff in resolving problems.

The suggested responsibilities of the NBS coordinator are:

1. Perform quality assurance activities:
  - a. Assure that there is a NBS protocol in place describing the hospital's NBS policies and procedures. See Appendix 12 for *Hospital Specific Procedure Template*
  - b. Assure that a log is maintained to track NBS specimens, courier pick-up, and receipt of screening results.
  - c. Assure adequate inventory of NBS cards.
  - d. Provide guidance/information to nursery and laboratory staff on the importance of accurately filling out all demographic fields on the NBS card.
  - e. Assist NBS program staff in resolving problems of missing/incorrect demographic information on the NBS card and in obtaining retests when specimens were unsatisfactory for testing.
  - f. Assure that hospital NBS policies and procedures include a protocol for notifying the NBS program if parents refuse NBS testing or if a newborn death occurs after a specimen was sent to the NBS laboratory.
2. Perform educational activities:
  - a. Serve as a contact person and facilitator between the NBS program and hospital staff involved in the NBS process to:
    - i. Inform and educate hospital staff about new program guidelines and protocol changes (new disorders added to test panel, changes in specimen collection requirements, and other NBS information, as necessary).
    - ii. Disseminate information (newsletters, quality assurance (QA) reports) received from the state NBS program to appropriate hospital staff (nursing, laboratory, clinicians).
  - b. Assure that there is an adequate supply of NBS and BioTrust brochures and a mechanism for distribution to all mothers.
  - c. Work with OB department staff to incorporate NBS and BioTrust educational information in existing and future prenatal classes offered to parents.

## Completing the Newborn Screening Card

It is extremely important to fill out the NBS card completely and accurately. Press firmly using a black or blue pen and **clearly print** the information. The card will be scanned into the NBS database, so legibility is critical. The specimen submitter is legally responsible for the accuracy and completeness of the information on the NBS card. Include the following information in the spaces provided:

### INFANT INFORMATION:

- ✓ **INFANT'S NAME:** Record last name followed by first name. If no first name is available at the time of specimen collection, the last name followed by "boy" or "girl" should be used. For single mothers, use the last name of mother or last name specified by mother. DO NOT LEAVE BLANK.
- ✓ **GENDER:** Completely shade in the appropriate oval to designate newborn's gender as male or female.
- ✓ **BIRTH DATE:** Use a six-digit number (mm/dd/yy) for date of birth. For example, a birth on January 4, 2012 would be recorded as 010412.
- ✓ **BIRTH TIME:** Record time of birth in military time. For example, a birth at 4:30 p.m. would be recorded as 1630. For help with time conversions see [Appendix 14](#)
- ✓ **BIRTH WEIGHT, GRAMS:** Record the birth weight in grams in the boxes provided. Do not use pounds and ounces. Note: This information is only required on the "blue" first sample card. For help with weight conversions see [Appendix 15](#)
- ✓ **CURRENT WEIGHT, GRAMS:** Record the current weight in grams in the boxes provided. Do not use pounds and ounces. Note: This information is only required on the "pink" repeat sample card. For help with weight conversions see [Appendix 15](#)
- ✓ **WEEKS GESTATION:** Record weeks of gestation at time of birth. Note: This information is requested for both "blue" first sample and "pink" repeat sample cards.
- ✓ **SINGLE BIRTH:** Completely shade in oval for single birth.
- ✓ **MULTIPLE BIRTH ORDER:** Completely shade in oval to record birth order by "A", "B", "C" for twins, triplets, etc.
- ✓ **ANTIBIOTICS:** For the first sample specimen, check "antibiotics" if the newborn is currently receiving antibiotics or the mother was receiving ongoing antibiotics at the time of birth. Do not check antibiotics if the mother received one dose prior to a cesarean section. For the 30-day specimen, do not check antibiotics if the newborn received antibiotics in the past and is not currently receiving them.
- ✓ **SPECIMEN DATE:** Use a six-digit number (mm/dd/yy) representing the date on which the specimen was obtained.
- ✓ **COLLECTION TIME:** Record time of specimen collection in military time. For help with time conversions see [Appendix 14](#).

- ✓ **COLLECTED BY:** Record initials or employee hospital identification number of person collecting the specimen.
- ✓ **NICU/SPECIAL CARE:** Indicate if the newborn was in the NICU or special care nursery (SP Care) at the time the specimen was collected. If neither, completely shade in the oval next to “no”.
- ✓ **RBC TRANSFUSION:** Completely shade in oval “no” or “yes” to indicate whether the newborn was ever transfused with red blood cells **prior** to specimen collection. If yes, give date (mm/dd/yy) and the start time (military) of the **most recent** transfusion. For example, if the transfusion started on October 13, 2012 at 11:20 p.m., enter 101312 2320.
- ✓ **MEDICAL RECORD NUMBER BABY:** Record the birth hospital's identification or medical record number.
- ✓ **ANY TPN FEEDING:** Completely shade in oval “yes” if the newborn is receiving total parenteral nutrition (TPN) at the time the specimen is obtained -OR- received TPN within 24 hrs of specimen collection.
- ✓ **ETHNICITY:** Completely shade in oval for Hispanic or non-Hispanic. Ethnicity should be filled in first and, in addition, one of the six boxes for race should be filled in.
- ✓ **RACE:** Completely shade in the oval for one of the six racial categories after the designation of Hispanic or non-Hispanic has been selected. If the newborn has a parent in one racial category and the other parent in a different racial category, fill in the Multi-Racial oval. It is very important to fill in either the Hispanic or non-Hispanic box and in addition fill in one of the six boxes for race.

*Example 1:* One parent identifies as Hispanic and both parents identify as Black. The card should be marked Hispanic and Black.

*Example 2:* One parent identifies as Hispanic and White; the other parent identifies as non-Hispanic and Black. The card should be marked Hispanic and Multi-Racial.

*Example 3:* Neither parent identifies as Hispanic. One parent identifies as White; the other parent identifies as Black. The card should be marked non-Hispanic and Multi-Racial.

- ✓ **TYPE OF COLLECTION:** The preferred collection method is by heel stick with a single drop of blood applied directly to each circle on the filter paper. Check both “heel” *and* “capillary” if the blood was collected from the heel using a capillary tube. Note that the use of a capillary tube can result in layered, serum, clotted and damaged specimens. If the heel was not used, indicate the alternate collection method.
- ✓ **OTHER FEEDING:** Check all that apply. For instance, if a mother is both breast and bottle feeding, mark both and indicate the type of formula. Note: Human milk fortifier may or may not be milk-based. Mark both milk-base and breast if using Similac Human Milk Fortifier or Enfamil Human Milk Fortifier Acidified Liquid. Mark breast if using Prolacta.

## MOTHER INFORMATION:

- ✓ **MOTHER'S NAME:** Record last name followed by first name. If the newborn is going to be released at birth to adoptive or foster parents, provide contact information of adoptive or foster mother. Please note in black ink above the mother's name that contact information is for adoptive or foster mother. Do not place sticky notes on the card or use red ink. Neither will be recorded when the card is scanned into the system. If contact information on new parents, foster parents, or the adoption agency is not on the card, we will not be able to contact the family if necessary. We would like to avoid calling the birth mother if she is no longer responsible for the care of the newborn.
- ✓ **MOTHER'S ADDRESS:** Record mother's current street address, followed by city, state and zip code. Information about the mother is needed to locate newborns in need of clinical evaluation or retesting.
- ✓ **MOTHER'S PHONE:** Record mother's area code and home telephone number.
- ✓ **MEDICAL RECORD NUMBER-MOTHER:** Record the hospital identification or medical record number. Note: This information is only required on the "blue" first sample card.
- ✓ **BIRTH DATE:** Record the mother's date of birth (mm/dd/yy).
- ✓ **HEPATITIS B SURFACE ANTIGEN (HBsAg):** Provide date of test (mm/dd/yy) and completely shade in the appropriate oval to indicate a positive or negative result. If there is no HBsAg test result in the mother's record, the test should be done immediately. Positive HBsAg results should be reported to the MDHHS Hepatitis B program at (517) 335 9443 or [fineisp@michigan.gov](mailto:fineisp@michigan.gov). This important information helps assure that infants at risk receive the proper immunizations WITHIN 12 HOURS OF BIRTH. Note: This information is only required on the "blue" first sample card.

## PROVIDER INFORMATION:

- ✓ **PROVIDER'S NAME:** Record last name, followed by first name, of the health care provider to be notified of an unsatisfactory or positive newborn screen. If the mother does not offer a primary care provider's name, the physician in charge of the newborn nursery should be listed on the NBS card. The physician should arrange for all retesting through the hospital's outpatient laboratory. If the newborn is expected to be in the NICU for at least a week, list a staff neonatologist as the physician and write the NICU phone and fax numbers on the NBS card. If discharge is expected within a week, write the name and clinic phone and fax number of the provider who will be taking care of the newborn after discharge.
- ✓ **PROVIDER'S PHONE:** Indicate the primary care provider's area code followed by the telephone number. It is very important to provide a complete and correct number. This information is used to contact the health care provider with positive screen results and follow-up information. If the hospital newborn nursery chooses to follow-up positive results directly, provide the name and telephone number of the staff person designated to contact the family. This option is preferred for newborns without a designated primary care provider.
- ✓ **PROVIDER'S FAX:** Indicate the primary care provider's area code followed by fax number. The fax number is needed to forward to the provider screening results that require further follow-up.

## SUBMITTER INFORMATION:

- ✓ **SUBMITTER NAME:** Record the name of the submitter (this should be the birth hospital or midwife on all initial newborn screens). If abbreviation of the hospital's name is necessary, use some letters from each word in the hospital's name. For example, the abbreviation for St. Joseph Mercy Hospital would be St. Jos. Mrcy. It is acceptable to apply a pre-printed hospital label that includes the hospital name, address, phone number and the appropriate hospital code.
- ✓ **HOSPITAL CODE:** MDHHS has assigned a 3-digit hospital code for each hospital that must be recorded in the boxes provided. The 3-digit code should be listed before the two preprinted zeros. For regular nurseries, a "0" should be added to the last box (after the two preprinted zeros). For the NICU, a "1" should be added to the last box. For the special care nursery, a "2" should be added to the last box.
- ✓ **SUBMITTER ADDRESS:** Record the submitter's street address followed by the city, state and zip code.
- ✓ **SUBMITTER PHONE:** Record submitter's area code and phone number.
- ✓ **BIRTH HOSPITAL:** Record name of the birth hospital here only if different from the submitter.

Note: It is extremely important to fill out the screening card completely and accurately.



## Michigan BioTrust for Health

The Michigan BioTrust for Health (BioTrust) is a program that oversees the storage of residual dried blood spots (DBS) from NBS for their potential use in medical and public health research. Hospital staff should provide the BioTrust consent brochure entitled, *After Newborn Screening, Your Baby's Blood Spots*, to parents and ask if they are willing to grant permission to make their infant's DBS available for health research once NBS is complete. Permission is granted by marking the "yes" check box and signing the consent form located on the back of the NBS first sample card. If parents decline permission for the BioTrust, please have them mark the "no" checkbox and sign the BioTrust form. NBS program staff, upon request, will provide on-site training on the BioTrust and the parental consent process. This training is also available at [www.michigan.gov/newbornscreening](http://www.michigan.gov/newbornscreening). See [Appendix 5](#) for information on how to obtain *After Newborn Screening: Your Baby's Blood Spots* consent brochures.

If a parent declines the BioTrust, his/her newborn's DBS will still be stored unless the parent requests that the specimen be destroyed. Parents who would like to have their newborn's DBS destroyed should sign and return the *Directive to Destroy Residual Newborn Screening Blood Specimen*. If a parent is comfortable with his/her newborn's DBS being stored but not made available for research, no additional steps are necessary other than marking the "no" checkbox and signing the BioTrust consent form located on the back of the NBS first sample card.

Residual DBS of persons born after July 1984 and prior to May 2010 are currently stored and available for research through the BioTrust. Persons over the age of 18 or parents of minor children who would like to have these samples destroyed must sign and return the *Directive to Destroy Residual Newborn Screening Blood Specimen* form. Persons over the age of 18 or parents of minor children who would like these samples to remain in storage but no longer made available for research must sign and return the *Directive to Store but Not Use Dried Blood Spot Specimen for Research* form. See [Appendix 10](#) for the directive forms.

### **BIOTRUST CONSENT FORM INSTRUCTIONS:**

1. Provide the *Michigan Newborn Screening Saves Babies* brochure and the *After Newborn Screening, Your Baby's Blood Spots* BioTrust consent brochure to parents. Clarify the difference between the mandatory NBS program and the optional Michigan BioTrust for Health, which allows residual DBS to be used for research.
2. Inform parents about the *Michigan Newborn Screening Saves Lives* video and that it can be viewed either on the state NBS website ([www.michigan.gov/newbornscreening](http://www.michigan.gov/newbornscreening)) or through your hospital TV channel, if available.
3. Complete the demographic information on the front of the NBS first sample card and collect the blood specimen as usual. The BioTrust consent form for residual DBS use is attached to the back of the NBS first sample card. See [Appendix 3](#). If parents are undecided or not available to make a decision about granting consent for the BioTrust at the time the NBS specimen is collected, remove the consent form for later use. Hospital staff should write the baby's name or affix the patient label on the back of the white copy of the consent form to keep track of the form more easily after it has been separated from the card.  
*Note: each NBS card has the same unique ID number on all pages, including the BioTrust consent form. This number is used to link a baby's NBS specimen to the parent's BioTrust consent form if received at a later time in the NBS Laboratory.*
4. Prior to obtaining consent, confirm that parents have received the NBS brochure and BioTrust consent brochure:
  - The *Michigan Newborn Screening Saves Babies* brochure explains NBS and introduces the Michigan BioTrust for Health.

- The *After Newborn Screening, Your Baby's Blood Spots* consent brochure details possible research use of residual DBS and information needed for parents to decide whether to grant permission for use of these DBS for research.
5. If parents wish to allow use of their newborn's residual DBS for research, ask one parent to mark the "yes" checkbox and sign the white copy of the BioTrust consent form located on the back of the blue first sample card.
    - If consent is not granted, ask one parent to mark the "no" checkbox and sign the white copy of the BioTrust consent form. Return the white copy to the NBS Laboratory once the parent marks his/her decision and signs the consent form.
    - The bottom pink copy is for the parent to keep.
  6. Submit the white copies of the BioTrust consent form in the same envelopes used for DBS specimen cards. *Note: A consent form does not need to be in the same envelope as a particular newborn's NBS specimen card. Do NOT delay returning a newborn's NBS specimen card while waiting for the consent form!*

# Ordering Newborn Screening First and Repeat Sample Cards, Specimen Return Envelopes and Brochures

Hospital and health system supply purchasing personnel are now expected to use the NBSOnline Ordering System (NBSO) to order NBS cards. See [Appendix 5](#) for additional information.

Replacement cards are available free of charge for any card that cannot be used. Reasons could include: card pieces are torn or separated, unsatisfactory specimen, wrong demographic information is entered or parental refusal. See [Appendix 7](#) for the replacement card form.

Brochures are free of charge and shipped in quantities of 50. They can be ordered through NBSO.

For ordering and current price information, please visit [www.michigan.gov/nbsorders](http://www.michigan.gov/nbsorders).

## Specimen Collection

- Direct specimen collection from a heel puncture is preferred for optimal laboratory results. Blood collection using capillary tubes is discouraged. See [Appendix 2](#).
- Specimens should be collected between 24-30 hours of age.
- Specimens should be air dried for at least three hours and sent by courier to the NBS Laboratory within 24 hours of collection time.

## Laboratory Testing Methods

- **Tandem Mass Spectrometry (TMS):** Amino acid, organic acid and fatty acid oxidation disorders are detected by evaluation of specific TMS acylcarnitine and amino acid profiles.
- **Fluoroimmunoassay (FIA):** Congenital hypothyroidism (CH), congenital adrenal hyperplasia (CAH), and cystic fibrosis (CF) are detected by FIA for thyroid stimulating hormone (TSH), 17-hydroxyprogesterone (17-OHP) and immunoreactive trypsinogen (IRT), respectively. If a CAH screen is positive, a secondary screen for CAH by steroid profile is performed by TMS at the Mayo Biochemical Genetics Laboratory. A secondary DNA screen for 40 CF mutations is performed by the NBS Laboratory on specimens with IRT values  $\geq 96^{\text{th}}$  percentile.
- **High Performance Liquid Chromatography (HPLC) and Isoelectric Focusing (IEF):** Hemoglobinopathies, including sickle cell anemia, sickle/beta thalassemia, hemoglobin SC disease and hemoglobin H disease, are detected by HPLC (primary screen) and further differentiated by IEF (secondary screen).
- **Direct enzyme assays:** Galactosemia (galactose-1-phosphate uridylyltransferase) and biotinidase deficiency (biotinidase).

**Disorders Identified in Michigan Newborn Residents via Newborn Screening, 1965-2014**

| <b>Type of Disorder Classification<br/>(Year Screening Began)</b> | <b>Cases in<br/>2014<br/>(N)</b> | <b>Cases<br/>Through<br/>2014<br/>(N)</b> | <b>Cumulative<br/>Detection<br/>Rate</b> |
|---|----------------------------------|---|--|
| Galactosemia (1985)   | 7                                | 188                                       | 1:20,904                                 |
| Biotinidase Deficiencies (1987)                                   | 23                               | 268                                       | 1:13,636                                 |
| Amino Acid Disorders (1965)                                       | 14                               | 716                                       | 1:9,621                                  |
| Organic Acid Disorders (2005)                                     | 9                                | 69  | 1:17,028                                 |
| Fatty Acid Oxidation Disorders (2003)                             | 16                               | 208                                       | 1:6,901                                  |
| Congenital Hypothyroidism (1977)                                  | 84                               | 2,050                                     | 1:1,783                                  |
| Congenital Adrenal Hyperplasia (1993)                             | 11                               | 148                                       | 1:18,782                                 |
| Sickle Cell Disease (1987)  | 52                               | 1,785                                     | 1:2,047                                  |
| Hemoglobin H Disease (2012)                                       | 1                                | 5   | 1:67,242                                 |
| Cystic Fibrosis (October 2007)                                    | 27                               | 219                                       | 1:3,775                                  |
| Primary Immunodeficiencies (October 2011)                         | 15                               | 55  | 1:8,182                                  |
| Total   | 259                              | 5,711                                     | -  |

# Quality Assurance

The NBS program evaluates each hospital's NBS performance and provides a quarterly report to each hospital that specifies if the following selected targets have been met:

1. < 2% of specimens collected > 36 hours of life.
2. > 90% of specimens received at the NBS laboratory by the appropriate day.
3. < 1% of first and repeat sample specimens unsatisfactory for testing.
4.  $\geq$  95% of birth certificates have the newborn screening kit number recorded.
5. > 90% of specimens have a returned BioTrust or health consent form with a parental signature or refusal (i.e., not blank)
6. >90% of newborns with a dried blood spot screen have pulse oximetry screening results reported

An example of a quarterly *Newborn Screening Quality Assurance Notification* appears below:



STATE OF MICHIGAN  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
LANSING

ROCK SNYDER  
GOVERNOR

NICK LYON  
DIRECTOR

**NEWBORN SCREENING QUALITY ASSURANCE NOTIFICATION**      Covering the period: 7/1/2015 - 9/30/2015

This quarterly report provides data on hospital performance measures. The report gives your hospital monthly and quarterly totals on initial specimens received and also provides a statewide comparison. The Newborn Screening Follow-up Program selected six performance measures and set a goal for each measure.

**The goals are:**

- **Late Screens:** Less than 2% of screens collected greater than 36 hours after birth
- **Receipt by Appropriate Day:** Greater than 90% of screens arrive in state laboratory by the appropriate day
- **Unsatisfactory Screens:** Less than 1% of screens are unsatisfactory (Unsatisfactory specimens based on initial and repeat screens received)
- **Newborn Screening Card Number:** Greater than 95% of electronic birth certificates have the newborn screening card number recorded
- **Returned BioTrust for Health Consent Forms:** At least 90% of specimens have a returned BioTrust for Health consent form that is completed appropriately
- **Reported Pulse Oximetry Screening Results:** At least 90% of newborns with a dried blood spot screen have pulse oximetry screening results reported

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| 1 STATE  | July     |          |             | August   |          |             | September |          |             | Quarter  |          |             |
|--|----------|----------|-------------|----------|----------|-------------|-----------|----------|-------------|----------|----------|-------------|
| <i>Total number specimens for your hospital</i>                      | 10,115   |          |             | 9,973    |          |             | 9,337     |          |             | 29,425   |          |             |
| <i>Total number of specimens for state</i>                           | 10,115   |          |             | 9,973    |          |             | 9,337     |          |             | 29,425   |          |             |
|  | <i>n</i> | <i>%</i> | <i>Goal</i> | <i>n</i> | <i>%</i> | <i>Goal</i> | <i>n</i>  | <i>%</i> | <i>Goal</i> | <i>n</i> | <i>%</i> | <i>Goal</i> |
| <i>Late Screens for your hospital</i>                                | 101      | 1        | Met         | 95       | 1        | Met         | 94        | 1        | Met         | 290      | 1        | Met         |
| <i>Late Screens for state</i>  | 101      | 1        | Met         | 95       | 1        | Met         | 94        | 1        | Met         | 290      | 1        | Met         |
| <i>Receipt by Appropriate Day for your hospital</i>                  | 9,003    | 89       | Not Met     | 8,848    | 88.7     | Not Met     | 8,108     | 86.8     | Not Met     | 25,959   | 88.2     | Not Met     |
| <i>Receipt by Appropriate Day for state</i>                          | 9,003    | 89       | Not Met     | 8,848    | 88.7     | Not Met     | 8,108     | 86.8     | Not Met     | 25,959   | 88.2     | Not Met     |
| <i>Unsatisfactory Screens for your hospital</i>                      | 133      | 1.2      | Not Met     | 104      | 1        | Not Met     | 98        | 1        | Not Met     | 335      | 1.1      | Not Met     |
| <i>Unsatisfactory Screens for state</i>                              | 133      | 1.2      | Not Met     | 104      | 1        | Not Met     | 98        | 1        | Not Met     | 335      | 1.1      | Not Met     |
| <i>Birth certificates* for your hospital</i>                         | 9,386    |          |             | 9,262    |          |             | 8,679     |          |             | 27,327   |          |             |
| <i>Birth certificates* for state</i>                                 | 9,386    |          |             | 9,262    |          |             | 8,679     |          |             | 27,327   |          |             |
| <i>Newborn Screening Card Number for your hospital</i>               | 9,023    | 96.1     | Met         | 8,956    | 96.7     | Met         | 8,395     | 96.7     | Met         | 26,374   | 96.5     | Met         |
| <i>Newborn Screening Card Number for state</i>                       | 9,023    | 96.1     | Met         | 8,956    | 96.7     | Met         | 8,395     | 96.7     | Met         | 26,374   | 96.5     | Met         |
| <i>Returned BioTrust for Health Consent Forms for your hospital</i>  | 8,701    | 86       | Not Met     | 8,614    | 86.4     | Not Met     | 8,019     | 85.9     | Not Met     | 25,334   | 86.1     | Not Met     |
| <i>Returned BioTrust for Health Consent Forms for state</i>          | 8,701    | 86       | Not Met     | 8,614    | 86.4     | Not Met     | 8,019     | 85.9     | Not Met     | 25,334   | 86.1     | Not Met     |
| <i>Reported Pulse Oximetry Screening Results** for your hospital</i> | 7,708    | 76.2     | Not Met     | 7,410    | 74.3     | Not Met     | 6,925     | 74.2     | Not Met     | 22,043   | 74.9     | Not Met     |
| <i>Reported Pulse Oximetry Screening Results** for state</i>         | 7,708    | 76.2     | Not Met     | 7,410    | 74.3     | Not Met     | 6,925     | 74.2     | Not Met     | 22,043   | 74.9     | Not Met     |

\*This is a preliminary estimate excluding all birth certificates with NICU admission marked on the birth certificate.  
 The number of birth certificates may be different than the number of specimens due to several factors including screening refusals, increased length of time between birth and release of birth certificate to the State, and inclusion of birth certificates of infants in the NICU or SCN if that information was not marked on the birth certificate.  
 \*\*This number may be an under-estimate for some hospitals as additional records may have been received but a link was not able to be made to the newborn screen blood spot screen based on demographics provided. This is usually related to a missing or incorrect newborn screening kit number.

## NICU Protocol (includes Special Care Nursery)

Initial NBS specimens for all NICU newborns, regardless of birth weight, should be obtained at 24-30 hours of life and prior to red blood cell (RBC) transfusion. A second specimen should be obtained on all NICU newborns at 30 days of life or at discharge, whichever comes first. See [Appendix 11](#). If discharge occurs prior to the eighth day of life, a second specimen does not need to be obtained.

### TRANSFUSIONS:

It is not necessary to repeat the NICU protocol if a baby is discharged from the NICU and is later readmitted.

It is not necessary to wait until discharge to obtain a second specimen. If a NBS disorder is suspected, a NBS specimen can be ordered by the physician, obtained and forwarded to the MDHHS NBS laboratory at any time prior to discharge. Follow-up immediately on requests for an additional specimen if you are notified that a previous specimen was positive, early or unsatisfactory.

In those rare cases when the first specimen cannot be obtained prior to RBC transfusion:

- A first specimen should be obtained 28 hours post RBC transfusion start time.
- A second specimen should be obtained at discharge or 30 days of life, whichever comes first.
- A third specimen should be obtained 90 days following the last RBC transfusion.

In those rare cases when the first specimen is obtained prior to RBC transfusion but less than 24 hours of life (early screen):

- A second specimen should be obtained at 28 hours post transfusion start time.
- A third specimen should be obtained at discharge or 30 days of life, whichever comes first.

For the typical NICU newborn, the first specimen should be obtained between 24-30 hours of life and prior to RBC transfusion:

- A second specimen should be obtained at discharge or 30 days of life, whichever comes first

### EARLY SPECIMENS:

Any specimen collected at less than 24 hours of life is considered an early specimen. For newborns not admitted to the NICU, a repeat specimen is required no later than two weeks of life. Certain clinical circumstances require obtaining a specimen at less than 24 hours of life.

Collect an early specimen prior to:

- Red blood cell transfusion.
- Surgery
- Initiating extracorporeal membrane oxygenation (ECMO)

If a newborn is unlikely to survive the first 24 hours of life, a NBS specimen should be collected at the parent's discretion.

## **TOTAL PARENTERAL NUTRITION (TPN):**

TPN affects the acylcarnitine and amino acid profiles for the amino acid, fatty acid oxidation and organic acid disorders. However, after several years of tandem mass spectrometry experience, the Michigan NBS Laboratory has detected several cases of each of these disorders in newborns on TPN feeding. There have been no false negatives. As a result of this experience and the complexities involved in devising a screening algorithm that would obtain a TPN free specimen for all newborns, the Michigan NBS program does not include TPN status in the NICU screening algorithm. For NICU newborns on TPN that test positive, repeat specimens are requested using the *Isolated Elevation of Acylcarnitines or Amino Acids* letter.

## **TRANSFERRED NEWBORNS:**

- The birth hospital is responsible for ensuring that NBS specimens are collected on all newborns, regardless of age, and sent to the NBS Laboratory.
- The birth hospital should notify the receiving facility of the NBS status and include verification of screening in the transport paperwork.
- The receiving hospital should verify the screening status of all transferred newborns. If screening cannot be verified, the receiving hospital should obtain the newborn screen.
- If the newborn screen was done prior to 24 hours of life, the receiving hospital should do the 24-30 hour and 30-day or discharge screens as with other NICU newborns.
- Some results are valid on early specimens (hemoglobin, galactosemia) and obtaining this specimen will avoid the request for a 90 day specimen if there is a transfusion before a second specimen is obtained. The birthing hospital specimen also provides a link to the electronic birth record, allowing all NBS results to be available later on the Michigan Care Improvement Registry (MCIR).
- Each state has different NBS policies. If you admit a newborn transferred from another state, you should try to obtain the screening status from the birth facility. If screening status cannot be verified, collect a newborn screen. If a Michigan newborn is transferred to another state, a NBS specimen should be obtained prior to transfer.

## **NEWBORN AT HIGH RISK OF HAVING A NBS DISORDER:**

The NBS program should be notified by telephone (toll free 1-866-673-9939) if a newborn or a newborn's sibling is suspected of having a NBS disorder. A sub-specialist will be contacted and provide recommendations on clinical management prior to diagnostic confirmation.

## **NEWBORN DEATH OR PENDING DEATH:**

The NBS program should be notified if a newborn dies or is expected to die. A NBS specimen should be obtained at the parent's discretion to determine if the newborn has a NBS disorder. This information is important for parents in planning future pregnancies. Notify the NBS follow-up program (fax 517-335-9419 or 517-335-9739) when death is expected or occurs. This will prevent unnecessary notification of parents regarding subsequent screening or diagnostic testing.

# HEALTH CARE PROVIDER INFORMATION

## Follow-up of Positive NBS Results

When the NBS program identifies a strong positive NBS result, the primary care provider is immediately notified by fax. The following items are included in the fax notification:

- NBS - results
- Action required
- Sub-specialist contact information

Simultaneously, the appropriate sub-specialist is notified. The health care provider will be contacted by the consulting sub-specialist to develop a plan of action for necessary diagnostic testing and evaluation that is congruent with clinical status.

The NBS program may ask the health care provider or hospital for additional information over time as part of program evaluation and long-term follow-up. The requests for information are required for NBS follow-up and are not subject to limitations of the Health Information Portability and Accountability Act (HIPAA). See [Appendix 4](#) for an explanation of why information pertaining to follow-up of abnormal NBS results is exempt from HIPAA.

## NBS Result Request Policy

The NBS program does not give NBS results over the telephone.

NBS results are available on the Michigan Care Improvement Registry (MCIR) website at <http://www.mcir.org/> after the NBS record is successfully linked to the newborn's birth certificate and immunization record.

Alternatively, if the laboratory has completed testing, results can be obtained by faxing a request on primary care provider letterhead to (517) 335-9419 or (517) 335-9739.

The request should include:

- Baby's name and birth date
- Mother's name at time of delivery
- Primary care provider fax number
- If you are not the provider recorded on the NBS card, a parent/guardian signed release should be included with the request

If there are results for a particular test needed, please specify the disorder on your request.

## Questions on Positive Reports Received

If you receive a positive report for a baby and have questions, contact the medical management center on the letter. Medical management centers are also listed in this guide, page 24.

The following are common calls received by the NBS program for information that is available on the NBS website or in this guide:

- List of disorders included in the Michigan NBS panel
- Medical management centers
- Written instructions for completing the NBS card
- NBS specimen collection presentation
- NBS educational online tutorial
- NBS Annual Reports that give the number of confirmed cases per year

## **Documentation of NBS Results**

Documentation that a newborn has been screened should be available for every newborn and included in the medical record. The NBS Program recommends that a log be kept of each bloodspot screen collected. The log should include the following information: Baby's demographic information, mother's name and birthdate, NBS card ("kit") number and the barcode number of the NBS envelope each screen was placed in. A separate courier log should be kept that includes: The barcode number of each NBS envelope and a place for the courier to sign and date the log.

Tracking repeat specimens (because initial specimen was borderline positive, collected before 24 hours of life, post-transfusion or unsatisfactory for testing) is important. The provider is responsible for facilitating subsequent testing.

Do not assume that no news is always good news. If you cannot locate NBS results, verify that screening was done. If results are not received within two weeks following sample submission, first contact your hospital laboratory and/or medical record department for results or contact the hospital of birth for newborns transferred to your hospital. Check the Michigan Care Improvement Registry (MCIR) for NBS results. If the NBS results report cannot be found, contact the NBS Follow-up Program, 866-673-9939, to obtain a copy of the results report.

# FREQUENTLY ASKED QUESTIONS:

## **Who informs parents about NBS?**

The birth hospital is ultimately responsible for informing parents about the NBS process. Education is ideally done during the prenatal period. To facilitate talking with parents, the NBS program recommends using the *Michigan Newborn Screening Saves Babies* parent brochure as a tool. For a Michigan NBS video and other training materials please visit [www.michigan.gov/newbornscreening](http://www.michigan.gov/newbornscreening).

## **What is the chance that a newborn will have a disorder detected by NBS?**

112,790 infants were screened in 2014 and 259 (0.2%) were diagnosed with a disorder. Overall, one infant out of 435 screened was diagnosed with one of the disorders included in the Michigan NBS panel.

## **What if a newborn has a family history of a disorder detected by NBS?**

In addition to NBS, if there is a family history of a disorder detected by NBS, there should also be definitive diagnostic testing for that particular disorder. This additional diagnostic testing after birth is necessary even if prenatal testing was performed. Please inform the NBS Program if a family has a history of a disorder on the Michigan NBS panel. You may also write this information on the top of the NBS card.

## **What is the NBS Program's specimen storage policy?**

Residual NBS specimens are stored indefinitely once NBS is completed. Stored specimens may be used for quality control purposes or for new test development. Medical or public health researchers may use coded specimens through the Michigan BioTrust for Health once their proposal has been reviewed and approved by the BioTrust Scientific Advisory Board and the MDHHS Institutional Review Board. NBS specimens collected after May 1, 2010 can only be used if parental consent was granted for such research. Specimens collected prior to May 1, 2010 are available for research unless parents contact the MDHHS and opt-out.

## **Who decides what disorders are included on the NBS panel?**

Based on nationally accepted criteria, the NBS Quality Assurance Advisory Committee makes recommendations on disorder inclusion to the MDHHS director. The NBS Quality Assurance Advisory Committee meets once each year. Members include parents of affected children, health care providers, hospital representatives, and other medical experts.

## **What if I need to talk to someone at the NBS Program or a medical sub-specialist?**

Call 1-866-673-9939 to reach someone in the NBS Program or see contact information on page 24 to contact a medical sub-specialist.

# RESOURCE LIST

## **Michigan Newborn Screening**

<http://www.michigan.gov/newbornscreening>

## **Genetics Home Reference**

<http://ghr.nlm.nih.gov/>

## **Course on Newborn Screening**

<http://training.mihealth.org/>

## **National Newborn Screening and Genetics Resource Center**

<http://genes-r-us.uthscsa.edu/>

The Michigan Department of Health and Human Services NBS Program has developed a 10 min DVD to explain newborn screening to parents.

Please go to [www.michigan.gov/newbornscreening](http://www.michigan.gov/newbornscreening) to view and order this DVD.

## **American Academy of Pediatrics**

[www.aap.org](http://www.aap.org)

### **National Newborn Hearing Websites**

## **Centers for Disease Control Early Hearing Detection and Intervention**

<http://www.CDC.GOV/ncbddd/ehdi>

## **Marion Downs National Center for Infant Hearing**

<http://www.uch.edu/conditions/ear-nose-throat/hearing-loss/marion-downs-hearing-center.aspx>

## **National Center for Hearing Assessment and Management**

<http://www.infanthearing.org>

## **National Institute on Deafness and Other Communication Disorders**

<http://www.nidcd.nih.gov>

## **American Speech Language Association**

[www.asha.org](http://www.asha.org)

## **American Academy of Audiology**

[www.audiology.org](http://www.audiology.org)

## **Hands and Voices**

[www.handsandvoices.org](http://www.handsandvoices.org)

# CONTACT INFORMATION – NBS FOLLOW-UP PROGRAM

## Michigan Department of Health and Human Services Newborn Screening Follow-up

333 S. Grand Avenue,  
PO Box 30195  
Lansing, Michigan 48909

**Toll-free:** (866) 673-9939

**Phone Tree/Menu:** (517) 335-9205 or (517) 335-4181

**Fax:** (517) 335-9739 or (517) 335-9419

**E-mail:** [newbornscreening@michigan.gov](mailto:newbornscreening@michigan.gov)

**Website:** <http://www.michigan.gov/newbornscreening>

## STAFF

### **Janice Bach**

Manager  
(517) 335-8497

### **Lois Turbett**

Nurse Consultant  
(517) 335-1966

### **Karen Andruszewski**

Departmental Specialist  
(517) 335-9205

### **Rosalind Lewis-McPhaul**

Departmental Technician  
(517) 335-9205

### **Carolyn Smith**

Departmental Technician  
(517) 335-9205

### **Valerie Ewald**

Administrative/NBSO Technical Assistant  
(517) 335-8887

### **Carrie Langbo**

BioTrust Coordinator  
(517) 335-6497

### **Mary Kleyn**

Epidemiologist/Acting Director  
(517) 335-9296

### **Kristy Tomasko**

Data Analyst  
(517) 241-0332

### **Dominic Smith**

Hemoglobinopathy  
Program Coordinator  
(517) 373-5818

### **Kristen Thompson**

Program Coordinator  
(517) 373-0937

# CONTACT INFORMATION – NBS LABORATORY

**Michigan Department of Health and Human Services  
Newborn Screening Laboratory**  
3350 N. Martin Luther King Jr. Blvd.  
P.O. Box 30689  
Lansing, Michigan 48909-8189

## STAFF

**Vacant**  
Director  
Division of Chemistry and Toxicology  
(517) 335-9490

**Harry Hawkins**  
Manager  
(517) 335-8095

**Denise Archambeault**  
Departmental Technician  
(517) 335-8543

# CONTACT INFORMATION - COURIER SERVICES

## Lower Peninsula

### **Quest Diagnostics**

Toll Free: 1-866-697-8378

Press 2 “Provider”

Press 6 “Transportation Department”

Your call will be routed to a Michigan Courier Service representative and you will be asked to provide your hospital code assigned by Quest.

### **A-1 Courier Services (Sunday courier service)**

248-786-2042

## Upper Peninsula

### **United Parcel Services**

Toll Free: 1-800-877-1497

Online tracking available at [www.ups.com/tracking](http://www.ups.com/tracking)

Use account 05V0R4 when ordering UPS Express Envelopes

e-mail [newbornscreening@michigan.gov](mailto:newbornscreening@michigan.gov) for UPS shipping labels

Contact [newbornscreening@michigan.gov](mailto:newbornscreening@michigan.gov) if you need detailed NBS courier information, such as your Quest hospital code, pickup time, days and locations for your hospital

# CONTACT INFORMATION - HEARING

**Michigan Department of Health and Human Services**  
**Early Hearing Detection and Intervention**  
109 W. Michigan Avenue, 3rd floor  
P.O. Box 30195  
Lansing, MI 48909

**Phone:** (517) 335-8955

**Fax:** (517) 335-8036

**Website:** <http://www.michigan.gov/EHDI>

## STAFF

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Infant Health Unit Manager  
(517) 335-8131

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(517) 373-8601

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(517) 335-8273

**Erin Estrada**

Data Analyst  
(517) 335-8916

**Lisa Borucki**

Infant Health Unit Secretary  
(517) 335-8955

**Karen Wisinski**

Parent Consultant  
(517) 241-7066

# CONTACT INFORMATION - HEPATITIS B

**Michigan Department of Health and Human Services  
Perinatal Hepatitis B Prevention Program**

201 Townsend St.  
P.O. Box 30195  
Lansing, MI 48909

**Toll Free:** (800) 964-4487

**Phone:** (517) 335-9443

**Website:** <http://www.michigan.gov/hepatitisb>

**Patrick Fineis**

Program Coordinator  
(517) 335-9443

**Detroit Regional Office**

**Michigan Department of Health and Human Services**

3056 W. Grand Blvd. Ste 3-220  
Detroit, MI 48202

**Phone:** (313) 456-4431

**Fax:** (313) 456-0639

**Kari Tapley**

Surveillance Specialist  
(313) 456-4431

# CONTACT INFORMATION – MEDICAL MANAGEMENT CENTERS

## Sickle Cell – *Hemoglobinopathies*

### **SICKLE CELL DISEASE ASSOCIATION OF AMERICA, MICHIGAN CHAPTER, INC.**

18516 James Couzens  
Detroit, MI 48235  
(P) 313-864-4406 (F) 313-864-9980

Social work and Counseling sites (ONLY) CALL Sickle Cell Assoc. for referral

|              |               |
|--------------|---------------|
| Grand Rapids | Benton Harbor |
| Pontiac      | Flint         |
| Kalamazoo    | Muskegon      |
| Lansing      | Saginaw       |

### **CHILDREN'S HOSPITAL OF MICHIGAN**

3901 Beaubien Blvd.  
Detroit, MI 48201-2192  
(P) 313-745-5613 (F) 313-745-5237

## **Metabolic – *Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorders, Other Disorders - Galactosemia and Biotinidase Deficiency***

### **CHILDREN'S HOSPITAL OF MICHIGAN METABOLIC CLINIC**

3950 Beaubien Blvd.  
Detroit, MI 48201-2192  
(P) 313-832-9330 (F) 313-745-8030

## **Endocrine – *Congenital Hypothyroidism (CH), Congenital Adrenal Hyperplasia (CAH)***

### **PEDIATRIC ENDOCRINE FOLLOW-UP CLINIC**

University of Michigan Health System  
Department of Pediatrics  
1500 E. Medical Ctr. Dr.  
D1225 MPB, Box 0718  
Ann Arbor, MI 48109-0718  
(P) 734-647-8938 (F) 734-936-7918

### **CAH - CENTER OF EXCELLENCE**

University of Michigan Health System  
Department of Pediatrics  
1500 E. Medical Ctr. Dr.  
D1225 MPB, Box 0718  
Ann Arbor, MI 48109-0718  
(P) 734-647-8938 (F) 734-936-7918

## **Cystic Fibrosis**

### **NEWBORN SCREENING AND COORDINATING PROGRAM FOR CYSTIC FIBROSIS**

University of Michigan Health System, Department of Pediatrics  
1500 E. Medical Ctr. Dr.  
D1225 MPB, Box 0718  
Ann Arbor, MI 48109-0718  
(P) 734-647-8938 (F) 734-936-7918

## **Severe Combined Immunodeficiency**

### **CHILDREN'S HOSPITAL OF MICHIGAN COORDINATING CENTER FOR PRIMARY IMMUNODEFICIENCIES**

3901 Beaubien St., 5th floor Carls Bldg.  
Detroit, MI 48201  
(P) 313-806-6571 (Pager) 313-745-0203, enter pager number 5706 (F) 313-966-9701

# Appendix 1 - Legislative Mandates

## Public Health Code

The NBS program applies to all newborns in the State of Michigan by law. You can find the law in its entirety at the following link:

[http://www.legislature.mi.gov/\(S\(cedw22550qdahg55ceyqja2n\)\)/mileg.aspx?page=getobject&objectname=mcl-333-5431](http://www.legislature.mi.gov/(S(cedw22550qdahg55ceyqja2n))/mileg.aspx?page=getobject&objectname=mcl-333-5431)

### PUBLIC HEALTH CODE (EXCERPT) Act 368 of 1978

**333.5431 Testing newborn infant for certain conditions; reporting positive test results to parents, guardian, or person in loco parentis; compliance; fee; "Detroit consumer price index" defined; violation as misdemeanor; hardship waiver; conduct of department regarding blood specimens; pamphlet; additional blood specimen for future identification.**

Sec. 5431.

(1) A health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant shall administer or cause to be administered to the infant a test for each of the following:

- (a) Phenylketonuria.
- (b) Galactosemia.
- (c) Hypothyroidism.
- (d) Maple syrup urine disease.
- (e) Biotinidase deficiency.
- (f) Sickle cell anemia.
- (g) Congenital adrenal hyperplasia.
- (h) Medium-chain acyl-coenzyme A dehydrogenase deficiency.
- (i) Other treatable but otherwise disabling conditions as designated by the department.

(2) The informed consent requirements of sections 17020 and 17520 do not apply to the tests required under subsection (1). The tests required under subsection (1) shall be administered and reported within a time and under conditions prescribed by the department. The department may require that the tests be performed by the department.

(3) If the results of a test administered under subsection (1) are positive, the results shall be reported to the infant's parents, guardian, or person in loco parentis. A person is in compliance with this subsection if the person makes a good faith effort to report the positive test results to the infant's parents, guardian, or person in loco parentis.

(4) Subject to the annual adjustment required under this subsection and subject to subsection (6), if the department performs 1 or more of the tests required under subsection (1), the department may charge a fee for the tests of not more than \$53.71. The department shall adjust the amount prescribed by this subsection annually by an amount determined by the state treasurer to reflect the cumulative annual percentage change in the Detroit consumer price index. As used in this subsection, "Detroit consumer price index" means the most comprehensive index of consumer prices available for the Detroit area from the bureau of labor statistics of the United States department of labor.

(5) A person who violates this section or a rule promulgated under this part is guilty of a misdemeanor.

(6) The department shall provide for a hardship waiver of the fee authorized under subsection (4) under circumstances found appropriate by the department.

(7) The department shall do all of the following in regard to the blood specimens taken for purposes of conducting the tests required under subsection (1):

(a) By April 1, 2000, develop a schedule for the retention and disposal of the blood specimens used for the tests after the tests are completed. The schedule shall meet at least all of the following requirements:

## Appendix 1 - Legislative Mandates Continued

- (i) Be consistent with nationally recognized standards for laboratory accreditation and federal law.
  - (ii) Require that the disposal be conducted in compliance with section 13811.
  - (iii) Require that the disposal be conducted in the presence of a witness. For purposes of this subparagraph, the witness may be an individual involved in the disposal or any other individual.
  - (iv) Require that a written record of the disposal be made and kept, and that the witness required under subparagraph (iii) signs the record.
- (b) Allow the blood specimens to be used for medical research during the retention period established under subdivision (a), as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks under subpart A of part 46 of subchapter A of title 45 of the code of federal regulations.
- (8) The department shall rewrite its pamphlet explaining the requirements of this section when the supply of pamphlets in existence on March 15, 2000 is exhausted. When the department rewrites the explanatory pamphlet, it shall include at least all of the following information in the pamphlet:
- (a) The nature and purpose of the testing program required under this section, including, but not limited to, a brief description of each condition or disorder listed in subsection (1).
  - (b) The purpose and value of the infant's parent, guardian, or person in loco parentis retaining a blood specimen obtained under subsection (9) in a safe place.
  - (c) The department's schedule for retaining and disposing of blood specimens developed under subsection (7) (a).
  - (d) That the blood specimens taken for purposes of conducting the tests required under subsection (1) may be used for medical research pursuant to subsection (7) (b).
- (9) In addition to the requirements of subsection (1), the health professional described in subsection (1) or the hospital or other facility in which the birth of an infant takes place, or both, may offer to draw an additional blood specimen from the infant. If such an offer is made, it shall be made to the infant's parent, guardian, or person in loco parentis at the time the blood specimens are drawn for purposes of subsection (1). If the infant's parent, guardian, or person in loco parentis accepts the offer of an additional blood specimen, the blood specimen shall be preserved in a manner that does not require special storage conditions or techniques, including, but not limited to, lamination. The health professional or hospital or other facility employee making the offer shall explain to the parent, guardian, or person in loco parentis at the time the offer is made that the additional blood specimen can be used for future identification purposes and should be kept in a safe place. The health professional or hospital or other facility making the offer may charge a fee that is not more than the actual cost of obtaining and preserving the additional blood specimen.

**History:** 1978, Act 368, Eff. Sept. 30, 1978;-- Am. 1986, Act 300, Eff. Mar. 31, 1987 ;-- Am. 1987, Act 14, Imd. Eff. Apr. 14, 1987;-- Am. 1988, Act 264, Imd. Eff. July 15, 1988;-- Am. 1992, Act 81, Imd. Eff. June 2, 1992;-- Am. 1998, Act 88, Imd. Eff. May 13, 1998;-- Am. 1999, Act 138, Imd. Eff. Oct. 5, 1999;-- Am. 2000, Act 33, Imd. Eff. Mar. 15, 2000;-- Am. 2002, Act 691, Eff. Apr. 1, 2003

**Popular Name:** Act 368

**Admin Rule:** R 325.1471 et seq. of the Michigan Administrative Code.

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Rendered 11/15/2005 08:30:46

Michigan Compiled Laws Complete Through PA 196 of 2005

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Courtesy of [www.legislature.mi.gov](http://www.legislature.mi.gov)

# Appendix 1 - Legislative Mandates Continued

You can find the law in its entirety at the following link:

[http://www.legislature.mi.gov/\(li5g3jafe4e5ad55oo2kgxym\)/documents/2005-2006/publicact/pdf/2006-PA-0031.pdf](http://www.legislature.mi.gov/(li5g3jafe4e5ad55oo2kgxym)/documents/2005-2006/publicact/pdf/2006-PA-0031.pdf)

PA 31 2006

STATE OF MICHIGAN

93RD LEGISLATURE

REGULAR SESSION OF 2006

Introduced by Senators George, Hardiman, Allen, Birkholz, Kuipers, Goschka, McManus, Jacobs and Bernero

## ENROLLED SENATE BILL No. 794

AN ACT to amend 1978 PA 368, entitled "An act to protect and promote the public health; to codify, revise, consolidate, classify, and add to the laws relating to public health; to provide for the prevention and control of diseases and disabilities; to provide for the classification, administration, regulation, financing, and maintenance of personal, environmental, and other health services and activities; to create or continue, and prescribe the powers and duties of, departments, boards, commissions, councils, committees, task forces, and other agencies; to prescribe the powers and duties of governmental entities and officials; to regulate occupations, facilities, and agencies affecting the public health; to regulate health maintenance organizations and certain third party administrators and insurers; to provide for the imposition of a regulatory fee; to provide for the levy of taxes against certain health facilities or agencies; to promote the efficient and economical delivery of health care services, to provide for the appropriate utilization of health care facilities and services, and to provide for the closure of hospitals or consolidation of hospitals or services; to provide for the collection and use of data and information; to provide for the transfer of property; to provide certain immunity from liability; to regulate and prohibit the sale and offering for sale of drug paraphernalia under certain circumstances; to provide for the implementation of federal law; to provide for penalties and remedies; to provide for sanctions for violations of this act and local ordinances; to provide for an appropriation and supplements; to repeal certain acts and parts of acts; to repeal certain parts of this act; and to repeal certain parts of this act on specific dates," (MCL 333.1101 to 333.25211) by adding sections 5430 and 5432.

*The People of the State of Michigan enact:*

Sec. 5430. (1) The newborn screening quality assurance advisory committee is created in the department. The newborn screening quality assurance advisory committee shall consist of 10 members and be appointed by the department as follows:

- (a) One individual representing a Michigan nonprofit health care corporation.
- (b) One individual representing the Michigan health and hospital association.
- (c) One individual representing the Michigan state medical society.
- (d) One individual representing the Michigan osteopathic association.
- (e) One individual representing the department's medical services administration.
- (f) One individual representing the department's public health administration.
- (g) One individual who is a neonatologist with experience and background in newborn screening.
- (h) One individual representing health maintenance organizations.
- (i) Two individuals representing the general public.
- (10)

Act No. 31

Public Acts of 2006

Approved by the Governor

February 22, 2006

# Appendix 1 - Legislative Mandates Continued

Filed with the Secretary of State

February 23, 2006

EFFECTIVE DATE: February 23, 2006

2

(2) The newborn screening quality assurance advisory committee shall meet annually to review the list of newborn screening tests required under section 5431 and under department rules, regulations, and guidelines. The newborn screening quality assurance advisory committee shall, on an annual basis, submit a written report to the department regarding the appropriateness of the existing list of required newborn screening tests. The newborn screening quality assurance advisory committee shall also include in the report recommendations to revise the list to include additional newborn screening tests that are nationally recognized in the scientific literature or national standards for conditions that can be ameliorated or treated if identified by a newborn screening test and to remove certain tests that are no longer supported in the scientific literature or national standard as being effective for ameliorating or treating conditions that can be identified by newborn screening.

(3) The newborn screening quality assurance advisory committee shall conduct a financial review of any recommended changes to the list of newborn screening tests and shall include in the written report required under subsection (2) a recommendation for the increase or decrease in the amount charged pursuant to section 5431 for newborn screening tests. The recommended change shall not exceed any net change in the amount of the actual cost of any proposed additional tests and follow-up minus savings from any proposed deleted tests and follow-up.

(4) Within 30 days after the department has received the report required under subsection (2), the department may approve or reject the recommendations of the newborn screening quality assurance advisory committee. If the department does not reject the recommendations or fails to act within the 30 days, then the recommendations shall be forwarded to the standing committees in the senate and house of representatives that consider issues pertaining to public health for approval.

(5) Within 45 days after the recommendations are forwarded and received, the legislature shall approve or reject those recommendations without amendment by concurrent resolution adopted by both standing committees of the senate and house of representatives that consider issues pertaining to public health and both houses of the legislature by recorded vote. If the proposed recommendations are not submitted on a legislative session day, the 45 days commence on the first legislative session day after the recommendations are submitted. The 45 days shall include not less than 9 legislative session days. If the recommendations are not rejected within the 45-day period, the recommendations shall be considered approved, shall be adopted by the department, and shall take effect 6 months after the recommendations are adopted by both houses of the legislature or considered approved as provided under this subsection.

Sec. 5432. If a health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant, the hospital, the health department, or other facility administers or causes to be administered to the infant a hearing test and screening, then that person or facility shall report to the department, on a form as prescribed by the department, the results of all hearing tests and screens conducted on infants who are less than 12 months of age and on children who have been diagnosed with hearing loss and are less than 3 years of age. The report shall include the type, degree, and symmetry of the diagnosis, along with where and when the diagnosis was made.

This act is ordered to take immediate effect.

Secretary of the Senate

Clerk of the House of Representatives

Approved

Governor

# Appendix 2 - Blood Specimen Collection and Handling Procedure

These instructions are found on the back of each NBS kit:

**DO NOT REMOVE OVERLAY**

See attached instructions for specimen collection and sending.

Allow blood to dry for a minimum of 3 hours using the overlay for support. Close the overlay when dry. Send within 24 hours of collection.



Do not send specimens in plastic bags.



**INSTRUCTIONS FOR SPECIMEN COLLECTION AND SENDING**

**COMPLETION OF FORM**

- Legibly print and complete all information required. **Do not use red ink.**
- List submitter's return address.
- List the provider or physician who will be following the infant for well care.
- List the mother's correct address and phone number.

**COLLECTION OF THE BLOOD SPECIMEN**

- Do not touch the filter paper circles before or after collection.
- Select puncture site and cleanse with 70% isopropanol and allow heel to air dry.
- Use a sterile, disposable incision device (2.5mm wide or less and 1.0mm deep or less) to perform a swift clean incision.
- Wipe away the first drop of blood with sterile gauze.
- Gently touch the filter paper against a large drop of blood and allow a sufficient quantity of blood to soak through to completely fill the preprinted circle. Blood must be applied to only one side of the filter paper and the circle should be fully saturated.
- Do not use capillary tubes or other devices that contain EDTA or Heparin.
- Apply one large drop of blood to each circle. Fill a minimum of 5 circles.
- Protect specimens from accidental contact with liquids.
- Allow blood specimen to air dry horizontal at room temperature for a minimum of 3 hours. Do not stack wet specimens. Do not expose specimens to heat, direct sunlight, or high humidity.

**RIGHT**



**WRONG**





**ACCEPTABLE**

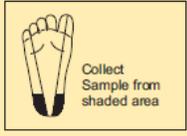
Circle filled and evenly saturated

**UNACCEPTABLE**

Layering

Insufficient, multiple applications

Serum rings present



Collect Sample from shaded area

**SEND SPECIMENS TO:**  
 Newborn Screening Laboratory  
 Michigan Department of Health & Human Services  
 3350 N. Martin Luther King Jr. Blvd.  
 PO Box 30689  
 Lansing, MI 48909-8189

**Program Phone Numbers**  
 Newborn Screening: 1-866-673-9939  
 Newborn Hearing: (517) 335-8955  
 Hepatitis Program: (517) 335-8122

**For information on Newborn Screening card, envelope and brochure ordering visit:**  
[www.michigan.gov/NBSorders](http://www.michigan.gov/NBSorders)  
 or call (517) 335-8887

**SEND SPECIMENS BY COURIER WITHIN 24 HOURS OF COLLECTION**

PerkinElmer Health Sciences, Inc.  
 07 Penn Plaza, Greenville, SC 29615 USA

Please follow the Clinical and Laboratory Standards Institute (CLSI) guidelines for NBS specimen collection. Refer to the CLSI website for additional information.

[www.clsi.org](http://www.clsi.org)

# Appendix 3 - NBS Card Images

## NBS First Sample ("blue") Card

DC18-1153 Printed: 10/15  
Newborn Screening - Michigan Department of Health and Human Services  
Bureau of Laboratories P.O. Box 20689 3350 N. MLK, Jr. Blvd. Lansing MI 48909  
Print Firmly with Black Pen  
DO NOT USE RED INK

|   |                       |  |                                       |   |                              |
|---|-----------------------|--|---------------------------------------|---|------------------------------|
| LAST NAME   |                       | FIRST NAME                             |                                       | GENDER<br><input type="radio"/> MALE<br><input type="radio"/> FEMALE  |                              |
| BIRTH DATE  | BIRTH TIME (Military) | BIRTH WT. (grams)                      | WGS GESTATION                         | BIRTH ORDER<br>A B C D  | ANTIBIOTICS?<br>NO YES       |
| SPECIMEN DATE   |                       | COLLECTION TIME (Military)             | Collected By: (initials)              | ANY REC TRANSFUSION?<br>NO YES  | TRANS. START TIME (Military) |
| MEDICAL RECORD #  |                       | TPN / AMINO ACIDS<br>NO YES            | NICU or SPECIAL CARE?<br>NICU SP CARE | HEPATITIS B SURFACE ANTIGEN (HbsAg)<br>TEST DATE RESULT<br><input type="radio"/> POSITIVE<br><input type="radio"/> NEGATIVE         |                              |
| TYPE OF COLLECTION:<br><input type="radio"/> Heel Stick <input type="radio"/> Capillary Tube <input type="radio"/> Line Draw (central, other) |                       | Type of Flush (heparin, saline, other) |                                       | OTHER FEEDING:<br><input type="radio"/> BREAST <input type="radio"/> MILK-BASE <input type="radio"/> SOY <input type="radio"/> NONE |                              |
| LAST NAME   |                       | FIRST NAME                             |                                       | HOSPITAL CODE (if applicable)<br>00   |                              |
| ADDRESS   |                       | CITY                                   |                                       | STATE ZIP   |                              |
| PHONE   |                       | FAX                                    |                                       | SUBMITTER NAME  |                              |
| CITY  |                       | STATE ZIP                              |                                       | PHONE   |                              |
| BIRTH HOSPITAL (if different from submitter)  |                       | MDHHS USE ONLY                         |                                       | EXP. 2018-10  |                              |

MDHHS  
By Authority of Act 568  
P.A. MCLA 333.5431  
PerkinElmer Z26

2097001

DO NOT REMOVE OVERLAY

See attached instructions for specimen collection and sending.

Allow blood to dry for a minimum of 3 hours using the overlay for support. Close the overlay when dry. Send within 24 hours of collection.

Do not send specimens in plastic bags.

BIOHAZARD

## Michigan BioTrust for Health Consent Form (Attached to the back of the NBS first sample card)

38371

Before you sign this form please read, *Your Baby's Blood Spots*. It explains in more detail how your baby's blood spots may be used in health research through the Michigan BioTrust for Health. If you still have questions, please call the Michigan Department of Health and Human Services (MDHHS) toll free at 1-866-673-9939.

**Yes, my baby's blood spots may be used for health research through the BioTrust.**  
By checking this box you understand:

- Unused blood spots are stored using a code and not your child's name. The spots are stored forever at a secure site (Biobank) unless you, or your grown child, change your mind.
- Stored blood spots may be used by the state lab to help ensure that newborn screening detects those at risk. Stored blood spots may also be used for research approved by MDHHS. Blood spots can only be used for studies to better understand disease or improve the public's health.
- Many types of laboratory methods are used to study biological factors like DNA or environmental factors like metals and toxins.
- The risk for using your baby's blood spots in research is that it could be identified. This risk is very low. Many steps are taken to protect privacy. Details that could identify your child or family are removed before your child's blood spots are given to a researcher.
- Most likely you or your child will not benefit from blood spot research.
- Participation is voluntary. You can call MDHHS at any time if you change your mind. There is no penalty or loss of benefits for saying no or changing your mind.

**No, my baby's blood spots may not be used for health research.**  
By checking this box you understand:

- Blood spots will be stored forever but not used for research. These stored blood spots may still be used by the state lab to help ensure that newborn screening detects those at risk.
- You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

Parent Signature \_\_\_\_\_ Date \_\_\_\_\_

Your choice applies to all blood spots collected for newborn screening. Please visit [www.michigan.gov/bidns](http://www.michigan.gov/bidns) for further information including research updates. For questions about your research rights or whom to contact in case of a research-related injury, please call the MDHHS IRB at 517-241-1928.

MDHHS Copy

2097001

If obtained, affix patient label on the back of the white consent form. Instruct parent to use BioTrust brochure. Collect parent decision and signature. Return completed white consent form to MDHHS. Give parent this copy.

DO NOT REMOVE OVERLAY

See attached instructions for specimen collection and sending.

Allow blood to dry for a minimum of 3 hours using the overlay for support. Close the overlay when dry. Send within 24 hours of collection.

Do not send specimens in plastic bags.

BIOHAZARD

## **Appendix 4 – Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule**

The HIPAA Privacy Rule recognizes the need for public health programs to access protected health information (PHI) to conduct public health activities to prevent or control disease, injury or disability. The Privacy Rule\* expressly permits release of PHI relating to newborn screening, without individual authorization, from a covered entity to state public health departments or agencies contacted, by public health departments, to provide newborn screening follow-up.

\* [www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm)

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# Appendix 5

## An Introduction to NBSOnline Ordering System (NBSO)

*For hospital & health system supply purchasing staff*

### ⇒ What is needed to place an order?

- a) For brochures and specimen mailing envelopes available at no charge, only registration in NBSO is required.
- b) For NBS cards that need to be purchased, registration in NBSO is also required, along with payment using eCheck or a credit card.\* Because NBSO requires immediate payment when an order is placed, check with your accounting office to see which form of payment will work best with your hospital's purchasing policies.

### ⇒ Use this URL to access the NBS Orders website: [www.michigan.gov/NBSorders](http://www.michigan.gov/NBSorders)

### ⇒ Then follow these steps to get started:

1. Click NBSOnline Web Store - Order NOW!
2. Click Register
3. If you are purchasing for multiple medical facilities, click on each of the hospitals for which you do purchasing - a check mark will appear.
4. Upon completion of registration process, a link will be sent to the email address used to register. Click the link. This will take you to the online ordering system and you're ready to place your first order.
5. If you are using eCheck to make your purchase, please call 517-335-8887 to get your permanent eCheck verification code, which will need to be used for all future orders.

### ⇒ Still have questions? For more instruction on using NBSO, please refer to the *NBSO Registration and Order Guide*, available at [www.michigan.gov/NBSorders](http://www.michigan.gov/NBSorders), or contact the NBSO Administrator Valerie Ewald at [nbsorders@michigan.gov](mailto:nbsorders@michigan.gov) or 517-335-8887 if you have trouble placing an order.

**\*NBSO Payment Options:** The NBSO system allows you to enter your hospital's purchase order number and assign it to your order. Payment options include eCheck or credit card. These payments will be processed through the PayPlace, a secure site used by the State of Michigan for financial transactions. (Read the privacy policy at <https://uat.thepayplace.com/epayconsumerweb/mi/dch/newbornscreencheck/cpprivacy.aspx>)

EChecks are an efficient and secure form of payment. They are used just like a check but the bank routing number and account number will be entered electronically on the web-based order form instead of on a paper check. ECheck is NOT the same as an electronic fund transfer (EFT). An eCheck is processed like a check and the account is not debited until the check clears. To learn more about eChecks, please see

<http://quickbooks.intuit.com/facts-about-electronic-checks/>.

If you are using a credit card, make sure the approved credit limit on the card is sufficient to cover the full cost of cards being purchased, and that the name, billing address and zip code associated with the credit card account match the information you enter in PayPlace.

## Appendix 6

### NEWBORN SCREENING TEST - WAIVER/CARD ORDER FORM

This form does not apply to hospital births. Refer to the *Michigan Newborn Screening Guide for Homebirths* for information on how to obtain a fee-waived NBS card.

---

# Appendix 7- NEWBORN SCREENING CARD REPLACEMENT FORM

Date: \_\_\_\_\_



FACILITY NAME: \_\_\_\_\_

ATTN: (DEPT) \_\_\_\_\_

ADDRESS: \_\_\_\_\_

CITY, STATE, ZIP: \_\_\_\_\_

CONTACT NAME: \_\_\_\_\_ TELEPHONE # \_\_\_\_\_

NUMBER OF CARDS RETURNED FOR REPLACEMENT: \_\_\_\_\_

I.D. NUMBERS ON THE CARDS RETURNED:

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

- This form should be filled out completely and mailed with the white face sheet(s) only of the card(s) intended for replacement to the address below. **It is not necessary to include the remaining portions of the kit.**
- To ensure a quicker turnaround time, send 10 face sheets or less.
- If there is blood on the white face sheet, place it in a biohazard bag.
- **DO NOT send card replacement requests to the NBS Laboratory.** Failure to send your request to the address below may result in no replacement card being issued. Please note: Courier envelopes are for bloodspot specimens. **DO NOT** use courier envelopes for card replacement requests.

SEND FACE SHEET(S) OF CARD(S) TO BE REPLACED AND THIS FORM TO:

**Michigan Department of Health and Human Services**  
**Attn: Newborn Screening**  
333 S. Grand Ave., 2<sup>nd</sup> floor  
PO Box 30195  
Lansing, Michigan 48909

## Appendix 8 - Parental Refusal for Newborn Screening

(Page 1 of 2)

I (We) \_\_\_\_\_, the parent(s) or guardian(s) of

\_\_\_\_\_, birth date \_\_\_\_\_, object to and refuse the requirement that my (our) child be screened for the presence of the disorders listed on the enclosed Michigan Department of Health & Human Services (MDHHS) newborn screening panel and posted at [www.michigan.gov/newbornscreening](http://www.michigan.gov/newbornscreening).

I (We) have been fully informed of and fully understand the possible devastating consequences to my (our) child's health, including severe mental and/or physical impairment or death resulting from the disorders screened for by the MDHHS Newborn Screening (NBS) Program.

Therefore, I (we) release the Michigan Department of Health & Human Services, the hospital of birth and the person responsible for collection of the specimen from responsibility for screening my (our) child for the disorders listed on the MDHHS newborn screening panel. Furthermore, I (we) release and hold the Michigan Department of Health & Human Services, the hospital of birth and the person responsible for collection of the specimen harmless for any injury, illness, and/or sequelae that may result to my (our) child as a consequence of my (our) refusal to consent to the screening for the disorders listed on the MDHHS newborn screening panel.

\_\_\_\_\_  
Signature of parent or guardian

\_\_\_\_\_  
date

\_\_\_\_\_  
Signature of parent or guardian

\_\_\_\_\_  
date

\_\_\_\_\_  
Signature of witness

\_\_\_\_\_  
date

\_\_\_\_\_  
Signature of witness

\_\_\_\_\_  
date

Return signed copy by mail:

MDHHS  
NBS Follow-up SG2  
P. O. Box 30195  
Lansing, MI 48909

Or fax to:

Fax: 517-335-9419 or 517-335-9739

To assist in improving the newborn screening program we ask that you please indicate why you are refusing the blood spot test for your baby:

Cannot afford to pay for the card       Religious reasons       Privacy concerns

Other: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

# Appendix 9 - Disorder List

(Page 2 of 2)

The Newborn Screening Laboratory screens all Michigan Infants for more than fifty disorders.

## Amino Acid Disorders

1. Argininemia (ARG)
2. Argininosuccinic acidemia (ASA)
3. Citrullinemia Type I (CIT-I)
4. Citrullinemia Type II (CIT-II)
5. Homocystinuria (HCY)
6. Hypermethioninemia (MET)
7. Maple syrup urine disease (MSUD)
8. Phenylketonuria (PKU)
  9. Benign hyperphenylalaninemia defect (H-PHE)
  10. Biopterin cofactor biosynthesis defect (BIOPT-BS)
  11. Biopterin cofactor regeneration defect (BIOPT-REG)
12. Tyrosinemia Type I (TYR-1)
  13. Tyrosinemia Type II (TYR-II)
  14. Tyrosinemia Type III (TYR-III)

## Fatty Acid Oxidation Disorders

15. Carnitine acylcarnitine translocase deficiency (CACT)
16. Carnitine palmitoyltransferase I deficiency (CPT-1A)
17. Carnitine palmitoyltransferase II deficiency (CPT-II)
18. Carnitine uptake defect (CUD)
19. Dienoyl-CoA reductase deficiency (DERED)
20. Glutaric acidemia type II (GA-2)
21. Long-chain L-3-hydroxy acyl-CoA dehydrogenase deficiency (LCHAD)
22. Medium/short-chain L-3-hydroxy acyl-CoA dehydrogenase deficiency (M/SCHAD)
23. Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)
24. Medium-chain ketoacyl-CoA thiolase deficiency (MCKAT)
25. Short-chain acyl-CoA dehydrogenase deficiency (SCAD)
26. Trifunctional protein deficiency (TFP)
27. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)

## Organic Acid Disorders

28. 2-Methyl-3-hydroxy butyric aciduria (2M3HBA)
29. 2-Methylbutyryl-CoA dehydrogenase deficiency (2MBG)
30. 3-hydroxy 3-methylglutaric glutaric aciduria (HMG)
31. 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC)
32. 3-Methylglutaconic aciduria (3MGA)

33. Beta-ketothiolase deficiency (BKT)
34. Glutaric acidemia type I (GA1)
35. Isobutyryl-CoA dehydrogenase deficiency (IBG)
36. Isovaleric acidemia (IVA)
37. Malonic Acidemia (MAL)
38. Methylmalonic acidemia cobalamin disorders (Cbl A,B)
39. Methylmalonic aciduria with homocystinuria (Cbl C,D)
40. Methylmalonic acidemia methylmalonyl-CoA mutase (MUT)
41. Multiple carboxylase deficiency (MCD)
42. Propionic acidemia (PROP)

## Hemoglobinopathies

43. S/Beta thalassemia
44. S/C disease
45. Sickle cell anemia
46. Variant hemoglobinopathies
47. Hemoglobin H disease

## Endocrine Disorders

48. Congenital adrenal hyperplasia (CAH)
49. Congenital hypothyroidism (CH)

## Other Disorders

50. Biotinidase deficiency (BIOT)
51. Galactosemia (GALT)
52. Cystic fibrosis (CF)
53. Severe combined immunodeficiency (SCID)
  54. T-cell related lymphocyte deficiencies
55. Hearing
56. Critical Congenital Heart Disease (CCHD)

## Disorders Coming Soon

These conditions have been approved for addition to Michigan's panel but implementation is in progress and screening has not yet begun.

- Glycogen Storage Disease Type II (Pompe)
- Mucopolysaccharidosis Type I (MPS I)
- X-linked Adrenoleukodystrophy (X-ALD)

# Appendix 10 – Specimen Directives

Michigan Department of Community Health

## Directive to Destroy Residual Newborn Screening Blood Specimen

|   |  |
|---|--|
| Child's Name at Birth:                  | Date of Birth:   |
| Child's Current Name:                   | Circle Birth Order if Multiple Birth:<br>1st 2nd 3rd 4th 5th |
| Mother's Name at Time of Child's Birth: | Hospital of Birth:   |

I am a legal representative\* of the child named above. By signing below, I hereby request the Michigan Department of Community Health to destroy my child's (or my own) blood specimen after newborn screening has been completed. I understand that by destroying this blood specimen, it will NOT be available for any future use including medical, identification, or research purposes.

|   |       |                        |        |
|---|-------|------------------------|--------|
| Signature of parent, guardian, or other legal representative: |       | Relationship to child: |        |
| Printed name:   |       | Date:                  |        |
| Street Address:   | City: | Zip:                   | Phone: |

\* **“Legal representative”** means a parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

The identity of the person(s) signing this form must be authenticated. Please attach a copy of:  
**1) the child's birth certificate and 2) driver's license, state-issued identification card, or passport** of person(s) who signed above. Additional identifying documents may be requested.

⇒ **Mail completed form with required copies to:**

Michigan Department of Community Health  
 Newborn Screening Laboratory Section  
 3350 N. Martin Luther King, Jr. Blvd.  
 P.O. Box 30035  
 Lansing, MI 48909

Please state why you are making this request. (*This will help improve the newborn screening program, but you do not have to complete this section.*)

Privacy concerns       Not comfortable with research       Other: \_\_\_\_\_

---



---

|                   |  |  |
|-------------------|--|--|
| <b>Authority:</b> | Michigan Public Health Code, Act 368 of 1978 | The Michigan Department of Community Health is an equal opportunity employer, services, and program provider |
|-------------------|--|--|

DCH-1448 Rev 10/2014

# Appendix 10 - Specimen Directives Continued

Michigan Department of Community Health

## Directive to Remove Residual Newborn Screening Blood Specimen from Possible Research Uses

|   |  |
|---|--|
| Child's Name at Birth:                  | Date of Birth:   |
| Child's Current Name:                   | Circle Birth Order if Multiple Birth:<br>1st 2nd 3rd 4th 5th |
| Mother's Name at Time of Child's Birth: | Hospital of Birth:   |

I am a legal representative\* of the child named above. By signing below, I hereby request the Michigan Department of Community Health to **not** use my child's (or my own) blood specimen for possible future research after newborn screening is complete. I understand that the specimen will be retained by the laboratory but not used for research of any kind unless directed otherwise in writing by a legal representative.

|   |       |                        |        |
|---|-------|------------------------|--------|
| Signature of parent, guardian, or other legal representative: |       | Relationship to child: |        |
| Printed name:   |       | Date:                  |        |
| Street Address:   | City: | Zip:                   | Phone: |

\* **“Legal representative”** means a parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

⇒ **Fax completed form to: (517) 335-9776**

**OR**

⇒ **Mail to:**

Michigan Department of Community Health  
Newborn Screening Laboratory Section  
3350 N. Martin Luther King, Jr. Blvd.  
P.O. Box 30035  
Lansing, MI 48909

Please state why you are making this request. (*This will help improve the newborn screening program, but you do not have to complete this section.*)

Privacy concerns       Not comfortable with research       Other: \_\_\_\_\_

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|                   |  |  |
|-------------------|--|--|
| <b>Authority:</b> | Michigan Public Health Code, Act 368 of 1978 | The Michigan Department of Community Health is an equal opportunity employer, services, and program provider |
|-------------------|--|--|

# Appendix 11 - NICU and Special Care Nursery Algorithm

## NICU SCREENING ALGORITHM

For All NICU Newborns **NOT** Transfused

**FIRST SPECIMEN**  
24-30 Hours of Life

**SECOND SPECIMEN**  
30 Days of Life or at Discharge  
*Whichever comes first*

For All NICU Newborns Transfused with Red Cells  
**PRIOR** to First Specimen

**TRANSFUSED**

**FIRST SPECIMEN**  
28 Hours Post Transfusion Start

**SECOND SPECIMEN**  
30 Days of Life or at Discharge  
*Whichever comes first*

**THIRD SPECIMEN**  
90 Days Post Last Transfusion

For All NICU Newborns Transfused with Red Cells  
**AFTER** First Specimen

**FIRST SPECIMEN**  
≥ 24 Hours of Life

**TRANSFUSED**

**SECOND SPECIMEN**  
30 Days of Life or at Discharge  
*Whichever comes first*

**OR**

**FIRST SPECIMEN**  
< 24 Hours of Life

**TRANSFUSED**

**SECOND SPECIMEN**  
28 Hours Post Transfusion Start

**THIRD SPECIMEN**  
30 Days of Life or at Discharge  
*Whichever comes first*

May, 2014

# Appendix 12

## MICHIGAN NEWBORN SCREENING HOSPITAL SPECIFIC PROCEDURE TEMPLATE

HOSPITAL # \_\_\_\_\_

NICU # \_\_\_\_\_

*(NICU will have a 01 at the end)*

### HOSPITAL COORDINATOR

Name: \_\_\_\_\_

Phone: \_\_\_\_\_

FAX: \_\_\_\_\_

### CARD INFORMATION

Cards are ordered by: \_\_\_\_\_

Cards are stored: \_\_\_\_\_

Cards are filled out by: \_\_\_\_\_

Cards are sent to the state lab by: \_\_\_\_\_

Contact information for Quest or UPS \_\_\_\_\_

### Reports for the State of Michigan Laboratories and Newborn Screening Follow-up

Reports are received by: \_\_\_\_\_

Process for notifying physicians \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

### ELECTRONIC BIRTH RECORDS

Person who enters electronic birth record: \_\_\_\_\_

Method to get "NBS CARD NUMBER" to them to add to the Electronic Birth Record (EBR)

### NURSE EDUCATION

- Procedure for training nurses or lab technician to get the blood specimen
- Procedure for drying the specimen and sending the specimen
- Procedure for training nurses/lab technician to be able to answer general information about NBS and BioTrust
- Procedure for informing parents about BioTrust; obtaining consent for possible research use
- Information about specific disorders that are screened by NBS

### NICU SPECIFIC INFORMATION

- NICU Algorithms

### DEATH OF AN INFANT

- Notifying NBS Follow-up when an infant dies (Please FAX to 517-335-9419)

# Appendix 13 – Fax Reporting



## Automatic Fax Reporting of Newborn Screening Results

The Michigan Department of Health and Human Services encourages the receipt of Newborn Screening laboratory reports via an AUTOMATIC FAX TRANSMISSION. Fax reporting provides significant improvement in screening result turn around time to your facility.

There are two requirements to convert your facility to an AUTOMATIC FAX TRANSMISSION AGENCY:

- 1) A letter on your agency letterhead must be sent to the MDHHS Bureau of Laboratories, Newborn Screening consenting to becoming an automatic fax agency, and be signed by a person who is authorized to make this request.
- 2) The following statement of understanding (on next page) must be completed, signed and returned along with the consenting letter.

The letter and agreement may be faxed to (517) 335-8550 or mailed to MDHHS at the following address:

Michigan Department of Health and Human Services  
Bureau of Laboratories, Newborn Screening Section  
3350 Martin Luther King, Jr. Boulevard  
Lansing, MI 48909

AUTO FAX reporting can occur anytime during the day or night, including weekends. Expect the same number of pages per patient as are currently mailed. Faxes that fail to get through after several automatic redial attempts will be resent promptly.

If your agency chooses this fax reporting option, the delivery of Newborn Screening laboratory reports through the United States Postal System will be eliminated.

**A secure FAX must be available 24 hours per day, 7 days per week (24/7) to receive reports.**

**Please notify MDHHS Newborn Screening Laboratory if your FAX machine is down for repairs.** If an alternate, secure FAX number is available; reporting can be promptly changed to the alternate FAX.

**Please notify MDHHS when your secure FAX number is again operational.** If your FAX machine is down, and you do not have an alternate secure FAX, reports will be mailed until your machine is operational, without any unnecessary delays.

**It is the responsibility of your agency to maintain a secure FAX line.**

If you have any further questions, please contact Harry Hawkins by telephone at 517-335-8095 or e-mail at [hawkinsh@michigan.gov](mailto:hawkinsh@michigan.gov)

Please keep this letter for your records

# Appendix 13 – Fax Reporting Continued



## STATEMENT OF UNDERSTANDING

### AGENCIES SELECTING AUTOMATIC FAX TRANSMISSION OPTION

1. I understand that all newborn screening reports of patient testing by the MDHHS Bureau of Laboratories will be sent to this agency by FAX transmission.
2. I understand that upon conversion to a fax transmission agency, no hard copy reports will be sent using the United States Postal Service.
3. The FAX number provided to MDHHS is a **secure facsimile machine**. To be a secure facsimile machine, the following criteria must be met:
  - ✓ Only persons authorized to review confidential clinical laboratory test results use or otherwise have access to incoming FAX transmissions.
  - ✓ The facsimile machine is in a secure location during non-business hours in the event that FAX transmittal occurs after normal business hours.

Date: \_\_\_\_\_ Hospital Code: \_\_\_\_\_

Hospital Name: \_\_\_\_\_

Address: \_\_\_\_\_

Authorized Signature: \_\_\_\_\_

Secure FAX Number: \_\_\_\_\_

Contact Person for FAX Problems *(please print)* \_\_\_\_\_

Contact Person's Phone Number for Problems \_\_\_\_\_

**Please keep a copy for your records**

## Appendix 14 - Military Time

Military time is a concise method of expressing time used by the military, law enforcement, hospitals, and other entities. Military time uses a 24-hour time scale that makes the use of a.m. or p.m. unnecessary. Midnight corresponds to 0000, 1 p.m. corresponds to 1300, and so on.

The following table provides a convenient way to convert between military time and regular time.

| Regular Time | Military Time | Regular Time | Military Time |
|--------------|---------------|--------------|---------------|
| Midnight     | 0000          | Noon         | 1200          |
| 1:00 a.m.    | 0100          | 1:00 p.m.    | 1300          |
| 2:00 a.m.    | 0200          | 2:00 p.m.    | 1400          |
| 3:00 a.m.    | 0300          | 3:00 p.m.    | 1500          |
| 4:00 a.m.    | 0400          | 4:00 p.m.    | 1600          |
| 5:00 a.m.    | 0500          | 5:00 p.m.    | 1700          |
| 6:00 a.m.    | 0600          | 6:00 p.m.    | 1800          |
| 7:00 a.m.    | 0700          | 7:00 p.m.    | 1900          |
| 8:00 a.m.    | 0800          | 8:00 p.m.    | 2000          |
| 9:00 a.m.    | 0900          | 9:00 p.m.    | 2100          |
| 10:00 a.m.   | 1000          | 10:00 p.m.   | 2200          |
| 11:00 a.m.   | 1100          | 11:00 p.m.   | 2300          |

# Appendix 15 - Weight Conversion Chart

## CONVERT POUNDS AND OUNCES TO GRAMS

| Ounces | Pounds |     |      |      |      |      |      |      |      |      |      |      |      |
|--------|--------|-----|------|------|------|------|------|------|------|------|------|------|------|
|        | 0      | 1   | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | 10   | 11   | 12   |
| 0      |        | 454 | 907  | 1361 | 1814 | 2268 | 2722 | 3175 | 3629 | 4082 | 4536 | 4990 | 5443 |
| 1      | 28     | 482 | 936  | 1389 | 1843 | 2296 | 2750 | 3203 | 3657 | 4111 | 4564 | 5019 | 5471 |
| 2      | 57     | 510 | 964  | 1417 | 1871 | 2325 | 2778 | 3232 | 3685 | 4139 | 4593 | 5046 | 5500 |
| 3      | 85     | 539 | 992  | 1446 | 1899 | 2353 | 2807 | 3260 | 3714 | 4167 | 4621 | 5075 | 5528 |
| 4      | 113    | 567 | 1021 | 1474 | 1928 | 2381 | 2835 | 3289 | 3742 | 4196 | 4649 | 5103 | 5557 |
| 5      | 142    | 595 | 1049 | 1503 | 1956 | 2410 | 2863 | 3317 | 3770 | 4224 | 4678 | 5131 | 5585 |
| 6      | 170    | 624 | 1077 | 1531 | 1984 | 2438 | 2892 | 3345 | 3799 | 4252 | 4706 | 5160 | 5613 |
| 7      | 198    | 652 | 1106 | 1559 | 2013 | 2466 | 2920 | 3374 | 3827 | 4281 | 4734 | 5188 | 5642 |
| 8      | 227    | 680 | 1134 | 1588 | 2041 | 2495 | 2949 | 3402 | 3856 | 4309 | 4763 | 5216 | 5670 |
| 9      | 255    | 709 | 1162 | 1616 | 2070 | 2523 | 2977 | 3430 | 3884 | 4337 | 4791 | 5245 | 5698 |
| 10     | 284    | 737 | 1191 | 1644 | 2098 | 2551 | 3005 | 3459 | 3912 | 4366 | 4819 | 5273 | 5727 |
| 11     | 312    | 765 | 1219 | 1673 | 2126 | 2580 | 3034 | 3487 | 3941 | 4394 | 4848 | 5301 | 5755 |
| 12     | 340    | 794 | 1247 | 1701 | 2155 | 2608 | 3062 | 3515 | 3969 | 4423 | 4876 | 5330 | 5783 |
| 13     | 369    | 822 | 1276 | 1729 | 2183 | 2637 | 3091 | 3544 | 3997 | 4451 | 4904 | 5358 | 5812 |
| 14     | 397    | 850 | 1304 | 1758 | 2211 | 2665 | 3119 | 3572 | 4026 | 4479 | 4933 | 5386 | 5840 |
| 15     | 425    | 879 | 1332 | 1786 | 2240 | 2693 | 3147 | 3600 | 4054 | 4508 | 4961 | 5415 | 5868 |

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