



MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

Newborn Screening
Guide for Hospitals
March 2022

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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, intellectual disability or death. Medication and changes in diet can help prevent many 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 270 Michigan newborns are identified with these disorders each year. This NBS guide is intended to be a reference tool and contains background information, general guidance on common issues related to NBS, 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 such as 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).
4. Maintaining tracking logs on NBS specimen collection, courier pickup, and screening results.
5. Courier pickup 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.

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 and critical congenital heart disease. [Appendix 8](#) contains a complete list of disorders on the NBS panel. Michigan law mandates NBS. [Appendix 1](#) summarizes NBS legislation. If parents will not permit collection of the screen, 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.

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](#).

Blood specimens should be collected at 24-36 hours of life, ideally 24-30 hours, and air dried a minimum of three hours. The NBS Program provides courier service to every hospital Monday through Friday. Hospitals in the Upper Peninsula have courier service on Saturday and those in the Lower Peninsula on Sunday. Blood specimens should be sent each day courier service is available. Laboratory testing is typically completed within one or two days of specimen receipt, and all NBS results are faxed or mailed to the hospital that submitted the specimen. The NBS Laboratory would like all hospitals to receive NBS results by fax to assure prompt receipt. [Appendix 11](#) contains instructions on how to receive faxed NBS results. The NBS Laboratory operates Monday through Saturday.

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 from each [NBS follow-up coordinating center](#) are available for guidance in such circumstances.

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

- Positive for a disorder
- Unsatisfactory for testing
- Early (collected before 24 hours of life)

When a newborn screen is a strong positive for a disorder, the NBS Program will contact the primary care provider or NICU by fax. In addition, the primary care provider will be contacted by the appropriate coordinating center to arrange for confirmatory testing, diagnosis, and treatment.

Hearing Screening

Approximately 150 newborns with hearing loss are identified annually by newborn hearing screening in Michigan. NICU infants are at increased risk for hearing loss 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 initiated 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.

Critical Congenital Heart Disease Screening

Congenital heart defects are the most common group of birth defects, affecting 9 in 1,000 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 mandated statewide pulse oximetry screening of all Michigan newborns for CCHDs prior to hospital discharge. The NBS Program and the CCHD Advisory Committee recommend that newborns be screened as close to 24 hours of age as possible, using the approved MDHHS CCHD Screening Algorithm.

The NBS Program evaluates each hospital's critical congenital heart disease (CCHD) screening performance and provides a quarterly report to each hospital that specifies if the following selected targets have been met:

1. Greater than 90% of newborns with a bloodspot screen have a right hand and foot pulse oximetry screen reported to the state.
2. Greater than 90% of newborns with a bloodspot screen have a right hand and foot pulse oximetry screen reported to the state less than 10 days after screen date.
3. Greater than 90% of newborns with a bloodspot screen have a right hand and foot pulse oximetry screen completed between 20 and 28 hours after birth.

More information about CCHD screening, data reporting, and educational materials for healthcare providers and parents is available on the [newborn screening CCHD](#) website (Michigan.gov/cchd). The [CCHD Guide for Hospitals](#) is located under the Provider Resources section.

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.
 - b. Assure that a log is maintained to track NBS specimens, courier pickup, and receipt of screening results.
 - c. Assure adequate inventory of NBS cards.
 - d. Ensure expired cards are removed from stock.
 - e. Provide guidance/information to nursery and laboratory staff on the importance of accurately filling out all demographic fields on the NBS card.
 - f. Assist NBS program staff in resolving problems of missing/incorrect demographic information on the NBS card and in obtaining repeat samples when specimens are unsatisfactory for testing.
 - g. Assure that hospital NBS policies and procedures include a protocol for notifying the NBS program if a newborn death occurs after a specimen was sent to the NBS laboratory.
2. Perform education 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) report) received from the MDHHS 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 obstetrical department staff to incorporate NBS and BioTrust educational information in existing and future prenatal classes offered to parents.
 - d. Attend trainings offered by the NBS Program.

Completing the Newborn Screening Card

It is extremely important to fill out the NBS card completely and accurately. Inaccurate information can lead to critical delays in identifying and reporting of abnormal results. 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. The *Completing the Newborn Screening Card* infographic is a simple tool to help hospital staff to correctly complete the demographic section of the card. This resource is available at the [newborn screening website](http://Michigan.gov/newbornscreening) (Michigan.gov/newbornscreening) in the “Resources for Hospitals and Health Professionals” section. Include the following information in the spaces provided on the NBS card:

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.**
- ✓ **SEX:** Completely shade in the appropriate oval to designate newborn’s sex as male, female, or ambiguous.
- ✓ **BIRTH DATE:** Use a six-digit number (mm/dd/yy) for date of birth. For example, a birth on January 4, 2021 would be recorded as 011421.
- ✓ **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 12](#).
- ✓ **BIRTH WEIGHT (grams):** Record the birthweight in grams in the boxes provided. **DO NOT** use pounds and ounces. Accuracy is critical as lab cutoff levels can be dependent on weight. Note: *Birth weight* is required on the first sample (“blue”) card *only*. For help with weight conversions, see [Appendix 14](#).
- ✓ **CURRENT WEIGHT (grams):** Record the current weight in grams in the boxes provided. Do not use pounds and ounces. Note: *Current weight* is required on the repeat sample (“pink”) card *only*. For help with weight conversions, see [Appendix 14](#).
- ✓ **WEEKS GESTATION:** Record weeks of gestation at time of birth. Note: This information is requested for the first sample (“blue”) card *only*. It is not necessary to add this information to the repeat sample (“pink”) card.
- ✓ **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:** Mark ‘yes’ next to antibiotics if the newborn received postnatal antibiotics prior to the first sample specimen collection or is currently receiving antibiotics at the time of a repeat sample collection. Do not check antibiotics if the newborn received antibiotics in the past but has not received them within 48 hours of collection. It is no longer necessary to include information about the mother’s perinatal antibiotic use.

- ✓ **COLLECTION DATE:** Use a six-digit number (mm/dd/yy) representing the date on which the specimen was collected. Previously referred to as specimen date.
- ✓ **COLLECTION TIME:** Record time of specimen collection in military time. For help with time conversions, see [Appendix 12](#).
- ✓ **COLLECTED BY:** Record initials or employee hospital identification number of the person collecting the specimen.
- ✓ **NICU/SPECIAL CARE:** Indicate if the newborn was in the NICU or special care nursery 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, including in utero. 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, 2021 at 11:20 p.m., enter 101321 2320.
- ✓ **MEDICAL RECORD NUMBER BABY:** Record the birth hospital’s identification or medical record number. Note that laboratory data coders are unable to enter letters, hyphens and spaces that appear in a 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 collected – OR – received TPN within 24 hours 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. Mark the mother’s ethnicity if the father’s ethnicity is unknown. Note: Ethnicity information is requested for the first sample (“blue”) card only.
- ✓ **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 is 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. Mark the mother’s race if the father’s race is unknown.

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 Asian. 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. Note that the use of capillary tubes can result in layered, serum, clotted, or damaged specimens. If the heel was not used, indicate the alternate collection method. The type of flush refers to the flush used prior to specimen collection, such as heparin, saline, or none.

- ✓ **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. It is no longer necessary to include information about use of human milk fortifier.

Mother Information

- ✓ **MOTHER'S NAME:** Record last name followed by first name as it will appear on the newborn's birth certificate. If the newborn is *not* going to be released to the care of the mother at birth, mark adoptive parent, foster parent, or adoption agency next to 'If Not Birth Parent'. Please provide the contact information for the adoptive parent, foster parent, or adoption agency in place of the mother's information* (refer to the HBsAg section on how to document the birth mother's HBsAg test date and result). Do not place sticky notes on the card or use red ink. Neither will be recorded when the card is scanned into the laboratory information management 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, apartment/unit/lot number, 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 primary 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. Laboratory data coders are unable to enter letters, hyphens and spaces that appear in a medical record number.
- ✓ **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 faxed to the MDHHS Perinatal Hepatitis B Prevention Program at 517-763-0470. This important information helps assure that infants at risk receive the proper interventions. Note: HBsAg information is requested for first sample ("blue") cards only. *If "Not Birth Parent", the birth mother's HBsAg results would not be documented under this section. However, if the birth mother's HBsAg result is positive, please contact the PHBPP at 517-242-8319.

Provider Information

- ✓ **PROVIDER'S NAME:** Record last name, followed by first name, of the primary care provider (PCP) to be notified of an unsatisfactory or positive newborn screen. At the time of collection, verify with the mother that the PCP's name entered on the card is correct. If the mother does not offer a PCP'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 telephone and fax numbers on the NBS card. If discharge is expected within a week, write the name and clinic telephone and fax

numbers of the provider who will be taking care of the newborn after discharge. DO NOT LEAVE BLANK.

- ✓ **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 primary 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 first sample 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, telephone 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 telephone number.
- ✓ **BIRTH HOSPITAL:** Record name of the birth hospital here only if different from the submitter.

Expiration Date:

- ✓ **EXPIRATION DATE:** The expiration date is located on the middle of the right-hand side on the newest cards and in the lower right-hand corner of older cards. Check the expiration date each time you collect a blood spot specimen. Cards used after the expiration date will be marked 'unsatisfactory/expired card' and a repeat specimen will be requested.

Notes Field:

NOTES FIELD: The Notes field added to the lower right-hand corner of newer cards can be used to notify the NBS Program of information such as newborn transfer, family history of a disorder, meconium ileus, the mother's name in the event the baby will not be released to her care, etc.

Internal Use Labels:

- ✓ **INTERNAL USE LABELS:** If internal hospital/lab use labels are placed on the NBS demographics card, do not affix to any area designated as DHHS Use Only. Labels can be placed on the back of the card or in the notes section.

Closed Adoption and Safe Surrender:

- ✓ **INFANT'S NAME:** Record as "Baby Doe" or as the hospital generated name used in hospital medical record.
- ✓ **INFANT'S BIRTH DATE/TIME:** If the date of birth is unknown, use the surrender date and time.
- ✓ **MOTHER'S SECTION:**
 - Mark the appropriate circle for the information provided. This may be adoptive parent, foster parent, or adoption agency.
 - Name and contact information should reflect who will be caring for the infant upon release. If the adoptive or foster parent information is not available, please place the name and contact information for the adoption agency.
 - Mother's medical record, birth date, and Hepatitis B Surface Antigen results can be left blank for these cases.
- ✓ **NOTES SECTION:** Adding a note in the lower right-hand corner of the card indicating this is a closed adoption or safe surrender will help ensure that this is clearly recorded in our system.
- ✓ **ADOPTION DECISION MADE AFTER NBS CARD SUBMITTED:** If the NBS card has already been sent to MDHHS with birth mother's information and then the decision is made to place the infant into closed adoption or safe surrender, please notify us immediately and request that the birth mother's information is removed from our system.
 - Notification can be faxed utilizing the NBS Follow-up Program Hospital Discharge Sheet found in [Appendix 7](#) or by calling the NBS Follow-up Program at 517-335-4181.

Notifying NBS Follow-up of Changes to Infant's Health or Guardian Status:

- ✓ It is very important that you notify NBS Follow-up of any changes to the infant's status that occurred after you sent the infant's blood spot specimen to the laboratory. Complete and return the NBS Follow-up Program Hospital Discharge Sheet found in [Appendix 7](#).

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

Recording the NBS Card Number

The hospital NBS protocol should include instructions to ensure that the NBS card number is forwarded to the staff person responsible for submitting the electronic birth certificate (EBC). The NBS card (“kit”) number is referred to as the “metabolic number” on the EBC. This number is in the lower right-hand side of the card above the barcode (as shown below) and goes in the upper right-hand box on the EBC.

Newborn Screening - Michigan Department of Health and Human Services
Bureau of Laboratories P.O. Box 30689 3350 N. MLK Jr. Blvd. Lansing MI 48909
DCB-1153 Printed: 05/19

DON'T USE RED INK

DHHS USE ONLY

BABY


| | | | | | | | |
|---|--|-------------------------------------|---|---|---|--|---|
| LAST NAME | | FIRST NAME | | | | SEX <input type="radio"/> MALE <input type="radio"/> FEMALE <input type="radio"/> AMBIGUOUS | |
| BIRTH DATE M M D D Y Y | BIRTH TIME (Military) H H M M | BIRTH WEIGHT (grams) | WKS GESTATION | SINGLE BIRTH <input type="radio"/> MULTIPLE BIRTH <input type="radio"/> → A B C D | | ANTIBIOTICS? <input type="radio"/> NO <input type="radio"/> YES | |
| COLLECTION DATE M M D D Y Y | COLLECTION TIME (Military) H H M M | COLLECTED BY: (Initials or ID #) | NICU or SPECIAL CARE? <input type="radio"/> NO <input type="radio"/> NICU <input type="radio"/> SP CARE | ANY RBC TRANSFUSION? <input type="radio"/> NO <input type="radio"/> YES → | TRANSFUSION DATE M M D D Y Y | TRANS. START TIME (Military) H H M M | |
| MEDICAL RECORD # | ETHNICITY <input type="radio"/> HISPANIC <input type="radio"/> NON-HISPANIC | | RACE <input type="radio"/> WHITE <input type="radio"/> AMERICAN INDIAN <input type="radio"/> MIDDLE EASTERN DESCENT <input type="radio"/> BLACK <input type="radio"/> ASIAN/PACIFIC ISLANDER <input type="radio"/> MULTI-RACIAL | | | | |
| TYPE OF COLLECTION: <input type="radio"/> Heel Stick <input type="radio"/> Venipuncture <input type="radio"/> Line Draw (central, other) | | | Type of Flush (heparin, saline, other) | | OTHER FEEDING: <input type="radio"/> BREAST <input type="radio"/> MILK-BASE <input type="radio"/> SOY <input type="radio"/> NONE | | TPN / AMINO ACIDS <input type="radio"/> NO <input type="radio"/> YES |
| IF NOT BIRTH PARENT: <input type="radio"/> ADOPTIVE PARENT <input type="radio"/> FOSTER PARENT <input type="radio"/> ADOPTION AGENCY | | | | | | | |
| MOTHER | | | | | | | |
| LAST NAME | | FIRST NAME | | ADDRESS | | PHONE | |
| CITY | | STATE | ZIP | HEPATITIS B SURFACE ANTIGEN (HBsAg) TEST DATE M M D D Y Y RESULT <input type="radio"/> POSITIVE <input type="radio"/> NEGATIVE | | | |
| MEDICAL RECORD # | | BIRTH DATE M M D D Y Y | | | | | |
| PROVIDER | | | | FIRST SAMPLE | | | |
| LAST NAME | | FIRST NAME | | PHONE | | FAX | |
| SUBMITTER | | | | HOSPITAL CODE (if applicable) 0 0 | | | |
| SUBMITTER NAME | | PHONE | | NOTES (ex: Meconium ileus, transfer, family history of NBS disorder, phototherapy) | | | |
| ADDRESS | | | | | | | |
| CITY | | STATE | ZIP | | | | |
| BIRTH HOSPITAL (if different from submitter) | | | | MDHHS USE ONLY | | | |

EXPIRES: 2025-07-31

113004 / 30510003

MDHHS
By Authority of Act 568
P.A. MCLA 333.5431
PerkinElmer 226

3007901



10

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. MDHHS staff, upon request, will provide onsite training on the BioTrust and the parental consent process. This training is also available on the [newborn screening](http://Michigan.gov/newbornscreening) website (Michigan.gov/newbornscreening) within the Resources for Hospitals and Health Professionals section. [Appendix 5](#) contains 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 for up to 100 years 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 *Residual Newborn Screening Blood Spot Directive* form. 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 *Residual Newborn Screening Blood Spot Directive* 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 *Residual Newborn Screening Blood Spot Directive* form. [Appendix 9](#) contains this form.

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 [newborn screening](http://Michigan.gov/newbornscreening) website (Michigan.gov/newbornscreening) within the General Information for Families section 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](#). 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* BioTrust 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 first sample ("blue") 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 the newborn's NBS specimen card. DO NOT delay returning a newborn's NBS specimen card while waiting for the consent form.
7. 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 first sample ("blue") 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.
 - Only the parent or legal guardian can sign the consent form. In cases of adoption, the birth mother could sign the consent form while she remains the legal guardian. However, the future adoptive parent may wish to select a different option. An option is to return the NBS specimen without the BioTrust consent form. Then send the form and brochure home with the family and/or adoption agency caring for the infant. Once legal guardianship is established, that person can make the BioTrust decision and return the form to MDHHS.

Ordering Newborn Screening Cards, Return Envelopes and Brochures

Hospital and health system supply purchasing personnel should use the [NBS Online Ordering System \(NBSO\)](#) to order NBS cards.

Replacement cards are available free of charge for any card that cannot be used. Reasons for replacement could include card pieces are torn or separated, the specimen is unsatisfactory for testing, the wrong demographic information was entered on the card, etc. Complete the [card replacement form](#) and return that and the white face sheet(s) of the cards intended for replacement to the address on the form. DO NOT send these requests to the State NBS Laboratory. Failure to send the request to the address on the form will result in delay and could result in no replacement cards being issued.

NBS brochures are free of charge and shipped in quantities of 50 (English version) and 25 (Spanish and Arabic versions). They can be ordered through NBSO free of charge. For ordering, please visit the [newborn screening ordering](http://Michigan.gov/nbso) website (Michigan.gov/nbso).

Specimen Collection

- Direct [specimen collection](#) from a heel puncture is preferred for optimal laboratory results. Blood collection using capillary tubes is discouraged.
- First sample specimens should be collected between 24-36 hours of age, preferably 24-30 hours.
- Specimens should be air dried in a horizontal position for a minimum of three hours and sent by courier
 - the same day if collected more than five hours before the scheduled courier pickup time that day.
 - or the next day the courier is scheduled to pick up specimens if collected less than five hours before the scheduled courier pickup time that day.
- Tips for avoiding unsatisfactory specimen collection can be found at the [newborn screening](#) website (Michigan.gov/newbornscreening) in the “Resources for Hospitals and Health Professionals” section.

Laboratory Testing Methods

- **Tandem Mass Spectrometry (MS/MS):** Amino acid, organic acid and fatty acid oxidation disorders are detected by evaluation of specific MS/MS acylcarnitine and amino acid profiles. If a screen is positive for propionic acidemia/methylmalonic acidemia, homocystinuria or malonic acidemia, a secondary screen is performed by the Mayo Biochemical Genetics Laboratory.
- **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 screen is positive for CAH, a secondary screen for CAH by steroid profile is performed by MS/MS by the Mayo Biochemical Genetics Laboratory. A secondary DNA screen for 60 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).
- **Enzyme assays:** Galactosemia (galactose-1-phosphate uridyltransferase) and biotinidase deficiency (biotinidase).
- **Digital Microfluidics:** Pompe disease and Mucopolysaccharidosis Type I (MPSI) are screened using a digital microfluidics platform. If a screen is positive for Pompe disease or MPSI, a secondary screen is performed by the Mayo Biochemical Genetics Laboratory.

Disorders Identified in Michigan Newborn Residents via Newborn Screening, 1965-2019

| Type of Disorder Classification (Year Screening Began) | Cases in 2019 (N) | Cases Through 2019 (N) | Cumulative Detection Rate |
|---|-------------------------|------------------------------|---------------------------------|
| Galactosemia (1985) | 9 | 219 | 1:20,436 |
| Biotinidase deficiencies (1987) | 8 | 360 | 1:11,667 |
| Amino acid disorders (1965) | 13 | 793 | 1:9,375 |
| Organic acid disorders (2005) | 9 | 100 | 1:17,205 |
| Fatty acid oxidation disorders (2003) | 12 | 287 | 1:6,903 |
| Congenital hypothyroidism (1977) | 126 | 2585 | 1:1,625 |
| Congenital adrenal hyperplasia (1993) | 5 | 175 | 1:19,002 |
| Sickle cell disease (1987) | 64 | 2092 | 1:2,004 |
| Hemoglobin H disease (2012) | 4 | 16 | 1:55,110 |
| Cystic fibrosis (October 2007) | 16 | 322 | 1:4,165 |
| Primary immunodeficiencies (October 2011) | 12 | 120 | 1:8,214 |
| Lysosomal storage disorders (August 2017) | 5 | 17 | 1:15,297 |
| X-linked adrenoleukodystrophy (October 2019) | 1 | 1 | 1:25,710 |
| Total | 284 | 7,092 | - |

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. Less than 2% of screens collected greater than 36 hours after birth.
2. Greater than 90% of screens arrive in State laboratory by the appropriate day.
3. Less than 1% of first and repeat sample specimens unsatisfactory for testing.
4. Greater than 95% of electronic birth certificates have the newborn screening card number recorded.
5. At least 90% of specimens have a returned BioTrust for Health consent form that is completed appropriately.
6. Less than 1% of specimens have errors in the birthdate/time, specimen collection date/time, birthweight in grams, and/or transfusion status on the NBS card.

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



NEWBORN SCREENING QUALITY ASSURANCE NOTIFICATION

Covering the period: 4/1/2021 - 6/30/2021

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 (NBS) 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
 - **NBS Cards with Incorrect Demographic Data:** Less than 1% of specimens have errors in the demographic data (i.e. dates, times, birth weights, etc) on the NBS card

1 STATE

| | April | | | May | | | June | | | Quarter | | |
|---|----------|----------|-------------|----------|----------|-------------|----------|----------|-------------|----------|----------|-------------|
| <i>Total number specimens for your hospital</i> | 8,257 | | | 8,627 | | | 9,196 | | | 26,080 | | |
| <i>Total number of specimens for state</i> | 8,257 | | | 8,627 | | | 9,196 | | | 26,080 | | |
| | <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> | 47 | 0.6 | Met | 41 | 0.5 | Met | 50 | 0.5 | Met | 138 | 0.5 | Met |
| <i>Late Screens for state</i> | 47 | 0.6 | Met | 41 | 0.5 | Met | 50 | 0.5 | Met | 138 | 0.5 | Met |
| <i>Receipt by Appropriate Day for your hospital</i> | 7,618 | 92.3 | Met | 7,955 | 92.2 | Met | 8,340 | 90.7 | Met | 23,913 | 91.7 | Met |
| <i>Receipt by Appropriate Day for state</i> | 7,618 | 92.3 | Met | 7,955 | 92.2 | Met | 8,340 | 90.7 | Met | 23,913 | 91.7 | Met |
| <i>Unsatisfactory Screens for your hospital</i> | 106 | 1.2 | Not Met | 95 | 1 | Not Met | 108 | 1.1 | Not Met | 309 | 1.1 | Not Met |
| <i>Unsatisfactory Screens for state</i> | 106 | 1.2 | Not Met | 95 | 1 | Not Met | 108 | 1.1 | Not Met | 309 | 1.1 | Not Met |
| <i>Birth certificates* for your hospital</i> | 8,435 | | | 8,788 | | | 9,246 | | | 26,469 | | |
| <i>Birth certificates* for state</i> | 8,435 | | | 8,788 | | | 9,246 | | | 26,469 | | |
| <i>Newborn Screening Card Number for your hospital</i> | 8,166 | 96.8 | Met | 8,506 | 96.8 | Met | 8,982 | 97.1 | Met | 25,654 | 96.9 | Met |
| <i>Newborn Screening Card Number for state</i> | 8,166 | 96.8 | Met | 8,506 | 96.8 | Met | 8,982 | 97.1 | Met | 25,654 | 96.9 | Met |
| <i>Returned BioTrust for Health Consent Forms for your hospital</i> | 7,203 | 87.2 | Not Met | 7,532 | 87.3 | Not Met | 7,947 | 86.4 | Not Met | 22,682 | 87 | Not Met |
| <i>Returned BioTrust for Health Consent Forms for state</i> | 7,203 | 87.2 | Not Met | 7,532 | 87.3 | Not Met | 7,947 | 86.4 | Not Met | 22,682 | 87 | Not Met |
| <i>NBS cards with incorrect demographic data for your hospital</i> | 194 | 2.3 | Not Met | 178 | 2.1 | Not Met | 228 | 2.5 | Not Met | 600 | 2.3 | Not Met |
| <i>NBS cards with incorrect demographic data for state</i> | 194 | 2.3 | Not Met | 178 | 2.1 | Not Met | 228 | 2.5 | Not Met | 600 | 2.3 | 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.

NICU Protocol (includes Special Care Nursery)

First sample NBS specimens for all NICU newborns, regardless of birth weight, should be collected at 24-30 hours of life and prior to red blood cell (RBC) transfusion. The [NICU protocol](#) contains guidelines to follow under certain circumstances. A repeat sample specimen is required at 30 days, or at discharge for any newborn hospitalized 8-30 days. This includes babies who have transferred from the NICU to a general floor without having been discharged home. If a newborn was discharged home before 8 days, had a normal first sample screen, and is later readmitted, a repeat sample specimen does not need to be collected. The NBS Program considers the day the baby is born as day of life one.

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 repeat sample specimen. If a NBS disorder is suspected, a NBS specimen can be ordered by the physician, collected, and forwarded to the NBS Laboratory at any time prior to discharge. Follow the instructions on the notification letter for obtaining an additional specimen if you are informed that a previous specimen was positive, early, or unsatisfactory.

Transfusions

For the typical NICU newborn, the first sample specimen should be collected between 24-30 hours of life and prior to RBC transfusion. A repeat sample specimen should be collected at discharge or 30 days of life, whichever comes first.

In those rare cases when the first sample specimen cannot be collected prior to RBC transfusion

- a first sample specimen should be collected 28 hours post RBC transfusion start time.
- a repeat sample specimen should be collected at discharge or 30 days of life, whichever comes first.
- another repeat sample specimen should be collected 90 days following the last RBC transfusion.

If the first sample specimen is collected prior to RBC transfusion but less than 24 hours of life (early screen):

- a repeat sample specimen should be collected at 28 hours post transfusion start time.
- another repeat sample should be collected 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. A repeat specimen is required as soon as possible, but 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)
- Transfer to another hospital

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 known 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 who test positive, repeat specimens are requested using the *General 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 birth hospital should write 'transferred to' and the name of the receiving hospital in the Notes section at the bottom of the card.
- 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 24-36 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.
- 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 (517-335-4181) if a newborn or a newborn's sibling is suspected of having a NBS disorder. This information can also be included in the Notes section on the card.

Newborn Death or Pending Death

The NBS Program should be notified if a newborn has died 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 a death is expected or occurs. This will prevent unnecessary notification of parents regarding subsequent screening or diagnostic testing.

PRIMARY 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 primary 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 primary 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 \(HIPAA\)](#).

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](#) website after the NBS record is successfully linked to the newborn's birth certificate and immunization record. The NBS results are not posted if the baby has been released for adoption or placed in foster care.

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 date of birth
- Mother's name at time of delivery
- Primary care provider fax number
- If you are not the provider recorded on the NBS card, the [NBS Report Request Form](#) must be completed, signed by the medical provider, and faxed to the number listed above. The form is in [appendix 13](#).

If 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 [NBS follow-up coordinating center](#) listed on the letter.

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
- NBS follow-up coordinating centers
- Written instructions for completing the NBS card and specimen collection instructions
- 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 blood spot screen collected. The log should include the following information:

- Baby's demographic information
- Mother's name and birth date
- NBS card ("kit") number
- Barcode number on the NBS envelope in which each screen was placed

A separate courier log should be kept that includes:

- The date the NBS envelope was prepared
- The barcode number of each NBS envelope
- A place for the courier to sign and date the log

The submitter of the NBS first sample, usually the hospital or homebirth attendant, should have a mechanism in place to track NBS results. Do not assume that no news is always good news. If you cannot locate NBS results, verify that the screening was done. If results are not received within two weeks following sample submission, first contact your hospital laboratory and/or medical records department for results or contact the birth hospital for newborns transferred to your hospital. Check the [Michigan Care Improvement Registry](#) (MCIR) website for NBS results. If the NBS results cannot be found, contact the NBS Follow-up Program via phone at 517-335-4181 to obtain a copy of the results.

The hospital (newborn remains hospitalized) or primary care provider (newborn has been discharged) are responsible for facilitating the collection of a repeat sample as needed. Repeat samples are requested whenever a first sample specimen is borderline positive, unsatisfactory for testing, inconclusive, collected before 24 hours of life or collected after RBC transfusion.

Missing Bloodspot Newborn Screens

Every year, approximately 40-50 hospital births have a missed newborn blood spot screen, which delays potential identification of life-threatening disorders. Each week the NBS Program staff link electronic birth certificate (EBC) records to newborn screening specimens received. This process enables quick identification of infants with a Michigan birth certificate, but no record of a blood spot screen. Hospitals are alerted of these potentially missed newborn screens.

After the linkage, a manual review occurs for all infants not listed as deceased who show as having no blood spot on file. This includes a search of the NBS database and review of faxes received from hospitals documenting why a screen was not collected. If explanatory records are not found, NBS Program staff send a "No Record of Blood Spot Screen" fax to the designated NBS coordinator at the birth facility. A request is made for additional information regarding the reason for the missing blood spot, such as if the infant died before a screen was collected, infant was transferred out of state, name change due to adoption, etc. If the screen was truly missed, the NBS Program requests that the birth facility contact the family to return to have a screen collected as soon as possible.

Due to the critical importance of identifying affected infants and initiating treatment as quickly as possible, the NBS Program implemented the following process to ensure timely response. If acknowledgment that the screen was missed and/or a reason for no blood spot collection is received, the further actions in the timeline will end. [Appendix 15](#) contains a detailed process timeline.

- Day One: Initial fax sent to birth facility's NBS Coordinator.
- Day Two: NBS staff calls to ensure the fax has been received.
- Day Three: Second attempt fax is sent to NBS Coordinator.
- Day Five: MDHHS NBS nurse consultant calls NBS Coordinator to review case and gather information.
- Day Seven: Letters will be sent to the parents letting them know that the NBS Program has not received a screen for their infant and to the risk management area at the birth facility.

It is ultimately the responsibility of the birth facility to ensure that all infants receive a newborn screen. Prevention of missed screenings is critical. Using a NBS specimen log is one method to track that collection takes place. Proactively informing the MDHHS NBS Program of reasons for not collecting a NBS can be completed utilizing NBS Follow-up Program Hospital Discharge Sheet found in [Appendix 7](#). If a parent will not permit collection, please fax the signed copy of your institution's refusal form to the MDHHS NBS Follow-up Program at 517-335-9419 or 517-335-9739.

FREQUENTLY ASKED QUESTIONS

Who informs parents about NBS?

Although education is ideally done during the prenatal period, the birth hospital is ultimately responsible for informing parents about the NBS process. To facilitate talking with parents, the NBS Program recommends using the *Michigan Newborn Screening Saves Babies* parent brochure and the *Newborn Screening Roadmap Infographic* as tools. NBS materials may be ordered on the [newborn screening ordering](#) website. Additional information is available on the [newborn screening](#) website.

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

Of the 106,126 infants screened in 2019, 284 were diagnosed with a disorder. Overall, one infant out of 374 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?

Please inform the NBS Program if a family has a history of a disorder on the Michigan NBS panel. You may write this information in the Notes section of the NBS card or call the NBS Follow-up Program at 517-335-4181.

What is the NBS Program's specimen storage policy?

Residual NBS specimens are stored for up to 100 years 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 is granted for such research. Specimens collected prior to May 1, 2010 are available for research unless parents contact the MDHHS and opt-out using the form in [Appendix 9](#).

Who decides what disorders are included on the NBS panel?

The legislatively mandated Quality Assurance Advisory Committee makes recommendations on disorder inclusion to the MDHHS director, typically following recommendations from the federal Advisory Committee on Heritable Disorders in Newborns and Children.

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, healthcare 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 517-335-4181 to reach someone in the NBS Program. You may also call the appropriate [NBS follow-up coordinating center](#) to speak to a sub-specialist.

RESOURCE LIST

| Newborn Screening Links | Website URL |
|---|---|
| <u>Michigan Newborn Screening</u> | Michigan.gov/newbornscreening |
| <u>Michigan Newborn Screening Online</u> (Order placement website) | Michigan.gov/nbsorders |
| <u>Michigan Critical Congenital Heart Disease Newborn Screening Program</u> | Michigan.gov/cchd |
| <u>Michigan BioTrust for Health Parental Consent Process Training</u> | Michigan.gov/biotrust |
| <u>Genetics Home Reference</u> | medlineplus.gov/genetics |
| <u>Centers for Disease Control and Prevention Genomics Resources</u> | cdc.gov/genomics/resources |
| <u>Newborn Screening Course</u> | https://courses.mihealth.org/PUBLIC/home.html |
| <u>American Academy of Pediatrics</u> | aap.org |
| <u>Sickle Cell Disease Association of America – Michigan Chapter, Inc.</u> | scdaami.org |

| National Newborn Hearing Links | Website URL |
|---|---|
| <u>Centers for Disease Control Early Hearing Detection and Intervention</u> | cdc.gov/ncbddd/hearingloss/ehdi-data.html |
| <u>Marion Downs Center</u> | mariondowns.org |
| <u>National Institute on Deafness and Other Communication Disorders</u> | nidcd.nih.gov |
| <u>American Speech-Language-Hearing Association</u> | asha.org |
| <u>American Academy of Audiology</u> | audiology.org |
| <u>Hands and Voices</u> | handsandvoices.org |

CONTACT INFORMATION

NBS Follow-up

| NBS Follow-up Program | MDHHS Newborn Screening Follow-up 333. S. Grand Ave., 2 nd floor PO Box 30195 Lansing, MI 48909 | Toll-free: 866-673-9939 Telephone: 517-335-4181 Fax: 517-335-9419 or 517-335-9739 | Email: NewbornScreening@Michigan.gov Website: Michigan Newborn Screening |
|------------------------------|---|---|--|
| Staff | Title | Phone Number | Contact for questions regarding: |
| Mary Kleyn | NBS Follow-up section manager | 517-335-9296 | Destroying leftover NBS specimens |
| Angela Aldrich | NBS nurse consultant | 517-335-1966 | NBS hospital education NBS collection Quality metrics performance |
| Becky Shaulis | NBS Quality Assurance specialist | 517-335-8532 | Preliminary results request due to clinical concerns Reporting updated hospital staff contact information |
| Lacey VanLoenen | NBS operations coordinator | 517-335-1207 | Courier issues |
| Valerie Ewald | NBSO technical administrator | 517-335-1400 | NBS card orders NBS educational brochure orders |
| Kristen Thompson | NBS program coordinator | 517-284-4992 | CCHD NBS parent education |
| Shelby Atkinson | Genomics and NBS Research Coordinator | 517-335-6497 | BioTrust for Health |

CONTACT INFORMATION

NBS Lab

| | | |
|-----------------------|--|--|
| NBS Laboratory | MDHHS Newborn Screening Laboratory 3350 N. Martin Luther King Blvd. PO Box 30689 Lansing, MI 48909 | Telephone: 517-241-6366 Fax: 517-335-9773 |
| Staff | Title | Phone Number |
| Vacant | NBS Laboratory Section Manager | 517-241-6366 |
| Shawn Moloney | NBS Laboratory Metabolic Unit Manager | 517-335-5097 |
| Joseph Hill | NBS Laboratory Endocrine Unit Manager | 517-335-9381 |
| Alayna Bunker | Departmental technician | 517-335-4031 |

CONTACT INFORMATION

Early Hearing Detection and Intervention

| | | |
|----------------------------|---|--|
| Hearing | MDHHS Early Hearing Detection and Intervention 109 W. Michigan Ave., 3 rd floor PO Box 30195 Lansing, MI 48909 | Telephone: 517-335-8955 Fax: 517-763-0183 Website: Michigan Early Hearing Detection and Intervention |
| Staff | Title | Phone Number |
| Nick Drzal | Infant Health Unit manager | 517-241-1914 |
| Erin Estrada | Data analyst | 517-335-8916 |
| Michelle Garcia | Follow-up consultant | 517-335-8878 |
| Krystina Trowbridge | Infant Health Unit secretary | 517-335-8955 |
| Gina Cooper | EHDI coordinator | 517-335-4941 |
| Nan Asher | Program consultant | 517-335-8273 |
| Dona McGovern | EHDI administrative assistant | 517-335-7835 |

CONTACT INFORMATION

NBS Hepatitis B

| | | |
|-----------------------------|--|--|
| Hepatitis B | MDHHS Perinatal Hepatitis B Prevention Program 333 S. Grand Ave., 3 rd floor PO Box 30195 Lansing, MI 48909 | Telephone: 517-242-8319 Fax: 517-763-0470 Website: Perinatal Hepatitis B Prevention Program |
| Staff | Title | Phone Number |
| Pat Fineis | Program coordinator | 517-242-8319 |
| Marcy Smith | Case manager/Out-state | 517-388-4815 |
| Naomi Scherman-Siver | Case manager/SE MI | 517-897-3236 |

CONTACT INFORMATION

NBS Follow-up Coordinating Centers

| | | |
|---|--|---|
| Hemoglobinopathies | Sickle cell anemia (Hb SS), hemoglobin SC disease, sickle beta thalassemia zero (Sβ ⁰), sickle beta thalassemia plus (Sβ ⁺), and hemoglobin H disease. | Sickle Cell Disease Association of America, Michigan Chapter 18516 James Couzens Detroit, MI 48235 Telephone: 313-864-4406 Toll-free: 800-842-0973 Fax: 313-864-9980 info@scdaami.org |
| Metabolic Disorders | Amino acid disorders, fatty acid oxidation disorders, organic acid disorders, galactosemia, biotinidase deficiency | Children's Hospital of Michigan Metabolic Clinic 3950 Beaubien Blvd. Detroit, MI 48201-2192 Telephone: 313-832-9330 Fax: 313-745-8030 |
| Lysosomal Storage Disorders (LSD) | Pompe Disease & Mucopolysaccharidosis Type (MPSI) | Children's Hospital of Michigan Genetics Clinic 3950 Beaubien Blvd. Detroit, MI 48201-2192 Telephone: 313-832-9330 Fax: 313-745-8030 Michigan Medicine at the University of Michigan Division of Pediatric Genetics, Metabolism, and Genomic Medicine D5240 Medical Professional Bldg. 1500 E. Medical Center Drive Ann Arbor, MI 48109-5718 Telephone: 734-764-0579 Fax: 734-763-6561 |
| Endocrine Disorders Cystic Fibrosis (CF) Spinal Muscular Atrophy (SMA) X-linked Adrenoleukodystrophy (X-ALD) | Congenital adrenal hyperplasia (CAH) Congenital hypothyroidism (CH), CF X-ALD SMA | Michigan Medicine at the University of Michigan Department of Pediatrics 1500 E. Medical Center Dr. D1225 MPB, Box -5718 Ann Arbor, MI 48109-0718 Telephone: 734-647-8938 Fax: 734-936-7918 |
| Primary Immunodeficiency Disorders | Severe combined immunodeficiency disorder (SCID) and other primary immunodeficiency disorders with T-cell lymphopenia | 3950 Beaubien St. Detroit, MI 48201 Telephone: 313-806-6571 Pager: 313-745-0203; pager number 5706 Fax: 313-966-9701 |

CONTACT INFORMATION

Courier Services

Lower Peninsula

Monday-Friday and Sunday pickup, including holidays.

Hospitals will be notified each time a Sunday pickup schedule will be followed for holidays that fall on a weekday.

STAT Courier Services, Inc.

Toll-free: 888-592-7828

Tresa Agee, Customer Care / Account Manager

Email: tagee@stat-courier.com

Michigan account number: 995

Upper Peninsula

Monday-Saturday pickup

United Parcel Services

Toll-free: 800-877-1797

Online tracking: [UPS tracking](#) website

Use account number 05V0R4 when ordering UPS Medical Envelopes

Email NewbornScreening@Michigan.gov for UPS shipping labels

| |
|--|
| Contact NewbornScreening@Michigan.gov if you need detailed NBS courier information such as your courier pickup time, days and location. |
|--|

APPENDIX 1 – LEGISLATIVE MANDATES

Public Health Code Act 368 of 1978

The NBS Program applies to all newborns in the State of Michigan by law. You can find the law in its entirety online on the [Public Health Code Act 368 of 1978](#) website.

Some highlights are:

- 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 must collect the newborn screen
- List of disorders screened
- Informed consent of the parent is not required
- Positive results shall be reported to the infant's parents, guardian or person in loco parentis
- NBS fee and adjustment
- Hardship waiver of the fee is authorized
- Retention and disposal schedule are established

Act No. 31, Public Acts of 2006 to amend 1978 PA 368

This amendment can be found in its entirety on the [Act No. 31, Public Acts of 2006 to amend 1978 PA 368](#) website.

Some highlights are:

- Creation of the newborn screening quality assurance advisory committee
 - Committee members
 - Review disorders screened and recommend new disorders for addition to the screening panel
 - Financial review of the NBS Program with recommendation to adjust the amount charged
- Addition of screening for hearing loss

APPENDIX 2 – BLOOD SPECIMEN COLLECTION AND HANDLING PROCEDURE

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


CHECKLIST:

- Newborn Screen
- Hearing Screen
- Pulse Oximetry Screen
- BioTrust Consent Form


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 specimens at next courier pick-up.



Do not send specimens in plastic bags.



INSTRUCTIONS FOR SPECIMEN COLLECTION AND SENDING

SUBMITTER RESPONSIBILITY

1. Complete the form.
2. Collect an adequate quality specimen.
3. Send specimens promptly i.e., within 24 hours.
4. List the health care provider who will care for the infant after discharge.

SCREENING REQUIREMENTS FOR ALL NEWBORNS


1. Initial screen should be collected prior to blood transfusion, regardless of age.
2. Collect sample at 24 - 30 hours of age, or before discharge or transfer.
3. Infants screened before 24 hours require a repeat screen within 7 days.
4. All premature and sick infants should be screened according to DHHS NICU guidelines.

COMPLETION OF FORM





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

COLLECTION OF THE BLOOD SPECIMEN

1. Do not touch the filter paper circles before or after collection.
2. Select puncture site and cleanse with 70% isopropanol and allow heel to air dry.
3. Use a sterile, disposable incision device (2.5mm wide or less and 1.0mm deep or less) to perform a swift clean incision.
4. Wipe away the first drop of blood with sterile gauze.
5. 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.
6. Do not use capillary tubes or other devices that contain EDTA or Heparin.
7. Apply one large drop of blood to each circle. Fill a minimum of 5 circles.
8. Protect specimens from accidental contact with liquids.
9. 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.



Collect Sample from shaded area



| | |
|---|-------------------------------------|
| RIGHT | ACCEPTABLE |
|  | Circle filled and evenly saturated |
| WRONG | UNACCEPTABLE |
|  | Layering |
|  | Insufficient, multiple applications |
|  | Serum rings present |


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 or call (517) 335-1400

SEND SPECIMENS AT NEXT COURIER PICK-UP



Please follow the Clinical and Laboratory Standards Institute (CLSI) guidelines for NBS specimen collection. Refer to the [Clinical and Laboratory Standards Institute](http://www.clinical-laboratory-standards.org) website for additional information.

APPENDIX 3 – NBS CARD IMAGES

NBS First Sample (“blue”) Card

DON'T USE RED INK

Newborn Screening - Michigan Department of Health and Human Services
Bureau of Laboratories P.O. Box 30689 3350 N. MLK Jr. Blvd. Lansing MI 48909
Print Firmly with Black Pen

DCI-1153 Printed: 05/19

| | | | | | |
|---|--|----------------------------------|---|--|---|
| LAST NAME | | FIRST NAME | | SEX <input type="radio"/> MALE <input type="radio"/> FEMALE <input type="radio"/> AMBIGUOUS | |
| BIRTH DATE | BIRTH TIME (Military) | BIRTH WEIGHT (grams) | WKS GESTATION | SINGLE BIRTH <input type="radio"/> MULTIPLE BIRTH <input type="radio"/> | BIRTH ORDER A B C D |
| COLLECTION DATE | COLLECTION TIME (Military) | COLLECTED BY: (Initials or ID #) | NICU or SPECIAL CARE? <input type="radio"/> NO <input type="radio"/> NICU <input type="radio"/> SP CARE | ANY RBC TRANSFUSION? <input type="radio"/> NO <input type="radio"/> YES | TRANS. START TIME |
| MEDICAL RECORD # | ETHNICITY <input type="radio"/> HISPANIC <input type="radio"/> NON-HISPANIC | | RACE <input type="radio"/> WHITE <input type="radio"/> AMERICAN INDIAN <input type="radio"/> MIDDLE EASTERN DESCENT <input type="radio"/> BLACK <input type="radio"/> ASIAN/PACIFIC ISLANDER <input type="radio"/> MULTI-RACIAL | | |
| TYPE OF COLLECTION: <input type="radio"/> Heel Stick <input type="radio"/> Venipuncture <input type="radio"/> Line Draw (central, other) | | | OTHER FEEDING: <input type="radio"/> BREAST <input type="radio"/> MILK-BASE <input type="radio"/> SOY <input type="radio"/> NONE | | TPN / AMINO ACIDS <input type="radio"/> NO <input type="radio"/> YES |
| IF NOT BIRTH PARENT: <input type="radio"/> ADOPTIVE PARENT <input type="radio"/> FOSTER PARENT <input type="radio"/> ADOPTION AGENCY | | | | | |
| LAST NAME | | FIRST NAME | | | |
| ADDRESS | | | PHONE | | |
| CITY | STATE | ZIP | | HEPATITIS B SURFACE ANTIGEN (HBsAg) | |
| MEDICAL RECORD # | BIRTH DATE | TEST DATE | RESULT | <input type="radio"/> POSITIVE <input type="radio"/> NEGATIVE | |
| LAST NAME | | FIRST NAME | | | |
| PHONE | | FAX | | FIRST SAMPLE | |
| SUBMITTER NAME | | PHONE | | | |
| ADDRESS | | | HOSPITAL CODE (if applicable) 00 | | |
| CITY | | STATE | | ZIP | |
| BIRTH HOSPITAL (if different from submitter) | | | MDHHS USE ONLY | | |

DHHS USE ONLY

EXPIRES: 2025-07-31

11 3604 / 3051 0003
MDHHS
By Authority of Act 568
P.A. MCLA 333.5431
PerkinElmer 226

3007901

Before signing this form please read, Your Baby's Blood Spots. It gives details on how small drops of blood (blood spots) collected for newborn screening may be used in research through the Michigan BioTrust for Health. If you have questions, please call the Michigan Department of Health and Human Services (MDHHS) toll free at 1-866-673-9939.

Yes, my baby's leftover newborn screening blood spots may be used for health research.
By checking this box you understand:

- After newborn screening, blood spots are coded only with a number and stored up to 100 years at a secure site (Biobank). MDHHS can link the coded blood spots to your baby. This allows use of specific spots for research. It also allows MDHHS to find the right spots if you, or your grown child, change your mind.
- Researchers only receive coded blood spots. Details that could identify you, or your baby, are not provided.
- The risk of using blood spots in research is that your baby could still be identified. This risk is very low because many steps are taken to protect privacy.
- Research using blood spots must be approved by MDHHS. Blood spots can only be used for studies to better understand disease or improve the public's health such as research on cancer, birth defects and diabetes.
- Many laboratory methods are used to study biological or environmental factors such as genes, infectious agents, toxins and metals.
- Blood spot research may not directly help you, your child or your family. This type of research aims to improve the health of communities.
- 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 leftover newborn screening blood spots may not be used for health research.
By checking this box you understand:

- Blood spots will be stored for up to 100 years but not used for research. The blood spots are stored so that the state lab can perform quality control tests and improve newborn screening.
- You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

MDHHS Copy

Parent Signature _____ Date _____

Your choice applies to all blood spots collected for newborn screening. Please visit www.michigan.gov/biotrust for further information. 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.

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

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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.

The Privacy Rule can be found in its entirety on the [HIPAA Privacy Rule and Public Health](#) website.

APPENDIX 5 – NBS ONLINE ORDERING SYSTEM (NBSO)

NBS brochures and mailing envelopes are available at no charge. NBS cards need to be purchased when the order is placed.

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 invoice, eCheck or credit card. These payments will be processed through the PayPlace, a secure site used by the State of Michigan for financial transactions. Learn more about PayPlace privacy on the [PayPlace privacy](#) website. Invoice orders and eCheck orders will require a unique verification code. Please call 517-335-1400 to get your permanent verification code, which you will need to use for all future orders. There is an annually adjusted processing fee of approximately 2.8% added to each credit card purchase.

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. Learn more on the [eCheck](#) website.

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.

Follow these steps to get started:

1. Visit Michigan.gov/nbsorders
2. Click NBSOnline Web Store – Order NOW!
3. Click *Register* if you don't have an account.
4. If you are ordering for multiple medical facilities, click on each of the hospitals for which you do purchasing – a check mark will appear.
5. Upon completion of the registration process, a link will be sent to the email address used to register.

Still have questions? Please email NBSOrders@Michigan.gov or call 517-335-1400.

APPENDIX 6 – NEWBORN SCREENING CARD REPLACEMENT FORM



Date: _____

Facility name: _____

Attention/Department: _____

Address: _____

City, state, zip: _____

Contact name: _____ Telephone: _____

Number of cards returned for replacement: _____

ID number(s) of the card(s) 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.**
- 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 blood spot 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
Attention: Newborn Screening
 333 S. Grand Ave., 2nd floor
 PO Box 30195
 Lansing, MI 48909

APPENDIX 7 – NBS FOLLOW-UP PROGRAM HOSPITAL DISCHARGE SHEET

Phone 517-335-4181 or 877-673-9939

Fax updated information to: 517-335-9419 or 517-335-9739

Place infant's hospital label here:

OR

Print infant's information here:

Name: _____

DOB: _____

Circle gender: boy girl ambiguous

NBS card (kit) number: _____

Hospital name: _____

NBS hospital code: _____

Check nursery type: NICU: _____ Regular: _____ Special Care: _____

Name of hospital infant transferred to: _____

Infant's primary care provider (PCP): _____
(Will care for infant after discharge)

PCP phone: _____ PCP fax: _____

Provide guardian contact information if infant is not released to the care of the mother:

Guardian name: _____

Guardian address: _____

Guardian phone: _____

Name of staff person completing form (please print): _____

Date: _____ Phone: _____ Fax: _____

Notes: (e.g., parent would not permit NBS, infant has meconium ileus, sibling has cystic fibrosis, etc.)

APPENDIX 8 – DISORDER LIST

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. Trifunctional protein deficiency (TFP)
26. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)

Organic Acid Disorders

27. 2-Methyl-3-hydroxy butyric aciduria (2M3HBA)
28. 2-Methylbutyryl-CoA dehydrogenase deficiency (2MBG)
29. 3-hydroxy 3-methylglutaric glutaric aciduria (HMG)
30. 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC)

31. 3-Methylglutaconic aciduria (3MGA)
32. Beta-ketothiolase deficiency (BKT)
33. Glutaric acidemia type I (GA1)
34. Isovaleric acidemia (IVA)
35. Malonic Acidemia (MAL)
36. Methylmalonic acidemia cobalamin disorders (Cbl A,B)
37. Methylmalonic aciduria with homocystinuria (Cbl C,D)
38. Methylmalonic acidemia methylmalonyl-CoA mutase (MUT)
39. Multiple carboxylase deficiency (MCD)
40. Propionic acidemia (PROP)

Hemoglobinopathies

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

Endocrine Disorders

46. Congenital adrenal hyperplasia (CAH)
47. Congenital hypothyroidism (CH)

Lysosomal Storage Disorders

48. Glycogen storage disease type II (Pompe)
49. Mucopolysaccharidosis type I (MPS I)

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. X-linked adrenoleukodystrophy (X-ALD)
56. Hearing
57. Critical congenital heart disease (CCHD)
58. Spinal muscular atrophy

Disorder Coming Soon

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

- Guanidinoacetate methyltransferase (GAMT) deficiency

Updated April 2020

APPENDIX 9 – SPECIMEN DIRECTIVES

The [Residual Newborn Screening Blood Spot Directive](#) form is located on the [newborn screening website](#).

RESIDUAL NEWBORN SCREENING BLOOD SPOT DIRECTIVE

Michigan Department of Health and Human Services

| | | | |
|---|--|---|------------------------|
| Child's Name at Birth [REDACTED] | | Date of Birth [REDACTED] | |
| Child's Current Name [REDACTED] | | Check Birth Order if Multiple Birth <input type="checkbox"/> 1 st <input type="checkbox"/> 2 nd <input type="checkbox"/> 3 rd <input type="checkbox"/> 4 th <input type="checkbox"/> 5 th | |
| Mother's Name at Time of Child's Birth [REDACTED] | | Hospital of Birth [REDACTED] | |
| <p>I am a legal representative* of the child named above. I am asking the Michigan Department of Health and Human Services (MDHHS) to (check one):</p> <p><input type="checkbox"/> Destroy all remaining blood spots. I understand that by checking this box, NO blood spots will be available for any future use including medical, identification, or research purposes.</p> <p><input type="checkbox"/> Destroy only the portion of blood spots stored for research use. I understand by checking this box, one blood spot will be held by MDHHS. I must direct any potential future use including medical, identification or research purposes.</p> <p><input type="checkbox"/> Store but not use blood spots for research after newborn screening is complete. I understand that the blood spots will be kept by the laboratory but not used for research of any kind unless directed in writing by me.</p> <p>* 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.</p> | | | |
| Signature of Parent, Guardian or other Legal Representatives [REDACTED] | | Relationship to Child [REDACTED] | |
| Print Name [REDACTED] | | Date [REDACTED] | |
| Street Address [REDACTED] | | City [REDACTED] | Zip Code [REDACTED] |
| | | Phone Number [REDACTED] | |
| <p>If you are asking MDHHS to destroy any blood spots, you must also attach a copy of the birth certificate belonging to the person whose blood spots are being destroyed AND the driver's license, state issued identification card or passport of the person who signed above.</p> <p>Return document(s) via: Email: biotrust@michigan.gov Fax: 517-335-9419 or Post Mail: BioTrust Coordinator, NBS Follow-up Program, PO Box 30195, Lansing, MI 48909</p> <p><i>Please note that MDHHS cannot guarantee email security if you choose to submit this form and accompanying documents to the department via email.</i></p> | | | |

The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability.

Authority: Michigan Public Health Code, Act 368 of 1978

APPENDIX 10 – 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 if discharged between 8-29 days of life

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 if discharged between 8-29 days of life

Whichever comes first

THIRD SPECIMEN

90 days post last transfusion

For All Newborns Transfused with Red Cells
AFTER First Specimen

FIRST SPECIMEN

\geq 24 hours of life

OR

FIRST SPECIMEN

< 24 hours of life

Transfused

Transfused

SECOND SPECIMEN

30 days of life or if discharged
between 8-29 days of life

Whichever comes first

SECOND SPECIMEN

28 hours post transfusion start

THIRD SPECIMEN

30 days of life or if discharged
between 8-29 days of life

Whichever comes first

APPENDIX 11 – FAX REPORTING

The Michigan Department of Health and Human Services (MDHHS) encourages the receipt of Newborn Screening (NBS) laboratory reports via an automatic fax transmission. Fax reporting provides significant improvement in screening result turnaround time to your practice. A secure fax must be available 24 hours per day, 7 days per week because 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 hospital chooses this fax reporting option, the delivery of NBS laboratory reports through the United States Postal System will be eliminated.

Please notify MDHHS NBS 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.
- If you do not have an alternate secure fax, reports will be mailed until you notify the MDHHS NBS Laboratory that your machine is again operational.

You must meet two requirements to receive newborn screening results by fax:

1. A letter on your hospital letterhead must be sent to the MDHHS Bureau of Laboratories, Newborn Screening, consenting to receive automatic faxed results. The letter must be signed by a person who is authorized to make this request.
2. The statement of understanding (next page) must be completed, signed and returned with the consenting letter.

Send both to:

MDHHS Newborn Screening Laboratory
3350 N. Martin Luther King Blvd.
PO Box 30689
Lansing, MI 48909

OR

Fax: 517-335-8550

Direct any questions to Alayna Bunker, 517-335-4031, email BunkerA@michigan.gov;
or Jenny Kramer, 517-335-8095, email KramerJ8@michigan.gov

STATEMENT OF UNDERSTANDING
PRACTICES 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 practice 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 outside of normal business hours.

Date:

Hospital name:

Address:

Authorized person (please print):

Authorized signature:

Secure fax number:

Contact person for fax problems (please print):

Contact person's phone number:

Please keep a copy for your records

APPENDIX 12 – 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.

| 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 |

Check to see if your smart phone can default to 24-hour time. Follow these easy steps to change your iPhone default time:

1. From the iPhone's home screen, tap Settings.
2. Tap General.
3. Scroll to the bottom of the screen and tap Date and Time.
4. Move the 24-hour time slider to the "on" position.
5. Your iPhone will now display the 24-hour clock at the top of the screen and in the Clock application.

APPENDIX 13 – NBS REPORT REQUEST FORM



Phone: 517-335-4181
 Fax: 517-335-9419 or
 517-335-9739

NBS Report Request Form

Please be sure ALL FIELDS are filled in before faxing your request.
 Fax this form, along with your cover page, to 517-335-9419 or 517-335-9739.

CHILD/PATIENT INFORMATION

| | | |
|--|-----------------------------|---|
| Child/patient name | First Name: | Last Name: |
| Child/patient date of birth | | Sex (circle one) F M |
| Birth facility/city | | |
| Baby from multiple birth delivery | Circle One Yes No | Specify birth order (e.g., Twin 1, Twin B, Triplet C) |
| Mother's name at time of patient's birth | First Name: | Last Name: |
| Mother's alternate last name(s) | | |

PROVIDER INFORMATION

| | | |
|---|-----------------------------------|------------|
| Requestor's name | First Name: | Last Name: |
| Facility name/city | | |
| Health care provider's name | First Name: | Last Name: |
| Health care provider's NPI#: | Credential: (MD, DO, NP, etc.) | |
| Direct phone number (+ extension) of requestor/provider | | |
| Fax number where report is to be sent | | |

The requested document(s) contains confidential patient health information that is legally privileged. This information is intended only for the use of the individual or entity named above. Any unauthorized review, use, disclosure, or distribution of this communication(s) is expressly prohibited.

I certify the child listed above is my patient and hereby grant permission to the Michigan Department of Health and Human Services Newborn Screening Program to release the newborn screening record, including laboratory test reports of the child state d above, for diagnosis and treatment purposes only.

 Signature of Health Care Provider

 Date

Please return this completed document with your office fax cover page to the MDHHS Newborn Screening Program at 517-335-9419 or 517-335-9739.

To access this form visit Michigan.gov/newbornscreening and select "Resources for Hospitals and Health Professionals"



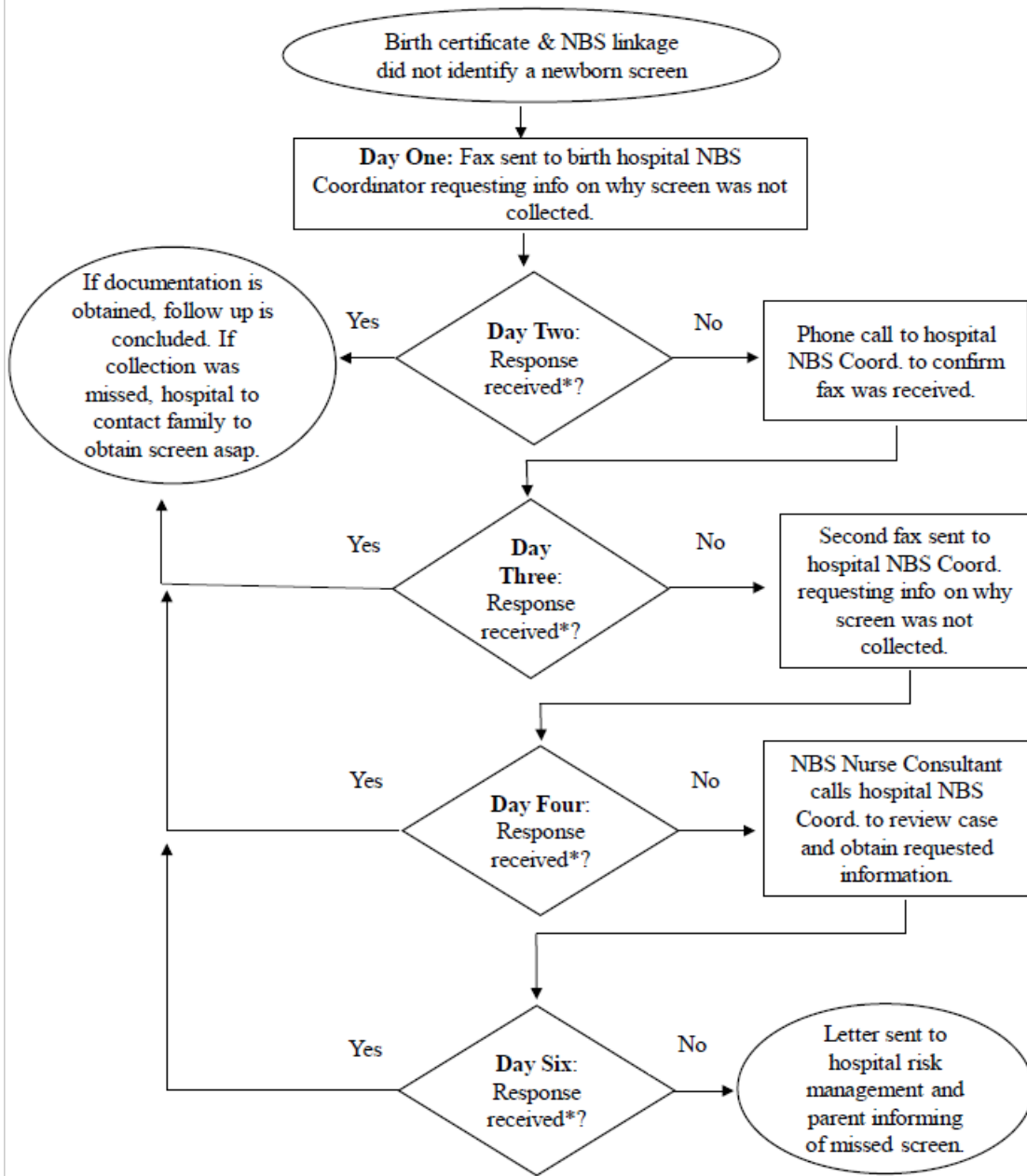
The [NBS Report Request](#) form is located on the [newborn screening](#) website (Michigan.gov/newbornscreening) in the "Resources for Hospitals and Health Professionals" section.

APPENDIX 14 – WEIGHT CONVERSION CHART

| | Pounds | | | | | | | | | | | | |
|--------|--------|-----|------|------|------|------|------|------|------|------|------|------|------|
| Ounces | 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 |

APPENDIX 15 – MISSING BLOODSPOT SPECIMEN PROCESS

Missing Newborn Screening Bloodspot Specimen



*Response received may include the return of fax or telephone call indicating details of collection (if records show collection occurred) or reason why collection did not occur. A copy of parent signature on form indicating they would not permit collection can also be sent via fax to 517-335-9419 or 517-335-9739.