Michigan Department of Community Health

Newborn Screening Guide for Hospitals

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Michigan Department of Community Health
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Table of Contents

INTRODUCTION

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

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

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

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

1) Maintaining an inventory of NBS supplies, i.e. NBS cards, forms and educational materials.
2) Educating hospital nursery and NICU staff on the NBS specimen collection protocol.
3) Recording and entering the NBS card ("kit") number on the electronic birth certificate (EBC). Note that the NBS card ("kit") number is referred to as the "metabolic number" on the EBC.
4) Maintaining tracking logs on NBS specimen collection, courier pick-up and screening results.
5) Courier pick-up for delivery of NBS specimens to the MDCH 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. See Appendix 10 for a complete list of disorders included in the NBS panel. Michigan law mandates NBS. If parents object to screening, it is suggested that the hospital request that parents sign a waiver stating that they were informed of the risk to their newborn if screening is declined and return the form to the NBS Program. See Appendix 1 for NBS legislation and Appendix 9 for a sample waiver form for parents who do not want their newborn to be screened. This form is just an example and each hospital should develop its own form in conjunction with the hospital legal department.

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

Ideally, blood specimens should be collected at 24-30 hours of life and air dried for at least three hours. The hospital should send specimens to the NBS Laboratory daily. Specimens should be sent by courier within 24 hours of collection. Courier service (same day or overnight delivery to the state NBS Laboratory) is now in place in all hospitals. Laboratory testing is typically completed within one or two days of specimen receipt, and all NBS results are mailed/faxed to the hospital that submitted the specimen. The NBS Laboratory would like all hospitals to receive NBS results by fax in order to assure prompt receipt. See Appendix 14. NBS Laboratory operations are Monday through Saturday, except for some state holidays.

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

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

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

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

Hearing Screening

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

Critical Congenital Heart Disease Screening

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

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

More information about CCHD screening, data reporting and educational materials for healthcare providers and parents are available on the MDCH CCHD website www.michigan.gov/cchd.

NEWBORN SCREENING PRACTICE AND PROCEDURE

Role of the Newborn Screening Coordinator

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

The suggested responsibilities of the NBS coordinator are:

1. Perform quality assurance activities:
    a. Assure that there is a NBS protocol in place describing the hospital's NBS policies and procedures. See Appendix 13 for *Hospital Specific Procedure Template*
    b. Assure that a log is maintained to track NBS specimens, courier pick-up, and receipt of screening results.
    c. Assure adequate inventory of NBS cards.
    d. Provide guidance/information to nursery and laboratory staff on the importance of accurately filling out all demographic fields on the NBS card.
    e. Assist NBS program staff in resolving problems of missing/incorrect demographic information on the NBS card and in obtaining retests when specimens were unsatisfactory for testing.
    f. Assure that hospital NBS policies and procedures include a protocol for notifying the NBS program if parents refuse NBS testing or if a newborn death occurs after a specimen was sent to the NBS laboratory.
2. Perform educational activities:
    a. Serve as a contact person and facilitator between the NBS program and hospital staff involved in the NBS process to:
        i. Inform and educate hospital staff about new program guidelines and protocol changes (new disorders added to test panel, changes in specimen collection requirements, and other NBS information, as necessary).
        ii. Disseminate information (newsletters, quality assurance (QA) reports) received from the state NBS program to appropriate hospital staff (nursing, laboratory, clinicians).
    b. Assure that there is an adequate supply of NBS brochures and a mechanism for distribution to all mothers.
    c. Work with OB department staff to incorporate NBS educational information in existing and future prenatal classes offered to parents.

Completing the Newborn Screening Card

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

INFANT INFORMATION:

- ✓ **INFANT'S NAME:** Record last name followed by first name. If no first name is available at the time of specimen collection, the last name followed by "boy" or "girl" should be used. For single mothers, use the last name of mother or last name specified by mother. DO NOT LEAVE BLANK.

- ✓ **GENDER:** Completely shade in the appropriate oval to designate newborn's gender as male or female.

- ✓ **BIRTH DATE:** Use a six-digit number (mm/dd/yy) for date of birth. For example, a birth on January 4, 2012 would be recorded as 010412.

- ✓ **BIRTH TIME:** Record time of birth in military time. For example, a birth at 4:30 p.m. would be recorded as 1630. For help with time conversions see Appendix 15

- ✓ **BIRTH WEIGHT, GRAMS:** Record the birth weight in grams in the boxes provided. Do not use pounds and ounces. Note: This information is only required on the “blue” first sample card. For help with weight conversions see Appendix 16

- ✓ **CURRENT WEIGHT, GRAMS:** Record the current weight in grams in the boxes provided. Do not use pounds and ounces. Note: This information is only required on the “pink” repeat sample card. For help with weight conversions see Appendix 16

- ✓ **WEEKS GESTATION:** Record weeks of gestation at time of birth. Note: This information is requested for both “blue” first sample and “pink” repeat sample cards.

- ✓ **SINGLE BIRTH:** Completely shade in oval for single birth.

- ✓ **MULTIPLE BIRTH ORDER:** Completely shade in oval to record birth order by "A”, “B”, “C" for twins, triplets, etc.

- ✓ **ANTIBIOTICS:** For the first sample specimen, check “antibiotics” if the newborn is currently receiving antibiotics or the mother was receiving ongoing antibiotics at the time of birth. Do not check antibiotics if the mother received one dose prior to a cesarean section. For the 30-day specimen, do not check antibiotics if the newborn received antibiotics in the past and is not currently receiving them.

- ✓ **SPECIMEN DATE:** Use a six-digit number (mm/dd/yy) representing the date on which the specimen was obtained.

- ✓ **COLLECTION TIME:** Record time of specimen collection in military time. For help with time conversions see Appendix 15.

- ✓ **COLLECTED BY:** Record initials or employee hospital identification number of person collecting the specimen.

- ✓ **NICU/SPECIAL CARE:** Indicate if the newborn was in the NICU or special care nursery (SP Care) at the time the specimen was collected. If neither, completely shade in the oval next to "no".

- ✓ **RBC TRANSFUSION:** Completely shade in oval "no" or "yes" to indicate whether the newborn was ever transfused with red blood cells **prior** to specimen collection. If yes, give date (mm/dd/yy) and the start time (military) of the **most recent** transfusion. For example, if the transfusion started on October 13, 2012 at 11:20 p.m., enter 101312 2320.

- ✓ **MEDICAL RECORD NUMBER BABY:** Record the birth hospital's identification or medical record number.

- ✓ **ANY TPN FEEDING:** Completely shade in oval "yes" if the newborn is receiving total parenteral nutrition (TPN) at the time the specimen is obtained -OR- received TPN within 24 hrs of specimen collection.

- ✓ **ETHNICITY:** Completely shade in oval for Hispanic or non-Hispanic. Ethnicity should be filled in first and, in addition, one of the six boxes for race should be filled in.

- ✓ **RACE:** Completely shade in the oval for one of the six racial categories after the designation of Hispanic or non-Hispanic has been selected. If the newborn has a parent in one racial category and the other parent in a different racial category, fill in the Multi-Racial oval. It is very important to fill in either the Hispanic or non-Hispanic box and in addition fill in one of the six boxes for race.

Example 1: One parent identifies as Hispanic and both parents identify as Black. The card should be marked Hispanic and Black.
Example 2: One parent identifies as Hispanic and White; the other parent identifies as non-Hispanic and Black. The card should be marked Hispanic and Multi-Racial.
Example 3: Neither parent identifies as Hispanic. One parent identifies as White; the other parent identifies as Black. The card should be marked non-Hispanic and Multi-Racial.

- ✓ **TYPE OF COLLECTION:** The preferred collection method is by heel stick with a single drop of blood applied directly to each circle on the filter paper. Check both "heel" *and* "capillary" if the blood was collected from the heel using a capillary tube. Note that the use of a capillary tube can result in layered, serum, clotted and damaged specimens. If the heel was not used, indicate the alternate collection method.

- ✓ **OTHER FEEDING:** Check all that apply. For instance, if a mother is both breast and bottle feeding, mark both and indicate the type of formula. Note: Human milk fortifier may or may not be milk-based. Mark both milk-base and breast if using Similac Human Milk Fortifier or Enfamil Human Milk Fortifier Acidified Liquid. Mark breast if using Prolacta.

MOTHER INFORMATION:

- ✓ **MOTHER'S NAME:** Record last name followed by first name. If the newborn is going to be released at birth to adoptive or foster parents, provide contact information of adoptive or foster mother. Please note in black ink above the mother's name that contact information is for adoptive or foster mother. Do not place sticky notes on the card or use red ink. Neither will be recorded when the card is scanned into the system. If contact information on new parents, foster parents, or the adoption agency is not on the card, we will not be able to contact the family if necessary. We would like to avoid calling the birth mother if she is no longer responsible for the care of the newborn.

- ✓ **MOTHER'S ADDRESS:** Record mother's current street address, followed by city, state and zip code. Information about the mother is needed to locate newborns in need of clinical evaluation or retesting.

- ✓ **MOTHER'S PHONE:** Record mother's area code and home telephone number.

- ✓ **MEDICAL RECORD NUMBER-MOTHER:** Record the hospital identification or medical record number. Note: This information is only required on the "blue" first sample card.

- ✓ **BIRTH DATE:** Record the mother's date of birth (mm/dd/yy).

- ✓ **HEPATITIS B SURFACE ANTIGEN (HBsAg):** Provide date of test (mm/dd/yy) and completely shade in the appropriate oval to indicate a positive or negative result. If there is no HBsAg test result in the mother's record, the test should be done immediately. Positive HBsAg results should be reported to the MDCH Hepatitis B program at (517) 335 9443 or fineisp@michigan.gov. This important information helps assure that infants at risk receive the proper immunizations WITHIN 12 HOURS OF BIRTH. Note: This information is only required on the "blue" first sample card.

PROVIDER INFORMATION:

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

- ✓ **PROVIDER'S PHONE:** Indicate the primary care provider's area code followed by the telephone number. It is very important to provide a complete and correct number. This information is used to contact the health care provider with positive screen results and follow-up information. If the hospital newborn nursery chooses to follow-up positive results directly, provide the name and telephone number of the staff person designated to contact the family. This option is preferred for newborns without a designated primary care provider.

- ✓ **PROVIDER'S FAX:** Indicate the primary care provider's area code followed by fax number. The fax number is needed to forward to the provider screening results that require further follow-up.

SUBMITTER INFORMATION:

- ✓ **SUBMITTER NAME:** Record the name of the submitter (this should be the birth hospital or midwife on all initial newborn screens). If abbreviation of the hospital's name is necessary, use some letters from each word in the hospital's name. For example, the abbreviation for St. Joseph Mercy Hospital would be St. Jos. Mrcy. It is acceptable to apply a pre-printed hospital label that includes the hospital name, address, phone number and the appropriate hospital code.

- ✓ **HOSPITAL CODE:** MDCH has assigned a 3-digit hospital code for each hospital that must be recorded in the boxes provided. The 3-digit code should be listed before the two preprinted zeros. For regular nurseries, a "0" should be added to the last box (after the two preprinted zeros). For the NICU, a "1" should be added to the last box. For the special care nursery, a "2" should be added to the last box.

- ✓ **SUBMITTER ADDRESS:** Record the submitter's street address followed by the city, state and zip code.

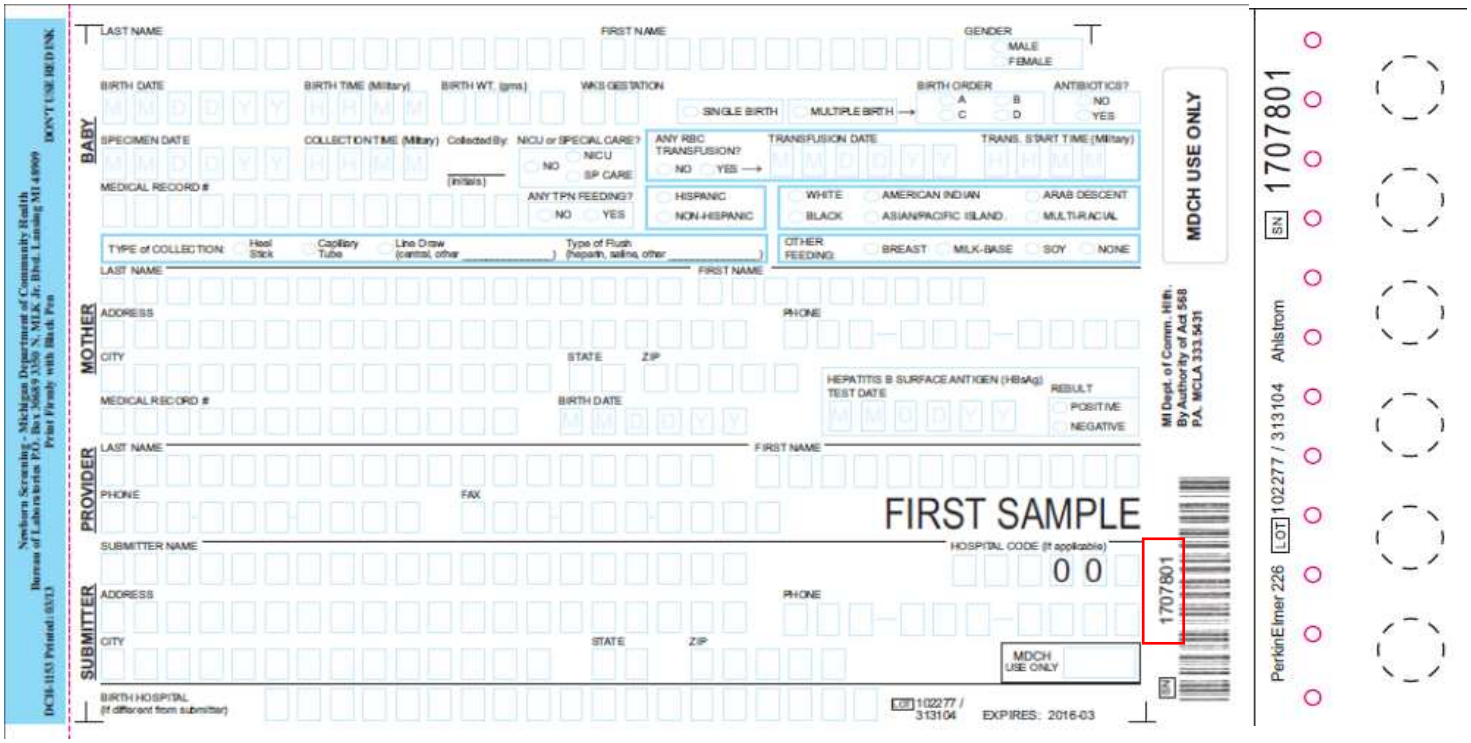
- ✓ **SUBMITTER PHONE:** Record submitter's area code and phone number.

- ✓ **BIRTH HOSPITAL:** Record name of the birth hospital here only if different from the submitter.

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

Recording the NBS Card Number

The hospital NBS protocol should include instructions to insure that the NBS card number is forwarded to the staff person responsible for filling out 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 corner of the card (as shown below) and goes in the upper right hand box on the EBC.



Parental Refusal of Newborn Screening

If parents object to NBS, they should be asked to sign a document that indicates that they have been informed of the risk to their newborn if screening is not done. Each hospital should develop its own document that meets the legal department's specifications. A sample form is included in Appendix 9. A copy of the signed document should be forwarded to the NBS follow-up program.

Parents whose only objection is that their child's specimen will be stored indefinitely by the state can choose to have the newborn screen done and then have the bloodspots destroyed by filling out the form *Directive to Destroy Residual Newborn Screening Blood Specimen*. See Appendix 11.

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 and their potential use in medical and public health research. Hospital staff should provide the BioTrust consent brochure entitled, *After Newborn Screening, Your Baby's Blood Spots,* to parents and ask if they are willing to grant permission to make their infant's DBS available for health research once NBS is complete. Permission is granted by marking the "yes" check box and signing the consent form located on the back of the NBS first sample card. If parents decline permission for the BioTrust, please have them mark the "no" checkbox and sign the BioTrust form. NBS program staff, upon request, will provide on-site training on the BioTrust and the parental consent process. This training is also available at www.michigan.gov/newbornscreening. See Appendix 7 for information on how to obtain *After Newborn Screening: Your Baby's Blood Spots* consent brochures.

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

Residual DBS of persons born after July 1984 and prior to May 2010 are currently stored and available for research through the BioTrust. Persons over the age of 18 or parents of minor children who would like to have these samples destroyed must sign and return the *Directive to Destroy Residual Newborn Screening Blood Specimen* form. Persons over the age of 18 or parents of minor children who would like these samples to remain in storage but no longer made available for research must sign and return the *Directive to Store but Not Use Dried Blood Spot Specimen for Research* form. See Appendix 11 for the Directive forms.

BIOTRUST CONSENT FORM INSTRUCTIONS:

1. Provide the *Michigan Newborn Screening Saves Babies* brochure and the *After Newborn Screening, Your Baby's Blood Spots* BioTrust consent brochure to parents. Clarify the difference between the mandatory NBS program and the optional Michigan BioTrust for Health, which allows residual DBS to be used for research.

2. Inform parents about the *Michigan Newborn Screening Saves Lives* video and that it can be viewed either on the state NBS website (www.michigan.gov/newbornscreening) or through your hospital TV channel, if available.

3. Complete the demographic information on the front of the NBS first sample card and collect the blood specimen as usual. The BioTrust consent form for residual DBS use is attached to the back of the NBS first sample card. See Appendix 3. If parents are undecided or not available to make a decision about granting consent for the BioTrust at the time the NBS specimen is collected, remove the consent form for later use. Hospital staff should fill in the baby's name or affix the patient label in the "Administrative Uses" box 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 booklet:
   - The *Michigan Newborn Screening Saves Babies* brochure explains NBS and introduces the Michigan BioTrust for Health.

- The *After Newborn Screening, Your Baby's Blood Spots* consent brochure details possible research use of residual DBS and information needed for parents to decide whether to grant permission for use of these DBS for research.

5. If parents wish to allow use of their newborn's residual DBS for research, ask one parent to mark the "yes" checkbox and sign the white copy of the BioTrust consent form located on the back of the blue first sample card.
   - If consent is not granted, ask one parent to mark the "no" checkbox and sign the white copy of the BioTrust consent form. Return the white copy to the NBS Laboratory once the parent marks his/her decision and signs the consent form.
   - The bottom pink copy is for the parent to keep.

6. Submit the white copies of the BioTrust consent form in the same envelopes used for DBS specimen cards. *Note: A consent form does not need to be in the same envelope as a particular newborn's NBS specimen card. Do NOT delay returning a newborn's NBS specimen card while waiting for the consent form!*

Ordering Newborn Screening Initial, Repeat and Replacement Specimen Cards, Specimen Return Envelopes and *Michigan Newborn Screening Saves Babies* Brochure

- Orders will be shipped by ground, same day or next business day. Make sure your hospital has a system for maintaining an inventory of cards, return envelopes and brochures. See Appendix 5 for specimen card order form.
- First Sample (blue) cards are sold in packages of 25. Cards may be ordered in quantities of less than 25 by midwives or birth parents. (Refer to the *Michigan Newborn Screening Guide for Homebirths*.)
- Repeat Sample (pink) cards are sold in packages of 25 and are no longer free of charge. Cards may be ordered in quantities of less than 25 by midwives or birth parents. (Refer to the *Michigan Newborn Screening Guide for Homebirths*.)
- Specimen-return envelopes are used to mail the NBS specimens to the NBS laboratory. Envelopes are free of charge and shipped in quantities of 50.
- Replacement cards are available free of charge for any card that cannot be used. Reasons could include: card pieces are torn or separated, unsatisfactory specimen, wrong demographic information is entered or parental refusal. See Appendix 8 for the replacement card form.
- *Michigan Newborn Screening Saves Babies* brochures are free of charge and shipped in quantities of 50.

For ordering and current price information, please contact Valerie Klasko, MDCH Accounting, at 517-241-5583 or e-mail MDCH-NBSCards@michigan.gov.

Specimen Collection

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

Laboratory Testing Methods

- **Tandem Mass Spectrometry (TMS):** Amino acid, organic acid and fatty acid oxidation disorders are detected by evaluation of specific TMS acylcarnitine and amino acid profiles.
- **Fluoroimmunoassay (FIA):** Congenital hypothyroidism (CH), congenital adrenal hyperplasia (CAH) and cystic fibrosis (CF) are detected by FIA for thyroid stimulating hormone (TSH), 17-hydroxyprogesterone (17-OHP) and immunoreactive trypsinogen (IRT), respectively. If a CAH screen is positive, a secondary screen for CAH by steroid profile is performed by TMS at the Mayo Biochemical Genetics Laboratory. A secondary DNA screen for 40 CF mutations is performed by the NBS Laboratory on specimens with IRT values ≥96th 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, 1965-2012

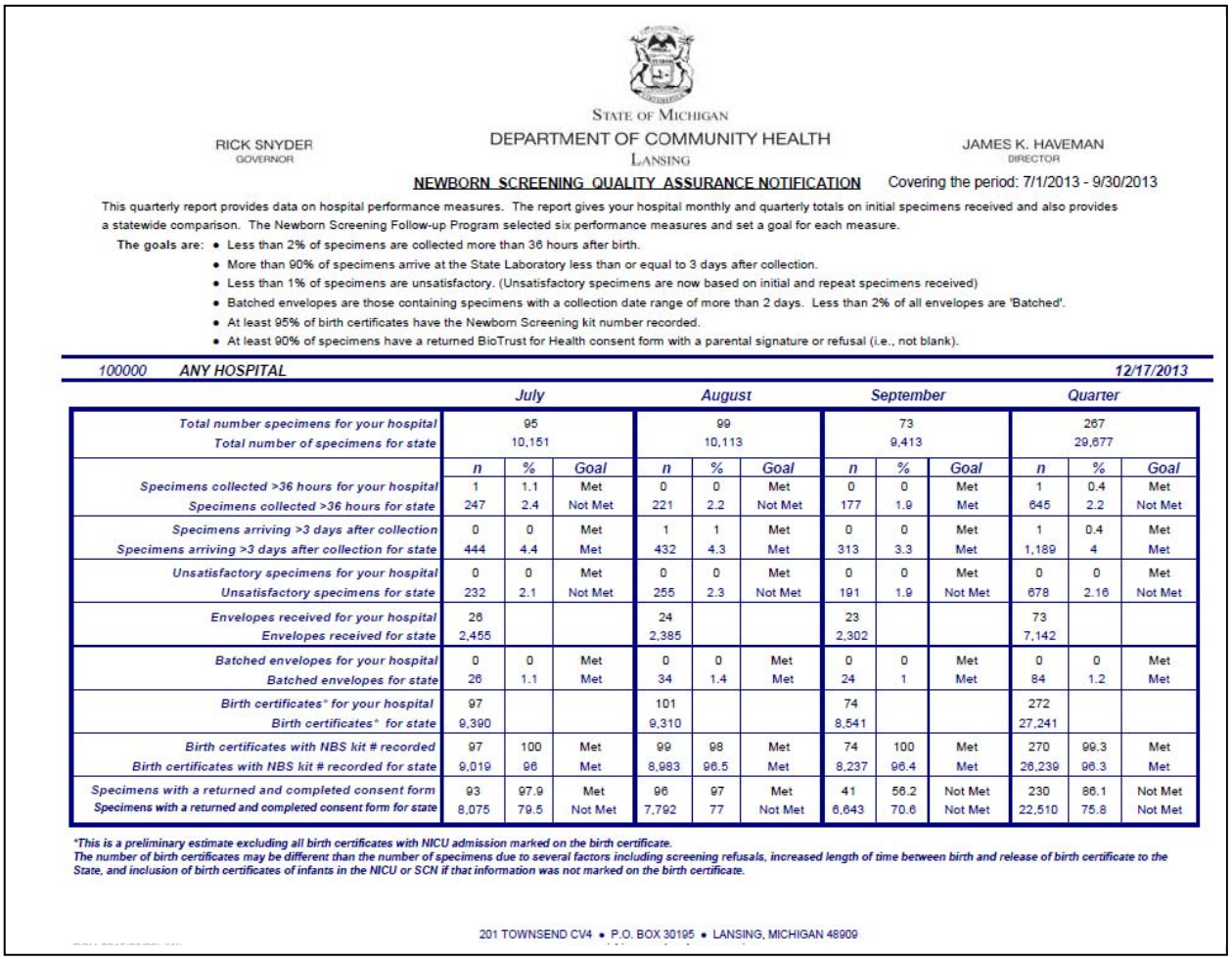
Type of Disorder Classification (Year Screening Began)	Cases in 2012 (N)	Cases Through 2012 (N)	Cumulative Detection Rate
Galactosemia (1985)	2	172	1:21,541
Biotinidase Deficiencies (1987)	17	224	1:14,809
Amino Acid Disorders (1965)	19	686	1:9,550
Organic Acid Disorders (2005)	5	54	1:15,514
Fatty Acid Oxidation Disorders (2003)	33	172	1:6,385
Congenital Hypothyroidism (1977)	78	1,876	1:1,768
Congenital Adrenal Hyperplasia (1993)	8	132	1:18,504
Sickle Cell Disease (1987)	51	1,677	1:1,978
Hemoglobin H Disease (2012)	3	3	1:37,061
Cystic Fibrosis (October 2007)	33	160	1:3,060
Primary Immunodeficiencies (October 2011)	25	25	1:5,569
Total	274	5,181	-

Quality Assurance

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

1. < 2% of specimens collected > 36 hours of life.
2. > 90% of specimens received at the NBS laboratory ≤ 4 days after collection.
3. < 1% of specimens unsatisfactory for testing.
4. < 2% of envelopes contains specimens with collection date range > 2 days.
5. ≥ 95% of birth certificates have the newborn screening kit number recorded.
6. > 90% of specimens have a returned BioTrust or health consent form with a parental signature or refusal (i.e., not blank)

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



STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

RICK SNYDER, GOVERNOR

JAMES K. HAVEMAN, DIRECTOR

NEWBORN SCREENING QUALITY ASSURANCE NOTIFICATION Covering the period: 7/1/2013 - 9/30/2013

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:
- Less than 2% of specimens are collected more than 36 hours after birth.
- More than 90% of specimens arrive at the State Laboratory less than or equal to 3 days after collection.
- Less than 1% of specimens are unsatisfactory. (Unsatisfactory specimens are now based on initial and repeat specimens received)
- Batched envelopes are those containing specimens with a collection date range of more than 2 days. Less than 2% of all envelopes are 'Batched'.
- At least 95% of birth certificates have the Newborn Screening kit number recorded.
- At least 90% of specimens have a returned BioTrust for Health consent form with a parental signature or refusal (i.e., not blank).

100000 ANY HOSPITAL 12/17/2013

	July			August			September			Quarter		
Total number specimens for your hospital	95			99			73			267		
Total number of specimens for state	10,151			10,113			9,413			29,677		
	n	%	Goal	n	%	Goal	n	%	Goal	n	%	Goal
Specimens collected >36 hours for your hospital	1	1.1	Met	0	0	Met	0	0	Met	1	0.4	Met
Specimens collected >36 hours for state	247	2.4	Not Met	221	2.2	Not Met	177	1.9	Met	645	2.2	Not Met
Specimens arriving >3 days after collection	0	0	Met	1	1	Met	0	0	Met	1	0.4	Met
Specimens arriving >3 days after collection for state	444	4.4	Met	432	4.3	Met	313	3.3	Met	1,189	4	Met
Unsatisfactory specimens for your hospital	0	0	Met	0	0	Met	0	0	Met	0	0	Met
Unsatisfactory specimens for state	232	2.1	Not Met	255	2.3	Not Met	191	1.9	Not Met	678	2.16	Not Met
Envelopes received for your hospital	26			24			23			73		
Envelopes received for state	2,455			2,385			2,302			7,142		
Batched envelopes for your hospital	0	0	Met	0	0	Met	0	0	Met	0	0	Met
Batched envelopes for state	26	1.1	Met	34	1.4	Met	24	1	Met	84	1.2	Met
Birth certificates* for your hospital	97			101			74			272		
Birth certificates* for state	9,390			9,310			8,541			27,241		
Birth certificates with NBS kit # recorded	97	100	Met	99	98	Met	74	100	Met	270	99.3	Met
Birth certificates with NBS kit # recorded for state	9,019	96	Met	8,983	96.5	Met	8,237	96.4	Met	26,239	96.3	Met
Specimens with a returned and completed consent form	93	97.9	Met	96	97	Met	41	56.2	Not Met	230	86.1	Not Met
Specimens with a returned and completed consent form for state	8,075	79.5	Not Met	7,792	77	Not Met	6,643	70.6	Not Met	22,510	75.8	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.

201 TOWNSEND CV4 • P.O. BOX 30195 • LANSING, MICHIGAN 48909

NICU Protocol (includes Special Care Nursery)

Initial NBS specimens for all NICU newborns, regardless of birth weight, should be obtained at 24-30 hours of life and prior to red blood cell (RBC) transfusion. A second specimen should be obtained on all NICU newborns at 30 days of life or at discharge, whichever comes first. See Appendix 12. If discharge occurs prior to the eighth day of life, a second specimen does not need to be obtained.

TRANSFUSIONS:

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

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

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

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

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

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

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

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

EARLY SPECIMENS:

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

Collect an early specimen prior to:

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

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

TOTAL PARENTERAL NUTRITION (TPN):

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

TRANSFERRED NEWBORNS:

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

NEWBORN AT HIGH RISK OF HAVING A NBS DISORDER:

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

NEWBORN DEATH OR PENDING DEATH:

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

HEALTH CARE PROVIDER INFORMATION

Follow-up of Positive NBS Results

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

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

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

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

NBS Result Request Policy

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

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

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

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

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

Questions on Positive Reports Received

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

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

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

Documentation of NBS Results

Documentation that a newborn has been screened should be available for every newborn and included in the medical record. Tracking repeat specimens (because initial specimen was borderline positive, collected before 24 hours of life, post-transfusion or unsatisfactory for testing) is important. The provider is responsible for facilitating subsequent testing.

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

FREQUENTLY ASKED QUESTIONS:

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

What is the chance that a newborn will have a disorder detected by NBS?
Each year, approximately 275 Michigan newborns are diagnosed with one of the disorders on the Michigan NBS panel out of approximately 112,000 screened births, meaning 1 out of 407 screened infants will be diagnosed with a disorder.

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

What is the NBS Program's specimen storage policy?
Residual NBS specimens are stored indefinitely once NBS is completed. Stored specimens may be used for quality control purposes or for new test development. Medical or public health researchers may use de-identified specimens through the Michigan BioTrust for Health once their proposal has been reviewed and approved by the BioTrust Scientific Advisory Board and the MDCH Institutional Review Board. NBS specimens collected after May 1, 2010 can only be used if parental consent was granted for such research. Specimens collected prior to May 1, 2010 are available for research unless parents contact the MDCH 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 MDCH director. The NBS Quality Assurance Advisory Committee meets once each year. Members include parents of affected children, health care providers, hospital representatives, and other medical experts.

What if I need to talk to someone at the NBS Program or a medical sub-specialist?
Call 1-866-673-9939 to reach someone in the NBS Program or see contact information on page 24 to contact a medical sub-specialist.

RESOURCE LIST - 2014

Michigan Newborn Screening
http://www.michigan.gov/newbornscreening

Genetics Home Reference
http://ghr.nlm.nih.gov/

Course on Newborn Screening
http://training.mihealth.org/

National Newborn Screening and Genetics Resource Center
http://genes-r-us.uthscsa.edu/

The Michigan Department of Community Health NBS Program has developed a 10 min DVD to explain newborn screening to parents.
Please go to www.michigan.gov/newbornscreening to view and order this DVD.

American Academy of Pediatrics
www.aap.org

National Newborn Hearing Websites

Centers for Disease Control Early Hearing Detection and Intervention
http://www.CDC.GOV/ncbddd/ehdi

Marion Downs National Center for Infant Hearing
http://www.uch.edu/conditions/ear-nose-throat/hearing-loss/marion-downs-hearing-center.aspx

National Center for Hearing Assessment and Management
http://www.infanthearing.org

National Institute on Deafness and Other Communication Disorders
http://www.nidcd.nih.gov

American Speech Language Association
www.asha.org

American Academy of Audiology
www.audiology.org

Hands and Voices
www.handsandvoices.org

CONTACT INFORMATION – NBS FOLLOW-UP PROGRAM

Michigan Department of Community Health
Newborn Screening Follow-up
201 Townsend St
P.O. Box 30195
Lansing, Michigan 48909

Toll-free: (866) 673-9939
Phone Tree/Menu: (517) 335-9205 or (517) 335-4181
Fax: (517) 335-9739 or (517) 335-9419
E-mail: newbornscreening@michigan.gov
Website: http://www.michigan.gov/newbornscreening

STAFF

William Young
Program Manager
(517) 335-8938

Lois Turbett
Nurse Consultant
(517) 335-1966

Karen Andruszewski
Departmental Specialist
(517) 335-9205

Rosalind Lewis-McPhaul
Departmental Technician
(517) 335-9205

Valerie Klasko
Accountant
(517) 241-5583

Keri Urquhart
CCHD Nurse Educator
(517) 335-8135

Carolyn Smith
Departmental Technician
(517) 335-9205

Valerie Ewald
Administrative Assistant
(517) 335-8887

Carrie Langbo
BioTrust Community
Engagement Coordinator
(517) 335-6497

Mary Kleyn
Epidemiologist
(517) 335-9296

Kristy Tomasko
Data Analyst
(517) 241-0332

Dominic Smith
Hemoglobinopathy
Program Coordinator
(517) 373-5818

CONTACT INFORMATION – NBS LABORATORY

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

STAFF

Bonita Taffe
Acting Director
Division of Chemistry and Toxicology
(517) 335-9490

Harry Hawkins
Manager
Newborn Screening Laboratory
(517) 335-8095

Denise Archambeault
Departmental Technician
(517) 335-8543

CONTACT INFORMATION - COURIER SERVICES

Lower Peninsula

Quest Diagnostics
Toll Free: 1-866-697-8378
Press 2 “Provider”
Press 6 “Transportation Department”
Your call will be routed to a Michigan Courier Service representative and you will be asked to provide your hospital code assigned by Quest.

A-1 Courier Services (Sunday courier service)
248-786-2042

Upper Peninsula

United Parcel Services
Toll Free: 1-800-877-1497
Online tracking available at www.ups.com/tracking
Use account 05V0R4 when ordering UPS Express Envelopes
e-mail newbornscreening@michigan.gov for UPS shipping labels

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

CONTACT INFORMATION - HEARING

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

Phone: (517) 335-8955
Fax: (517) 335-8036
Website: http://www.michigan.gov/EHDI

STAFF

Jeff Spitzley
Infant Health Unit Manager
(517) 335-8131

Michelle Garcia
Follow-up Consultant
(517) 335-8878

Dee Robertson
Community Consultant
(517) 373-8601

Nan Asher
Program Consultant
(517) 335-8273

Erin Estrada
Data Analyst
(517) 335-8916

Amanda Brunger
Secretary
(517) 335-8955

Karen Wisinski
Parent Consultant
(517) 241-7066

CONTACT INFORMATION - HEPATITIS B

Michigan Department of Community Health
Perinatal Hepatitis B Prevention Program
201 Townsend St.
P.O. Box 30195
Lansing, MI 48909

Toll Free: (800) 964-4487
Phone: (517) 335-9443
Website: http://www.michigan.gov/hepatitisb

Patrick Fineis
Program Coordinator
(517) 335-9443

Detroit Regional Office
Michigan Department of Community Health
3056 W. Grand Blvd. Ste 3-220
Detroit, MI 48202

Phone: (313) 456-4431
Fax: (313) 456-0639

Kari Tapley
Surveillance Specialist
(313) 456-4431

CONTACT INFORMATION – MEDICAL MANAGEMENT CENTERS

Sickle Cell – *Hemoglobinopathies*

SICKLE CELL DISEASE ASSOCIATION OF AMERICA, MICHIGAN CHAPTER, INC.
18516 James Couzens
Detroit, MI 48235
(P) 313-864-4406 (F) 313-864-9980

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

Grand Rapids	Benton Harbor
Pontiac	Flint
Kalamazoo	Muskegon
Lansing	Saginaw

CHILDREN'S HOSPITAL OF MICHIGAN
3901 Beaubien Blvd.
Detroit, MI 48201-2192
(P) 313-745-5613 (F) 313-745-5237

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

CHILDREN'S HOSPITAL OF MICHIGAN METABOLIC CLINIC
3950 Beaubien Blvd.
Detroit, MI 48201-2192
(P) 313-832-9330 (F) 313-745-8030

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

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

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

Cystic Fibrosis

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

Severe Combined Immunodeficiency

CHILDREN'S HOSPITAL OF MICHIGAN COORDINATING CENTER FOR PRIMARY IMMUNODEFICIENCIES
3901 Beaubien St., 5th floor Carls Bldg.
Detroit, MI 48201
(P) 313-806-6571 (Pager) 313-745-0203, enter pager number 5706 (F) 313-966-9701

Appendix 1 - Legislative Mandates

Public Health Code

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

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

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

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

Sec. 5431.
(1) A health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant shall administer or cause to be administered to the infant a test for each of the following:
(a) Phenylketonuria.
(b) Galactosemia.
(c) Hypothyroidism.
(d) Maple syrup urine disease.
(e) Biotinidase deficiency.
(f) Sickle cell anemia.
(g) Congenital adrenal hyperplasia.
(h) Medium-chain acyl-coenzyme A dehydrogenase deficiency.
(i) Other treatable but otherwise disabling conditions as designated by the department.
(2) The informed consent requirements of sections 17020 and 17520 do not apply to the tests required under subsection (1). The tests required under subsection (1) shall be administered and reported within a time and under conditions prescribed by the department. The department may require that the tests be performed by the department.
(3) If the results of a test administered under subsection (1) are positive, the results shall be reported to the infant's parents, guardian, or person in loco parentis. A person is in compliance with this subsection if the person makes a good faith effort to report the positive test results to the infant's parents, guardian, or person in loco parentis.
(4) Subject to the annual adjustment required under this subsection and subject to subsection (6), if the department performs 1 or more of the tests required under subsection (1), the department may charge a fee for the tests of not more than $53.71. The department shall adjust the amount prescribed by this subsection annually by an amount determined by the state treasurer to reflect the cumulative annual percentage change in the Detroit consumer price index. As used in this subsection, "Detroit consumer price index" means the most comprehensive index of consumer prices available for the Detroit area from the bureau of labor statistics of the United States department of labor.
(5) A person who violates this section or a rule promulgated under this part is guilty of a misdemeanor.
(6) The department shall provide for a hardship waiver of the fee authorized under subsection (4) under circumstances found appropriate by the department.
(7) The department shall do all of the following in regard to the blood specimens taken for purposes of conducting the tests required under subsection (1):
(a) By April 1, 2000, develop a schedule for the retention and disposal of the blood specimens used for the tests after the tests are completed. The schedule shall meet at least all of the following requirements:

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

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

Popular Name: Act 368

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

Appendix 1 - Legislative Mandates Continued

You can find the law in its entirety at the following link:
http://www.legislature.mi.gov/(li5g3jafe4e5ad55oo2kgxym)/documents/2005-2006/publicact/pdf/2006-PA-0031.pdf

PA 31 2006

STATE OF MICHIGAN
93RD LEGISLATURE
REGULAR SESSION OF 2006

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

ENROLLED SENATE BILL No. 794

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

The People of the State of Michigan enact:

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

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

(10)

Act No. 31
Public Acts of 2006
Approved by the Governor
February 22, 2006

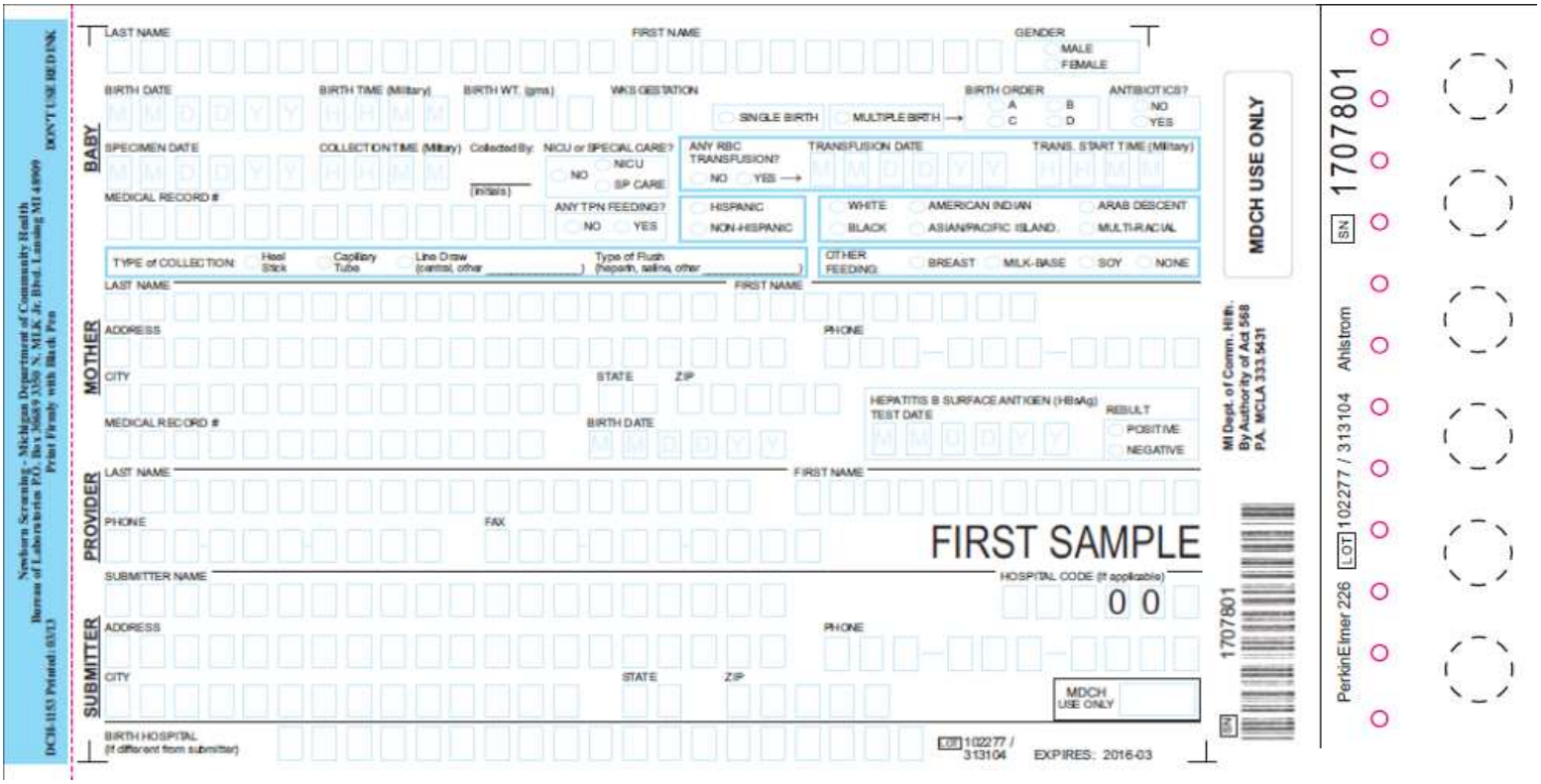
Filed with the Secretary of State
February 23, 2006
EFFECTIVE DATE: February 23, 2006
2
(2) The newborn screening quality assurance advisory committee shall meet annually to review the list of newborn screening tests required under section 5431 and under department rules, regulations, and guidelines. The newborn screening quality assurance advisory committee shall, on an annual basis, submit a written report to the department regarding the appropriateness of the existing list of required newborn screening tests. The newborn screening quality assurance advisory committee shall also include in the report recommendations to revise the list to include additional newborn screening tests that are nationally recognized in the scientific literature or national standards for conditions that can be ameliorated or treated if identified by a newborn screening test and to remove certain tests that are no longer supported in the scientific literature or national standard as being effective for ameliorating or treating conditions that can be identified by newborn screening.
(3) The newborn screening quality assurance advisory committee shall conduct a financial review of any recommended changes to the list of newborn screening tests and shall include in the written report required under subsection (2) a recommendation for the increase or decrease in the amount charged pursuant to section 5431 for newborn screening tests. The recommended change shall not exceed any net change in the amount of the actual cost of any proposed additional tests and follow-up minus savings from any proposed deleted tests and follow-up.
(4) Within 30 days after the department has received the report required under subsection (2), the department may approve or reject the recommendations of the newborn screening quality assurance advisory committee. If the department does not reject the recommendations or fails to act within the 30 days, then the recommendations shall be forwarded to the standing committees in the senate and house of representatives that consider issues pertaining to public health for approval.
(5) Within 45 days after the recommendations are forwarded and received, the legislature shall approve or reject those recommendations without amendment by concurrent resolution adopted by both standing committees of the senate and house of representatives that consider issues pertaining to public health and both houses of the legislature by recorded vote. If the proposed recommendations are not submitted on a legislative session day, the 45 days commence on the first legislative session day after the recommendations are submitted. The 45 days shall include not less than 9 legislative session days. If the recommendations are not rejected within the 45-day period, the recommendations shall be considered approved, shall be adopted by the department, and shall take effect 6 months after the recommendations are adopted by both houses of the legislature or considered approved as provided under this subsection.
Sec. 5432. If a health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant, the hospital, the health department, or other facility administers or causes to be administered to the infant a hearing test and screening, then that person or facility shall report to the department, on a form as prescribed by the department, the results of all hearing tests and screens conducted on infants who are less than 12 months of age and on children who have been diagnosed with hearing loss and are less than 3 years of age. The report shall include the type, degree, and symmetry of the diagnosis, along with where and when the diagnosis was made.
This act is ordered to take immediate effect.
Secretary of the Senate
Clerk of the House of Representatives
Approved
Governor

Appendix 2 - Blood Specimen Collection and Handling Procedure

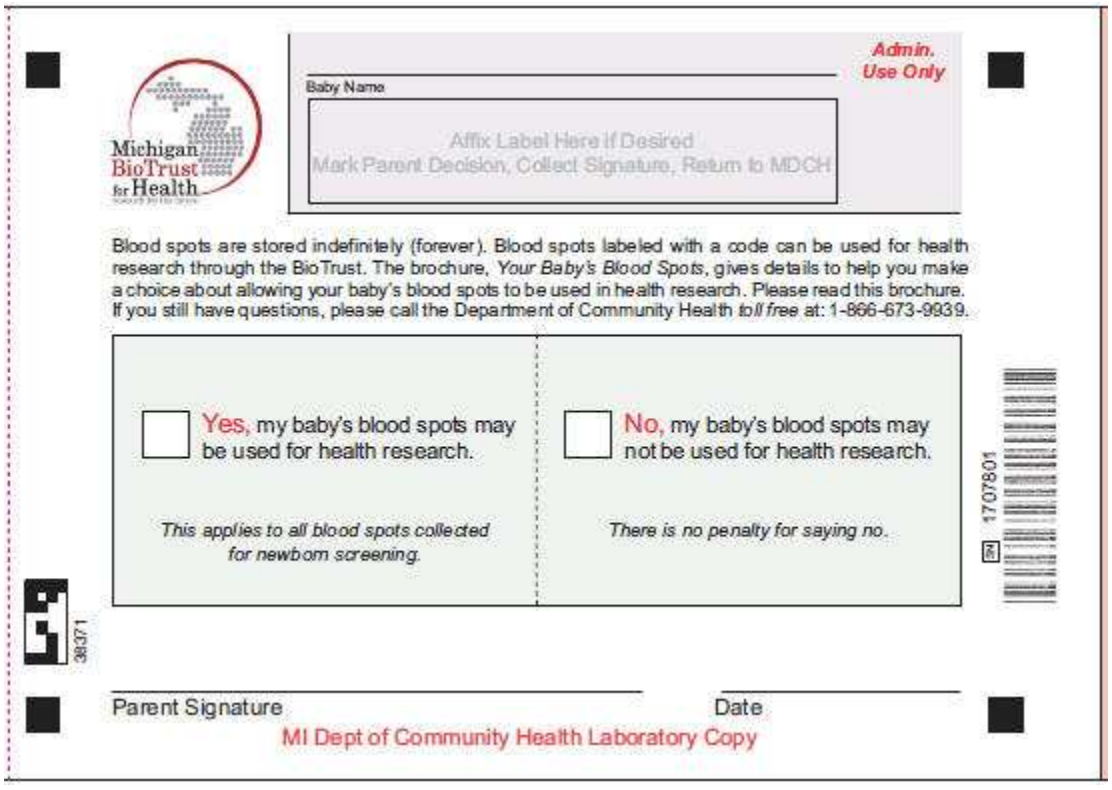
This appendix is currently being revised. Please follow the Clinical and Laboratory Standards Institute (CLSI) guidelines for NBS specimen collection. Refer to the CLSI website for additional information.
www.clsi.org

Appendix 3 - NBS Card Images

NBS First Sample ("blue") Card



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



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

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

* www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm

Appendix 5

Phone: (517) 241-5583
FAX: (517) 241-5531
EMAIL MDCH-NBSCards@michigan.gov

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
NEWBORN SCREENING CARD ORDER FORM

PLEASE COMPLETE THE FOLLOWING:

HOSPITAL NAME	CONTACT NAME AND TELEPHONE NUMBER

BILLING ADDRESS

STREET	ORDER DATE	TELEPHONE NUMBER
CITY	STATE MICHIGAN	ZIP CODE

CUSTOMER PURCHASE ORDER NUMBER

FIRST SAMPLE NBS CARD (BLUE)
25 per pkg – Indicate # of packages

$3,134.00 per package (Effective October 1, 2014)

	TOTAL PRICE

FIRST SAMPLE NBS CARD (BLUE)
Individual cards – Indicate # of cards

$125.36 per card (Effective October 1, 2014)

	TOTAL PRICE

REPEAT SAMPLE NBS CARD (PINK)
25 per pkg – Indicate # of packages

$2,932.25 per package (Effective October 1, 2014)

	TOTAL PRICE

REPEAT SAMPLE NBS CARD (PINK)
Individual cards – Indicate # of cards

$117.29 per card (Effective October 1, 2014)

	TOTAL PRICE

Following items are FREE

SPECIMEN RETURN ENVELOPE 50 per pkg - # of packages	**BROCHURES** **Michigan BioTrust for Health** 50 per pkg- # of packages English _____ Spanish _____ Arabic _____	**Michigan Newborn Screening Saves Babies** 50 per pkg- # of packages English _____ Spanish _____ Arabic _____

M.D.C.H. INTERNAL USE

SALES ORDER NUMBER	ORDER DATE	CUSTOMER NUMBER
CHECK NUMBER	AMOUNT	DEPOSIT NUMBER

Cashier Coding 70090/84893/9501

PLEASE USE SHIPPING ADDRESS BELOW

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH – NBS
4TH FLOOR LEWIS CASS BLDG, 320 SOUTH WALNUT
LANSING, MI 48913

FACILITY NAME
ATTENTION/DEPARTMENT
STREET ADDRESS
CITY, STATE, ZIP CODE

MAKE CHECK PAYABLE TO:

MICHIGAN DEPARTMENT
OF COMMUNITY HEALTH

MAIL TO:

MICHIGAN DEPARTMENT OF
COMMUNITY HEALTH
CASHIER – NBS CARDS
P.O. BOX 30437
LANSING, MI 48909

Appendix 6

NEWBORN SCREENING TEST - WAIVER/CARD ORDER FORM

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

Appendix 7 - Program Resource Order Form

NEWBORN SCREENING - BIOTRUST PROGRAM RESOURCES

ORDER FORM

Please circle or provide the number of copies you are requesting.
Most products may be viewed on the website listed.

		Number of copies:
	**Michigan NBS Saves Babies:** NBS educational brochure. Describes NBS Program, benefits of newborn screening and introduction to Michigan BioTrust for Health. www.michigan.gov/newbornscreening	1 25 50 100 ____ (other) # of Spanish copies: ____ # of Arabic copies: ____
	**After Newborn Screening - Your Baby's Blood Spots - Michigan BioTrust for Health Consent Brochure:** Describes Michigan's BioTrust, privacy protections, benefits and risks and consent process. www.michigan.gov/biotrust	1 25 50 100 ____ (other) # of Spanish copies: ____ # of Arabic copies: ____
	**Michigan Newborn Screening Saves Babies:** Educational video describes newborn screening and introduces the Michigan BioTrust for Health. Approximately 10 minutes long and great for parent education. www.michigan.gov/newbornscreening	1 5 10 ____ (other)
	**Michigan Newborn Screening and BioTrust pocket script cards:** Two minute script cards for hospital staff highlighting key points to share with parents on newborn screening and the BioTrust.	1 5 10 ____ (other)
	**BioTrust Newborn Screening Flipcard** Key facts introducing Michigan's newborn screening program and the BioTrust. Useful for expectant parents.	1 25 50 100 ____ (other)

MAIL, FAX OR EMAIL YOUR ORDER TO:	Michigan Department of Community Health **Newborn Screening Program** **P.O. Box 30195,** **Lansing, MI 48909** ***FAX: 517-335-9790*** ***EMAIL*: newbornscreening@michigan.gov** ***PHONE: 517-335-8887 or Toll Free 1-866-852-1247***

Name: _____

Organization: _____

Phone: _____ E-mail: _____

Address: _____

City: _____ State: _____ Zip: _____

Appendix 8

Michigan Department of Community Health

MDCH

NEWBORN SCREENING CARD REPLACEMENT FORM

Date: _____

FACILITY NAME: _____

ATTN: (DEPT) _____

ADDRESS: _____

CITY, STATE, ZIP: _____

CONTACT NAME: _____ TELEPHONE # _____

NUMBER OF CARDS RETURNED FOR REPLACEMENT: _____

I.D. NUMBERS ON THE CARDS RETURNED:

_____

_____

_____

_____

_____

FIN 324 (4/98) ATHY:PA 14 OF 1987

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH USE ONLY

NUMBER OF CARDS REPLACED: _____

REPLACEMENT CARD I.D. NUMBERS:

_____

_____

_____

FACILITY # _____ SALES ORDER # _____

ACCTG APPROVAL _____ DATE _____

Remove the filter paper from the cards before sending to the address below.

PLEASE SEND CARDS TO BE REPLACED AND THIS FORM TO:

MI Department of Community Health
Attn: Newborn Screening
4th Floor Lewis Cass Bldg
320 South Walnut
Lansing, MI 48913

10/12

Appendix 9

Parental Refusal for Newborn Screening

I (We)_____, the parent(s) or guardian(s) of

_____, birth date_____, object to and refuse the requirement that my (our) child be screened for the presence of the disorders listed on the enclosed Michigan Department of Community Health (MDCH) newborn screening panel and posted at www.michigan.gov/newbornscreening.

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

Therefore, I (we) release the Michigan Department of Community Health, 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 MDCH newborn screening panel. Furthermore, I (we) release and hold the Michigan Department of Community Health, 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 MDCH newborn screening panel.

_____ _____
Signature of parent(s) or guardian(s) date

_____ _____
Signature of parent(s) or guardian(s) date

_____ _____
Signature of witness date

_____ _____
Signature of witness date

cc: Michigan Department of Community Health
Newborn Screening Program
201 Townsend Street CV-4
P. O. Box 30195
Lansing, MI 48909
Fax signed copy to: 517-335-9419

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

☐ Cannot afford to pay for the card ☐ Religious reasons ☐ Privacy concerns

☐ Other:_____

_____

Appendix 10 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 biosysnthesis defect (BIOPT-BS)
11. Biopterin cofactor regeneration defect (BIOPT-REG)
12. Tyrosinemia Type I (TYR-1)
13. Tyrosinemia Type II (TYR-II)
14. Tyrosinemia Type III (TYR-III)

Fatty Acid Oxidation Disorders

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

Organic Acid Disorders

28. 2-Methyl-3-hydroxy butyric aciduria (2M3HBA)
29. 2-Methylbutyryrl-CoA dehydrogenase deficiency (2MBG)
30. 3-hydroxy 3-methylglutaric glutaric aciduria (HMG)
31. 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC)
32. 3-Methylglutaconic aciduria (3MGA)
33. Beta-ketothiolase deficiency (BKT)
34. Glutaric acidemia type I (GA1)
35. Isobutyryl-CoA dehydrogenase deficiency (IBG)
36. Isovaleric acidemia (IVA)
37. Methylmalonic acidemia cobalamin disorders (Cbl A,B)
38. Methylmalonic aciduria with homocystinuria (Cbl C,D)
39. Methylmalonic acidemia methylmalonyl-CoA mutase (MUT)
40. Multiple carboxylase deficiency (MCD)
41. Propionic acidemia (PROP)

Hemoglobinopathies

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

Endocrine Disorders

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

Other Disorders

49. Biotinidase deficiency (BIOT)
50. Galactosemia (GALT)
51. Cystic fibrosis (CF)
52. Severe combined immunodeficiency (SCID)
53. T-cell related lymphocyte deficiencies

Point of Care Screening

54. Critical Congenital Heart Disease (CCHD)
55. Hearing

Revised April 2014

Appendix 11 – Specimen Directives

Michigan Department of Community Health

Directive to Destroy Residual Newborn Screening Blood Specimen

Child's Name at Birth:	Date of Birth:
Child's Current Name:	Circle Birth Order if Multiple Birth: 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

Authority:	Michigan Public Health Code, Act 368 of 1978	The Michigan Department of Community Health is an equal opportunity employer, services, and program provider

DCH-1448 Rev 2/2010

Appendix 11 - Specimen Directives Continued

Michigan Department of Community Health

Directive to Store But Not Use Dried Blood Spot Specimen For Research

This form should be completed and signed by the legal representative to request storage but no research use of the remaining newborn screening blood specimen on the individual named below:*

Child's Name at Birth:	Date of Birth:
Child's Current Name:	Circle Order if Multiple Birth: A B C D E
Mother's Name at Time of Child's Birth:	Hospital of Birth:

I am the legal representative of the child named above. By signing below, I hereby request the Michigan Department of Community Health, after newborn screening has been completed, to **not** use this child's blood specimen for possible future research. 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 mother, guardian, or other legal representative:		Relationship to child:	
Printed name:		Date:	
Street Address:	City:	Zip:	Phone:
Signature of father, guardian, or other legal representative:		Relationship to child:	
Printed name:		Date:	
Street Address:	City:	Zip:	Phone:

* **"Legal representative"** means the 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

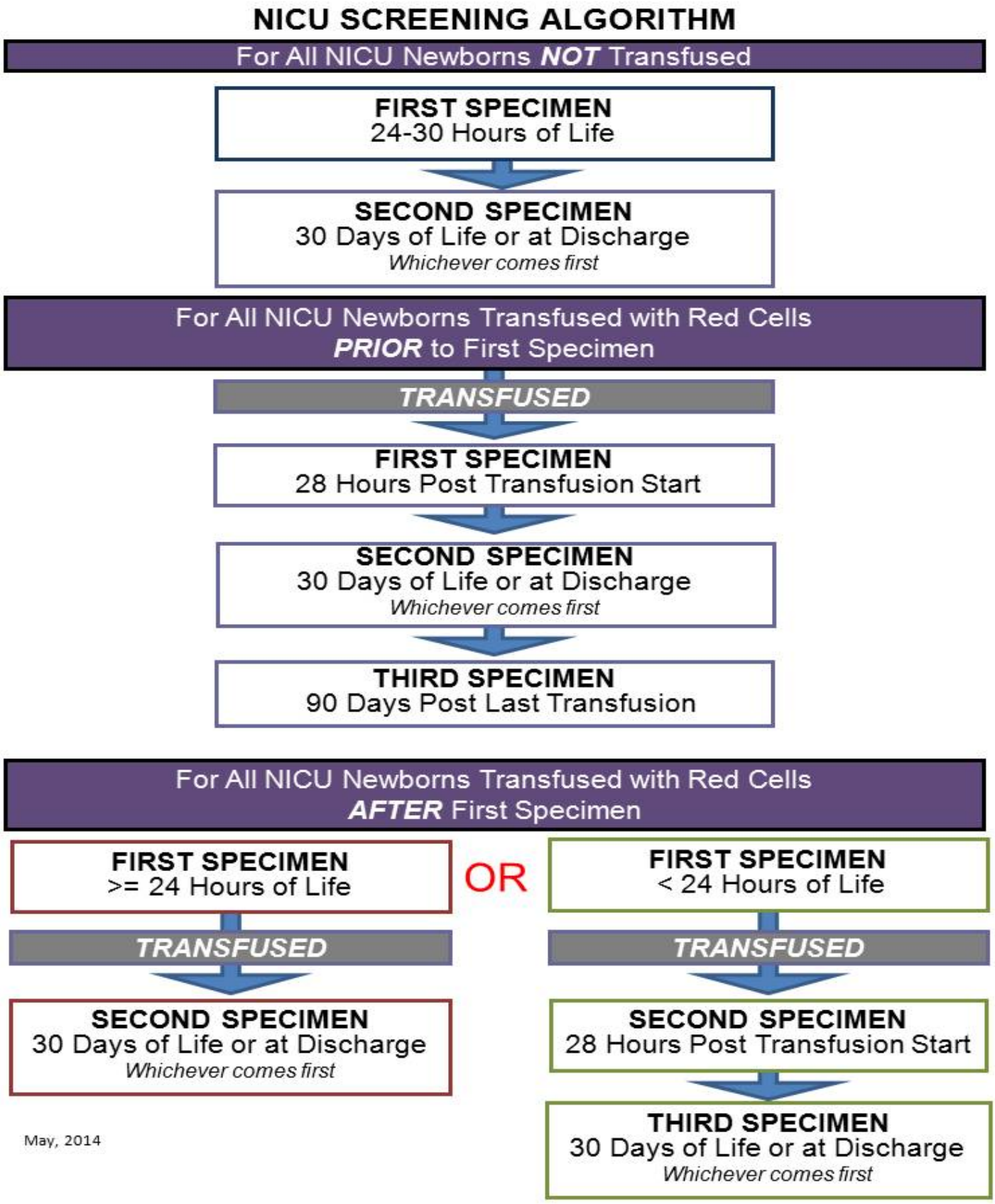
⇨Mail to:

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

Authority:	Michigan Public Health Code, Act 368 of 1978	The Michigan Department of Community Health is an equal opportunity employer, services, and program provider

DCH-1465 Rev 7/2012

Appendix 12 - NICU and Special Care Nursery Algorithm



Appendix 13

MICHIGAN NEWBORN SCREENING
HOSPITAL SPECIFIC PROCEDURE TEMPLATE

HOSPITAL #_____
NICU #_____
(NICU will have a 01 at the end)

HOSPITAL COORDINATOR

Name:_____

Phone:_____

FAX:_____

CARD INFORMATION

Cards are ordered by:_____

Cards are stored:_____

Cards are filled out by:_____

Cards are sent to the state lab by:_____

Contact information for Quest or UPS_____

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

Reports are received by:_____

Process for notifying physicians_____

_____

_____

_____

_____

ELECTRONIC BIRTH RECORDS

Person who enters electronic birth record:_____

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

NURSE EDUCATION

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

NICU SPECIFIC INFORMATION

- NICU Algorithms

DEATH OF AN INFANT

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

Appendix 14 – Fax Reporting

Automatic Fax Reporting of Newborn Screening Results

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

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

1) A letter on your agency letterhead must be sent to the MDCH Bureau of Laboratories, Newborn Screening consenting to becoming an automatic fax agency, and be signed by a person who is authorized to make this request.

2) The following statement of understanding (on next page) must be completed, signed and returned along with the consenting letter.

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

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

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

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

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

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

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

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

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

Please keep this letter for your records

Appendix 14 – Fax Reporting Continued

Michigan Department of Community Health
MDCH

STATEMENT OF UNDERSTANDING

AGENCIES SELECTING AUTOMATIC FAX TRANSMISSION OPTION

1. I understand that all newborn screening reports of patient testing by the MDCH Bureau of Laboratories will be sent to this agency by FAX transmission.

2. I understand that upon conversion to a fax transmission agency, no hard copy reports will be sent using the United States Postal Service.

3. The FAX number provided to MDCH is a **secure facsimile machine**. To be a secure facsimile machine, the following criteria must be met:

   - ✓ Only persons authorized to review confidential clinical laboratory test results use or otherwise have access to incoming FAX transmissions.
   - ✓ The facsimile machine is in a secure location during non-business hours in the event that FAX transmittal occurs after normal business hours.

Date: _____ Hospital Code: _____

Hospital Name: _____

Address: _____

Authorized Signature: _____

Secure FAX Number: _____

Contact Person for FAX Problems *(please print)* _____

Contact Person's Phone Number for Problems _____

Please keep a copy for your records

Appendix 15 - Military Time

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

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

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

Appendix 16 - Weight Conversion Chart

CONVERT POUNDS AND OUNCES TO GRAMS

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