

Spring 2021



Michigan Department of Health and Human Services Newborn Screening News

The Michigan Department of Health and Human Services (MDHHS) Newborn Screening Follow-up Program works together with the State Newborn Screening Laboratory and coordinating centers to find and treat infants who need early medical care.



NBS Quarterly Reports and Stellar Performance



During the fourth quarter of 2021, three hospitals met all six of the NBS blood spot screening performance goals. We would like to congratulate the following hospitals on their impressive efforts!

- Henry Ford Allegiance Health
- Spectrum Health Ludington Hospital
- St. Joseph Mercy Ann Arbor

Performance Goals for NBS Blood Spot Quarterly Reports

1. Less than 2% of screens are collected >36 hours after birth
2. Greater than 90% of screens arrive in the state laboratory by the appropriate day
3. Less than 1% of screens are unsatisfactory
4. Greater than 95% of electronic birth certificates have the NBS card number recorded
5. Greater than 90% of specimens have a returned BioTrust for Health consent form that is completed appropriately
6. Greater than 90% of newborns with a dried blood spot have pulse oximetry screening results reported

We hope you will be able to use information in the quarterly reports to improve your part of the NBS system. If you have any questions, please call the NBS Follow-up Program at 517-335-4181.

In this newsletter:

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- ✓ Blood Spot Destruction
- ✓ Common Card Errors – Unsatisfactory Specimen - Cannot Identify (CID)
- ✓ Verbal Consent for the BioTrust Form

During the fourth quarter of 2021, 27 hospitals met all three of the critical congenital heart disease (CCHD) screening performance goals. Ten hospitals had 100% of CCHD results reported for newborns with a blood spot screen. Congratulations to the following hospitals on their impressive efforts:

- UP Health System – Bell
- Munson Healthcare Charlevoix
- Dickinson County Healthcare System
- Hillsdale Hospital
- Munson Healthcare Grayling
- UP Health System – Portage
- Sparrow Hospital
- ProMedica Monroe Regional Hospital
- Ascension St. Joseph Hospital
- Three Rivers Health

Performance Goals for CCHD Quarterly Reports

1. At least 90% of newborns with a blood spot screen have pulse oximetry screen results reported.
2. At least 90% newborns with a blood spot screen have pulse oximetry screen results reported to the state less than 10 days after screen date.
3. At least 90% of newborns with a bloodspot screen have pulse oximetry screen completed between 20 and 28 hours after birth.



NBS Follow-up Program Contact Information

Phone: 517-335-4181

Email: NewbornScreening@Michigan.gov



2019 NBS Annual Report Summary

Every year, the Newborn Screening (NBS) Program releases an annual report that provides detailed information about the previous birth year. These reports are available on the NBS Program website (www.michigan.gov/newbornscreening) and contain information on updates that occurred during that birth year, the number of babies screened overall and the number identified with disorders on the NBS panel, performance metrics for each disorder including detection rate, false positive rate, and positive predictive value, and quality assurance information including the performance measures on the quarterly reports and time to treatment by disorder. The 2018 report is available now and the 2019 report will be finalized and available later in 2021.

In 2019, a total of 106,126 infants were screened in Michigan and 267 (0.3%) were diagnosed with a disease on the blood spot panel. Overall, one infant out of 397 screened was diagnosed with one of the disorders. Since the NBS Program began in 1965, more than 7,000 Michigan newborns have been identified with disorders on the NBS blood spot panel. Congenital hypothyroidism and sickle cell disease are the most commonly identified disorders, affecting 126 and 60 infants born in 2019, respectively. The third most commonly diagnosed disorder is cystic fibrosis, with 15 cases diagnosed in 2019. X-linked adrenoleukodystrophy was added to the Michigan NBS panel in October 2019 and one case was detected that year.



Blood Spot Destruction

Sometimes BioTrust consent forms are returned to the state lab marked with a note to “destroy”. Parents need to understand that the consent form cannot be used to make this request. The consent form is used to mark the parent’s choice about allowing their newborn’s left-over blood spots to be used in de-identified health research. If a parent wants their newborn’s blood spots destroyed, a separate *Newborn Screening Directive* form must be completed.

You can help parents fulfill this request by following a few quick and easy steps.

- ✓ Instruct parents to mark “No” and sign the BioTrust consent form. Return this form to the state lab. Blood spots will not be made available for research.
- ✓ Tell parents where to find a *Newborn Screening Directive* form. The form is found on the BioTrust website (Michigan.gov/biotrust) or by calling toll free 1-866-673-9939.
- ✓ Instruct parents to complete and return the *Newborn Screening Directive* form to the Michigan Department of Health and Human Services along with a copy of their child’s birth certificate and their proof of identity. *After receipt, blood spots will be destroyed in the state lab and parents receive a confirmation letter.*

The BioTrust consent brochure explains the process for requesting blood spots collected in or after 1986 may also be destroyed upon request. Parents or individuals over 18 years may follow the last two steps outlined above to request destruction of these spots. Please encourage any individual to contact the Newborn Screening Program for additional details at NewbornScreening@michigan.gov or toll free at 1-866-673-9939.

Notation on the below consent form is NOT sufficient for destruction of blood spots.

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

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

- After newborn screening, blood spots are coded only with a number and stored up to 100 years at a secure site (biobank). MDHHS can link the coded blood spots to your baby. This allows use of specific spots for research. It also allows MDHHS to find the right spots if you, or your grown child, change your mind.
- Researchers only receive coded blood spots. Details that could identify you, or your baby, are not provided.
- The risk of using blood spots in research is that your baby could still be identified. This risk is very low because many steps are taken to protect privacy.
- Research using blood spots must be approved by MDHHS. Blood spots can only be used for studies to better understand disease or improve the public's health such as research on cancer, birth defects and diabetes.
- Many laboratory methods are used to study biological or environmental factors such as genes, infectious agents, toxins and metals.
- Blood spot research may not directly help you, your child or your family. This type of research aims to improve the health of communities.
- Participation is voluntary. You can call MDHHS at any time if you change your mind. There is no penalty or loss of benefits for saying no or changing your mind.

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

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

Parent Signature: _____ Date: _____

Your choice applies to all blood spots collected for newborn screening. Please visit www.michigan.gov/biotrust for further information. For questions about your research rights or when to contact in case of a research-related injury, please call the MDHHS 800 at 517-243-3108.

MDHHS Copy

Common Card Errors – Unsatisfactory Specimen - Cannot Identify (CID)

One of the goals of the Newborn Screening (NBS) program is: less than 1% of first and repeat sample specimens unsatisfactory for testing. Often what comes to mind when we think of unsatisfactory specimens are problems with the actual blood spot, such as layering or clotting. Did you know that there is another easily avoidable reason that a specimen is deemed unsatisfactory? It is called a “Cannot Identify” (CID) unsatisfactory specimen.

A CID unsatisfactory specimen occurs when the NBS Lab cannot be certain whether the blood specimen received belongs to the baby whose demographics are filled out on the specimen card. In these cases, the bloodspot specimen will be considered unsatisfactory and a repeat specimen will be required. This can occur when:

- Multiple fields of the NBS demographic card have been crossed out making it difficult to read the information accurately.
- The kit number on the demographic portion of the card does not match the kit number on the filter paper. For example, a kit was separated and portions of two different kits are pieced together for an infant.

Important points to remember to avoid CID unsatisfactory specimens:

1. Put a single line strikeout line on incorrect information and clearly write the correct information above it. Initial next to the correction. Make a notation in the notes field attesting that the corrections are accurate and the right infant’s blood is on the card.
2. If multiple errors occur, please consider using a new NBS card. It is easier to complete another collection at this point rather than at an outpatient lab after discharge. Remember replacement cards are available free of charge for any card that cannot be used. 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.
3. Do not combine different kits for a baby. The kit number for the demographic portion must match the filter paper. If you find that blood was collected for a baby that does not match the demographics, start over with a new card for each infant.



Unsatisfactory specimens can result in:



- ✓ Infant distress caused by the need for a repeat specimen collection
- ✓ Additional work for hospital and NBS staff
- ✓ Unnecessary burden on parents who have to bring their baby back for a repeat screen
- ✓ Delayed valid test results that could have a negative impact on the health of the baby
- ✓ Increased cost to the hospital

Verbal Consent Form

Important Reminders for the BioTrust Consent Process: Verbal Consent

Recently, MDHHS has identified an increase in the number of BioTrust consent forms that indicate verbal consent has been obtained from parents. Per departmental policy, these forms are not considered complete and not valid because the BioTrust requires written consent from families.

Only a parent or legal guardian of the child can sign the BioTrust consent form. There is never a situation where it is appropriate for a staff member to collect a verbal decision or to sign on behalf of the family. When this occurs, the BioTrust for Health is unable to honor a family's decision to allow blood spots to be used for de-identified health research.

Consent forms do not have to be returned at the same time as the blood spots. If a family needs additional time to make their consent decision, **do not delay** sending the blood spots back for newborn screening. The white copy of the consent form can be picked up by the courier on a different day.

We understand that the COVID-19 pandemic has changed the workflow for providers in many ways. Below are resources to help staff members who may have questions on how to collect the BioTrust consent decision from families:

- https://www.michigan.gov/documents/mdch/BioTrust_Consent_Revisions_Staff_Instruction_Sheet_43269_6_7.pdf
- <https://breeze.mdch.train.org/brochure2020/>

For any questions related to the BioTrust consent process, please contact Shelby Atkinson at 517-335-6497 or at BioTrust@michigan.gov.

Lower Peninsula Hospitals:

- Monday, May 31, 2021 – holiday/Sunday schedule
- Sunday, July 4, 2021 – holiday/Sunday schedule
- Monday, July 5, 2021 – normal Monday schedule

Upper Peninsula Hospitals:

- Monday, May 31, 2021 – **no** UPS pickup
- Saturday, July 3, 2021 –UPS will pickup
- Monday, July 5, 2021 – UPS will pickup



TECHNICAL ASSISTANCE

Kristen Thompson, NBS Coordinator, is available to work with hospitals on CCHD pulse oximetry screening and reporting and can be reached at thompsonk23@michigan.gov. Together we can achieve our goal that all children diagnosed through newborn screening receive prompt and careful treatment in order to live the healthiest lives possible.

Please remember to share the quarterly newsletter with staff!

If you have questions, please contact the NBS Follow-up Program at 517-335-4181 or newbornscreening@michigan.gov or visit our website at Michigan.gov/NewbornScreening