



**MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Newborn Screening  
Guide for Hospitals  
December, 2017



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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. If parents object to screening, it is suggested that the hospital request that parents sign a waiver stating that they were informed of the risk to their newborn if screening is declined and return the form to the NBS Program. [Appendix 1](#) summarizes NBS legislation. [Appendix 7](#) contains a sample waiver form for parents who do not want their newborn to be screened. This form is just an example, and each hospital should develop its own form in conjunction with the hospital legal department.

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

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 mailed/faxed to the hospital that submitted the specimen. The NBS Laboratory would like all hospitals to receive NBS results by fax in order to assure prompt receipt. [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 sub-specialist 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.

More information about CCHD screening, data reporting, and educational materials for healthcare providers and parents is available on the [newborn screening CCHD](#) website.

# **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. Provide guidance/information to nursery and laboratory staff on the importance of accurately filling out all demographic fields on the NBS card.
  - e. Assist NBS program staff in resolving problems of missing/incorrect demographic information on the NBS card and in obtaining repeat samples when specimens are unsatisfactory for testing.
  - f. Assure that hospital NBS policies and procedures include a protocol for notifying the NBS program if parents refuse NBS testing or if a newborn death occurs after a specimen was sent to the NBS laboratory.
2. Perform 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 State NBS Program to appropriate hospital staff (nursing, laboratory, clinicians).
  - b. Assure that there is an adequate supply of NBS and BioTrust brochures and a mechanism for distribution to all mothers.
  - c. Work with 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. Press firmly using a black or blue pen and **clearly print** the information. The card will be scanned into the NBS database, so legibility is critical. The specimen submitter is legally responsible for the accuracy and completeness of the information on the NBS card. Include the following information in the spaces provided:

## Infant Information

- ✓ **INFANT'S NAME:** Record last name followed by first name. If no first name is available at the time of specimen collection, the last name followed by "boy" or "girl" should be used. For single mothers, use the last name of mother or last name specified by mother. **DO NOT LEAVE BLANK.**
- ✓ **GENDER:** Completely shade in the appropriate oval to designate newborn's gender as male or female.
- ✓ **BIRTH DATE:** Use a six-digit number (mm/dd/yy) for date of birth. For example, a birth on January 4, 2017 would be recorded as 011417.
- ✓ **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. Note: Birthweight is only required on the first sample ("blue") card. For help with weight conversions, visit [New Zealand's Newborn Services Clinical Guideline](#) website.
- ✓ **CURRENT WEIGHT (grams):** Record the current weight in grams in the boxes provided. Do not use pounds and ounces. Note: This information is only required on the repeat sample ("pink") card. For help with weight conversions, visit [New Zealand's Newborn Services Clinical Guideline](#) website.
- ✓ **WEEKS GESTATION:** Record weeks of gestation at time of birth. Note: This information is requested for both the first sample ("blue") and repeat sample ("pink") cards.
- ✓ **SINGLE BIRTH:** Completely shade in oval for single birth.
- ✓ **MULTIPLE BIRTH ORDER:** Completely shade in oval to record birth order by "A", "B", "C" for twins, triplets, etc.
- ✓ **ANTIBIOTICS:** 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.
- ✓ **SPECIMEN DATE:** Use a six-digit number (mm/dd/yy) representing the date on which the specimen was collected.

- ✓ **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 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. If yes, give date (mm/dd/yy) and the start time (military) of the **most recent** transfusion. For example, if the transfusion start on October 13, 2016 at 11:20 p.m., enter 101316 2320.
- ✓ **MEDICAL RECORD NUMBER BABY:** Record the birth hospital’s identification or medical record number.
- ✓ **ANY TPN FEEDING:** Completely shade in oval “yes” if the newborn is receiving total parenteral nutrition (TPN) at the time the specimen is 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.
- ✓ **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.

*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. Check both “heel” *and* “capillary” if the blood was collected from the heel using a capillary tube. Note that the use of a capillary tube can result in layered, serum, clotted, or damaged specimens. If the heel was not used, indicate the alternate collection method.
- ✓ **OTHER FEEDING:** Check all that apply. For instance, if a mother is both breast and bottle feeding, mark both and indicate the type of formula. Note: Human milk fortifier may or may not be milk-based. Mark both milk-base and breast if using Similac® Human Milk Fortifier or Enfamil® Human Milk Fortifier Acidified Liquid. Mark breast if using Prolacta.

## Mother Information

- ✓ **MOTHER'S NAME:** Record last name followed by first name. If the newborn is going to be released at birth to adoptive or foster parents, provide contact information of adoptive mother, foster mother, or adoption agency. Please note in black ink above the mother's name that contact information is for adoptive or foster mother. Do not place sticky notes on the card or use red ink. Neither will be recorded when the card is scanned into the 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, followed by city, state and zip code. Information about the mother is needed to locate newborns in need of clinical evaluation or retesting.
- ✓ **MOTHER'S PHONE:** Record mother's area code and home telephone number.
- ✓ **MEDICAL RECORD NUMBER – MOTHER:** Record the hospital identification or medical record number. Note: This information is only required on the "blue" first sample card.
- ✓ **BIRTH DATE:** Record the mother's date of birth (mm/dd/yy).
- ✓ **HEPATITIS B SURFACE ANTIGEN (HBsAg):** Provide date of test (mm/dd/yy) and completely shade in the appropriate oval to indicate a positive or negative result. If there is no HBsAg test result in the mother's record, the test should be done immediately. Positive HBsAg results should be faxed to the MDHHS Perinatal Hepatitis B Prevention Program at 517-335-9855. This important information helps assure that infants at risk receive the proper interventions. Note: This information is only required on the first sample ("blue") card.

## Provider Information

- ✓ **PROVIDER'S NAME:** Record last name, followed by first name, of the primary care provider to be notified of an unsatisfactory or positive newborn screen. If the mother does not offer a primary care provider's name, the physician in charge of the newborn nursery should be listed on the NBS card. The physician should arrange for all retesting through the hospital's outpatient laboratory. If the newborn is expected to be in the NICU for at least a week, list a staff neonatologist as the physician and write the NICU 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.
- ✓ **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.

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



## Michigan BioTrust for Health

The Michigan BioTrust for Health (BioTrust) is a program that oversees the storage of residual dried blood spots (DBS) from NBS for their potential use in medical and public health research. Hospital staff should provide the BioTrust consent brochure entitled *After Newborn Screening, Your Baby's Blood Spots* to parents and ask if they are willing to grant permission to make their infant's DBS available for health research once NBS is complete. Permission is granted by marking the "yes" check box and signing the consent form located on the back of the NBS first sample card. If parents decline permission for the BioTrust, please have them mark the "no" checkbox and sign the BioTrust form. NBS program staff, upon request, will provide onsite training on the BioTrust and the parental consent process. This training is also available on the [newborn screening](#) website. [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 unless the parent requests that the specimen be destroyed. Parents who would like to have their newborn's DBS destroyed should sign and return the *Directive to Destroy Residual Newborn Screening Blood Specimen* 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 *Directive to Destroy Residual Newborn Screening Blood Specimen* form. Persons over the age of 18 or parents of minor children who would like these samples to remain in storage but no longer made available for research must sign and return the *Directive to Store but Not Use Dried Blood Spot Specimen for Research* form. [Appendix 9](#) contains both directive forms.

### **BioTrust Consent Form Instructions**

1. Provide the *Michigan Newborn Screening Saves Babies* brochure and the *After Newborn Screening, Your Baby's Blood Spots* BioTrust consent brochure to parents. Clarify the difference between the mandatory NBS Program and the optional Michigan BioTrust for Health, which allows residual DBS to be used for research.
2. Inform parents about the *Michigan Newborn Screening Saves Lives* video and that it can be viewed either on the [newborn screening](#) website 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!

# Ordering Newborn Screening Cards, Return Envelopes and Brochures

Hospital and health system supply purchasing personnel are now expected to 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, or the family refused NBS. 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 could result in no replacement cards being issued.

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

For ordering and current price information, please visit the [newborn screening ordering](#) website.

## 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 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.

## Laboratory Testing Methods

- **Tandem Mass Spectrometry (TMS):** Amino acid, organic acid and fatty acid oxidation disorders are detected by evaluation of specific TMS acylcarnitine and amino acid profiles.
- **Fluoroimmunoassay (FIA):** Congenital hypothyroidism (CH), congenital adrenal hyperplasia (CAH), and cystic fibrosis (CF) are detected by FIA for thyroid stimulating hormone (TSH), 17-hydroxyprogesterone (17-OHP) and immunoreactive trypsinogen (IRT), respectively. If a CAH screen is positive, a secondary screen for CAH by steroid profile is performed by TMS at the Mayo Biochemical Genetics Laboratory. A secondary DNA screen for 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).
- **Direct enzyme assays:** Galactosemia (galactose-1-phosphate uridyltransferase) and biotinidase deficiency (biotinidase).

## Disorders Identified in Michigan Newborn Residents via Newborn Screening, 1965-2015

Type of Disorder Classification (Year Screening Began)	Cases in 2015 (N)	Cases Through 2015 (N)	Cumulative Detection Rate
Galactosemia (1985)	4	192	1:21,044
Biotinidase Deficiencies (1987)	24	292	1:12,893
Amino Acid Disorders (1965)	13	729	1:9,601
Organic Acid Disorders (2005)	4	73	1:17,607
Fatty Acid Oxidation Disorders (2003)	22	230	1:6,721
Congenital Hypothyroidism (1977)	94	2,144	1:1,756
Congenital Adrenal Hyperplasia (1993)	5	153	1:18,890
Sickle Cell Disease (1987)	64	1,849	1:2,036
Hemoglobin H Disease (2012)	1	6	1:74,428
Cystic Fibrosis (October 2007)	19	238	1:3,937
Primary Immunodeficiencies (October 2011)	20	75	1:7,450
Total	270	5,981	-

# 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. At least 90% of newborns with a dried blood spot screen have pulse oximetry screening results reported.

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



STATE OF MICHIGAN  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
LANSING

RICK SNYDER GOVERNOR      NICK LYON DIRECTOR

**NEWBORN SCREENING QUALITY ASSURANCE NOTIFICATION**      Covering the period: 7/1/2016 - 9/30/2016

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

The goals are:

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

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1 STATE	July			August			September			Quarter		
<i>Total number specimens for your hospital</i>	9,840			9,962			9,518			29,320		
<i>Total number of specimens for state</i>	9,840			9,962			9,518			29,320		
	<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>	97	1	Met	96	1	Met	90	0.9	Met	283	1	Met
<i>Late Screens for state</i>	97	1	Met	96	1	Met	90	0.9	Met	283	1	Met
<i>Receipt by Appropriate Day for your hospital</i>	8,698	88.4	Not Met	8,737	87.7	Not Met	8,314	87.4	Not Met	25,749	87.8	Not Met
<i>Receipt by Appropriate Day for state</i>	8,698	88.4	Not Met	8,737	87.7	Not Met	8,314	87.4	Not Met	25,749	87.8	Not Met
<i>Unsatisfactory Screens for your hospital</i>	99	0.9	Met	76	0.7	Met	95	0.9	Met	270	0.9	Met
<i>Unsatisfactory Screens for state</i>	99	0.9	Met	76	0.7	Met	95	0.9	Met	270	0.9	Not Met
<i>Birth certificates* for your hospital</i>	9,195			9,284			8,689			27,168		
<i>Birth certificates* for state</i>	9,195			9,284			8,689			27,168		
<i>Newborn Screening Card Number for your hospital</i>	8,787	95.6	Met	8,928	96.2	Met	8,337	95.9	Met	26,052	95.9	Met
<i>Newborn Screening Card Number for state</i>	8,787	95.6	Met	8,928	96.2	Met	8,337	95.9	Met	26,052	95.9	Met
<i>Returned BioTrust for Health Consent Forms for your hospital</i>	8,359	84.9	Not Met	8,536	85.7	Not Met	7,942	83.4	Not Met	24,837	84.7	Not Met
<i>Returned BioTrust for Health Consent Forms for state</i>	8,359	84.9	Not Met	8,536	85.7	Not Met	7,942	83.4	Not Met	24,837	84.7	Not Met
<i>Reported Pulse Oximetry Screening Results** for your hospital</i>	8,105	82.4	Not Met	7,897	79.3	Not Met	7,416	77.9	Not Met	23,418	79.9	Not Met
<i>Reported Pulse Oximetry Screening Results** for state</i>	8,105	82.4	Not Met	7,897	79.3	Not Met	7,416	77.9	Not Met	23,418	79.9	Not Met

\*This is a preliminary estimate excluding all birth certificates with NICU admission marked on the birth certificate. The number of birth certificates may be different than the number of specimens due to several factors including screening refusals, increased length of time between birth and release of birth certificate to the State, and inclusion of birth certificates of infants in the NICU or SCN if that information was not marked on the birth certificate.

\*\*This number may be an under-estimate for some hospitals as additional records may have been received but a link was not able to be made to the newborn screen blood spot screen based on demographics provided. This is usually related to a missing or incorrect newborn screening kit number.

333 S Grand Ave • P.O. BOX 30195 • LANSING, MICHIGAN 48909  
www.michigan.gov/newbornscreening

DCH-0045(03/03) (W)

## **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 should be collected on all NICU newborns at 30 days of life or at discharge, whichever comes first. If discharge occurs prior to the eighth day of life, a repeat sample specimen does not need to be collected.

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-up immediately on requests for an additional specimen if you are notified 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. For newborns not admitted to the NICU, 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)

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

### **Total Parenteral Nutrition (TPN)**

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

### **Transferred Newborns**

- The birth hospital is responsible for ensuring that NBS specimens are collected on all newborns, regardless of age, and sent to the NBS Laboratory.
- The birth hospital should notify the receiving facility of the NBS status and include verification of screening in the transport paperwork.
- The receiving hospital should verify the screening status of all transferred newborns. If screening cannot be verified, the receiving hospital should obtain the newborn screen.
- If the newborn screen was done prior to 24 hours of life, the receiving hospital should do the 24-36 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 (866-673-9939) if a newborn or a newborn's sibling is suspected of having a NBS disorder. A sub-specialist will be contacted and provide recommendations on clinical management prior to diagnostic confirmation.

### **Newborn Death or Pending Death**

The NBS Program should be notified if a newborn dies or is expected to die. A NBS specimen should be obtained at the parent's discretion to determine if the newborn has a NBS disorder. This information is important for parents in planning future pregnancies. Notify the NBS Follow-up Program (fax 517-335-9419 or 517-335-9739) when 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.

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
- Parent/guardian signed release if you are not the provider recorded on the NBS card

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

## Questions on Positive Reports Received

If you receive a positive report for a baby and have questions, contact the [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
- NBS specimen collection instructions
- NBS educational online tutorial
- NBS annual reports that give the number of confirmed cases per year

## Documentation of NBS Results

Documentation that a newborn has been screened should be available for every newborn and included in the medical record.

The NBS Program recommends that a log be kept of each 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, 866-673-9939, 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, collected before 24 hours of life or collected after RBC transfusion.

## 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 as a tool. NBS materials may be ordered on the [newborn screening ordering](#) website. Additional information, including a Michigan NBS video, is available on the [newborn screening](#) website.

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

Of the 111,725 infants screened in 2015, 270 were diagnosed with a disorder. Overall, one infant out of 414 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 also write this information on the top of the NBS card.

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

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

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

Based on nationally accepted criteria, the NBS Quality Assurance Advisory Committee makes recommendations on disorder inclusion to the MDHHS director. The NBS Quality Assurance Advisory Committee meets once each year. Members include parents of affected children, 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 866-673-9939 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**

[Michigan Newborn Screening](#)

[Genetics Home Reference](#)

[Newborn Screening Course](#)

[National Newborn Screening and Genetics Resource Center](#)

[American Academy of Pediatrics](#)

### **National Newborn Hearing Websites**

[Centers for Disease Control Early Hearing Detection and Intervention](#)

[Marion Downs Center](#)

[National Institute on Deafness and Other Communication Disorders](#)

[American Speech-Language-Hearing Association](#)

[American Academy of Audiology](#)

[Hands and Voices](#)

## CONTACT INFORMATION

### NBS Follow-up Program

Michigan Department of Health and Human Services

Newborn Screening Follow-up

333. S. Grand Ave., 2<sup>nd</sup> 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](mailto:newbornscreening@michigan.gov)

**Website:** [Michigan Newborn Screening](#)

### Staff

**Mary Kleyn**

Manager - Newborn Screening Section

517-335-9296

**Lois Turbett**

Nurse Consultant

517-335-1966

**Karen Andruszewski**

Departmental Specialist

517-335-9205

**Isabel Hurden**

NBS Epidemiologist

517-284-4231

**Lacey VanLoenen**

Departmental Technician

517-335-4181

**Carolyn Smith**

Departmental Technician

517-335-4181

**Valerie Ewald**

Administrative/NBSO Technical Assistant

517-335-8887

**Kristen Thompson**

Program Coordinator

517-373-0937

# **NBS Laboratory**

**Michigan Department of Health and Human Services**

**Newborn Screening Laboratory**

3350 N. Martin Luther King Blvd.

PO Box 30689

Lansing, MI 48909

## **Staff**

**Director (vacant)**

Division of Chemistry and Toxicology

517-335-9490

**Harry Hawkins, Manager**

NBS Laboratory Section

517-335-8095

**Denise Archambeault**

Departmental Technician

517-335-8543

## **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

Brian Clingen, Regional Manager Operations-Logistics

**Email:** [bclingen@stat-courier.com](mailto:bclingen@stat-courier.com)

### **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 Express Envelopes

**Email** [newbornscreening@michigan.gov](mailto:newbornscreening@michigan.gov) for UPS shipping labels

Contact <a href="mailto:newbornscreening@michigan.gov">newbornscreening@michigan.gov</a> if you need detailed NBS courier information such as your courier pickup time, days and location.
--

# Hearing

## Michigan Department of Health and Human Services Early Hearing Detection and Intervention

109 W. Michigan Ave., 3<sup>rd</sup> floor  
PO Box 30195  
Lansing, MI 48909

**Telephone:** 517-335-8955

**Fax:** 517-335-8036

**Website:** [Michigan Early Hearing Detection and Intervention](#)

### Staff

**(vacant)**

Infant Health Unit Manager  
517-335-8131

**Michelle Garcia**

Follow-up Consultant  
517-335-8878

**Debra Behringer**

EHDI Coordinator  
517-335-8601

**Nan Asher**

Program Consultant  
517-335-8273

**Erin Estrada**

Data Analyst  
517-335-8916

**Lisa Borucki**

Infant Health Unit Secretary  
517-335-8955

**Karen Wisinski**

Parent Consultant  
517-241-7066

# Hepatitis B

## Michigan Department of Health and Human Services

### Perinatal Hepatitis B Prevention Program

333 S. Grand Ave., 3<sup>rd</sup> floor

PO Box 30195

Lansing, MI 48909

**Toll-free:** 800-964-4487

**Telephone:** 517-335-9443

**Website:** [Perinatal Hepatitis B Prevention Program](#)

## Staff

### **Pat Fineis**

Program Coordinator

517-335-9443

### **Kari Tapley**

Surveillance Specialist

313-456-4431

### **Aleisha Phillips**

Case Manager/SE MI

313-456-4432

### **Marcy Smith**

Case Manager/Out-state

517-284-4893

# NBS Follow-up Coordinating Centers

## Follow-up Coordinating Centers

**Hemoglobinopathies – Sickle cell anemia (Hb SS), hemoglobin SC disease, sickle beta thalassemia zero ( $S\beta^0$ ), sickle beta thalassemia plus ( $S\beta^+$ ), 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](mailto:info@scdaami.org)

**Children's Hospital of Michigan**

3901 Beaubien Blvd.  
Detroit, MI 48201-2192  
Telephone: 313-745-5613  
Fax: 313-745-5237  
Call for a referral to social work and counseling sites in Benton Harbor, Kalamazoo, Grand Rapids, Muskegon, Lansing, Flint, Saginaw and Pontiac.

**Metabolic – Amino acid disorders, fatty acid oxidation disorders, organic acid disorders, galactosemia, biotinidase deficiency, lysosomal storage disorders.**

**Children's Hospital of Michigan Metabolic Clinic**

3950 Beaubien Blvd.  
Detroit, MI 48201-2192  
Telephone: 313-832-9330  
Fax: 313-745-8030

**Endocrine - cystic fibrosis and congenital hypothyroidism  
Metabolic - lysosomal storage disorders**

**Michigan Medicine at the University of Michigan**

Department of Pediatrics  
1500 E. Medical Center Dr.  
D1225 MPB, Box 0718  
Ann Arbor, MI 48109-0718  
Telephone: 734-647-8938  
Fax: 734-936-7918

**Severe Combined Immunodeficiency**

**Children's Hospital of Michigan Coordinating Center for Primary Immunodeficiencies**

3901 Beaubien St., 5th floor Carls Building  
Detroit, MI 48201  
Telephone: 313-806-6571  
Pager: 313-745-0203; enter pager number 5706  
Fax: 313-966-9701

## **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 is 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:

**DO NOT REMOVE OVERLAY**

See attached instructions for specimen collection and sending.

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



Do not send specimens in plastic bags.



**INSTRUCTIONS FOR SPECIMEN COLLECTION AND SENDING**

**COMPLETION OF FORM**

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

**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.

**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](http://www.michigan.gov/NBSorders)  
or call (517) 335-8887

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

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

Newborn Screening - Michigan Department of Health and Human Services  
Bureau of Laboratories 2700 Zeeb Road, Lansing, MI 48999  
Print Form with Black Pen  
DON'T USE RED INK  
DCFH-1153 Printed: 10/15

LAST NAME		FIRST NAME		GENDER MALE FEMALE	
BIRTH DATE	BIRTH TIME (Military)	BIRTH WT. (grams)	WKS GESTATION	BIRTH ORDER A B C D	
SPECIMEN DATE		COLLECTION TIME (Military)	Collected By: (Initials)	ANTIBIOTICS? NO YES	
MEDICAL RECORD #		NICU or SPECIAL CARE? NICU NO YES SP CARE NO YES		ANY RBC TRANSFUSION? NO YES	
TYPE OF COLLECTION: Heel Stick Capillary Tube Line Draw (central, other)		TPN / AMINO ACIDS NO YES		TRANSFUSION DATE	
TYPE OF FLUSH: Propath, saline, other		HISPANIC NON-HISPANIC		TRANS. START TIME (Military)	
LAST NAME		FIRST NAME		OTHER FEEDING: BREAST MILK-BASE SOY NONE	
ADDRESS		CITY		PHONE	
STATE		ZIP		HEPATITIS B SURFACE ANTIGEN (HBsAg) TEST DATE	
MEDICAL RECORD #		BIRTH DATE		RESULT POSITIVE NEGATIVE	
LAST NAME		FIRST NAME		PHONE	
PHONE		FAX		FIRST SAMPLE	
SUBMITTER NAME		HOSPITAL CODE (if applicable)		00	
ADDRESS		CITY		PHONE	
STATE		ZIP		MDHHS USE ONLY	
BIRTH HOSPITAL (if different from submitter)		CO 105178 / 315145		EXPIRES: 2018-10	

DHHS USE ONLY

MDHHS  
By Authority of Act 968  
P.A. MCLA 333.5431  
PerkinElmer Z26

2097001

SEN 2097001

DO NOT REMOVE OVERLAY

See attached instructions for specimen collection and sending.

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

Do not send specimens in plastic bags.

BIOHAZARD

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

38371

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

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

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

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

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

MDHHS Copy

SEN 2097001

DO NOT REMOVE OVERLAY

See attached instructions for specimen collection and sending.

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

Do not send specimens in plastic bags.

BIOHAZARD

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

## **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 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.

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. If you are using eCheck to make your purchase, please call 517-335-8887 to get your permanent eCheck verification code, which you will need to use for all future orders. 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.

Place your order on the [newborn screening ordering](#) website.

**Follow these steps to get started:**

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

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

# 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.**
- To ensure a quicker turnaround time, send 10 face sheets or less.
- If there is blood on the white face sheet, place it in a biohazard bag.
- **DO NOT send card replacement requests to the NBS Laboratory.** Failure to send your request to the address below may result in no replacement card being issued. Please note: Courier envelopes are for 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., 2<sup>nd</sup> floor  
PO Box 30195  
Lansing, MI 48909

# APPENDIX 7 - PARENTAL REFUSAL FOR NEWBORN SCREENING EXAMPLE

---

Baby's Name

Baby's Date of Birth

---

Mother's Name or Guardian

Father's Name or Guardian

I(We), the parent(s) of this baby, object to and refuse the requirement that my (our) child be screened for the presence of the disorders listed on the enclosed Michigan Department of Health and Human Services (MDHHS) newborn screening (NBS) panel and posted on the [newborn screening](#) website.

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

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

---

Print mother's/guardian's name

Signature

Date

---

Print father's/guardian's name

Signature

Date

---

Print witness's name

Signature

Date

---

Print witness's name

Signature

Date

Returned signed copy by mail:

**MDHHS**

OR

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

**Attention: Newborn Screening**

333 S. Grand Ave., 2<sup>nd</sup> floor

PO Box 30195

Lansing, MI 48909

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

Please circle:

Cannot afford to pay for the card

Religious reasons

Privacy concerns

Other reason:

---

## 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-I)
  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 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. Sick 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. Hearing
56. Critical congenital heart disease (CCHD)

### Disorder Coming Soon

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

- X-linked adrenoleukodystrophy (X-ALD)

Updated December, 2017

# APPENDIX 9 – SPECIMEN DIRECTIVES

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

*Michigan Department of Community Health*  
**Directive to Destroy Residual Newborn Screening Blood Specimen**

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

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

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

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

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

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

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

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

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

<b>Authority:</b>	Michigan Public Health Code, Act 368 of 1978	The Michigan Department of Community Health is an equal opportunity employer, services, and program provider
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The [Directive to Store But Not Use Dried Blood Spot Specimen For Research](#) form is located on the [newborn screening](#) website.

*Michigan Department of Community Health*

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

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

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

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

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

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

**OR**

⇒ **Mail to:**

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

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

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

\_\_\_\_\_

\_\_\_\_\_

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

Transfused

**SECOND SPECIMEN**

30 days of life or at discharge

OR

**FIRST SPECIMEN**

< 24 hours of life

Transfused

**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 Paul Kramer, 517-335-9103 or email [KramerP@michigan.gov](mailto:KramerP@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.