

Important Notice: Specimen Transit and Shipping for Newborn Screening

Timely and proper shipment of newborn screening specimens is critical to ensure accurate and reliable results. The use of U.S. Mail is causing significant delays in specimen delivery. Currently, newborn specimens are taking an average of two days to reach the lab while subsequent specimens, often sent via U.S. Mail, experience longer transit times, averaging six days to reach the lab.

Why Does This Matter?

Newborn screening specimens are time-sensitive. According to COMAR (<u>Code of Maryland Regulations</u>), specimens should ideally be sent by courier service or overnight express mail to reduce transit time and maintain specimen integrity within 24 hours of collection.

What Can You Do?

- Please review your current shipping methods and select the fastest, most reliable option available.
- Coordinate with courier services or use overnight shipping when possible to ensure specimens arrive quickly.

ICYMI- In Case You Missed It

Provider Request Form Click here to update specimen information, submit a newborn screening refusal form, order lab slips, or request sickle cell trait results.

Webinar

Click <u>here</u> to view recordings of the recent NBS webinars.

Educational Materials Click here to order Newborn Screening educational materials for your patients and families.

Provider Contact Information Please complete this form to provide the direct

- Confirm specimen collection dates and shipping dates to track transit times effectively.
- Do not batch specimens.

phone number for a clinical staff member at your facility/practice. This will prevent delays in notifying providers of critical results.

Employee Corner: Sharing Our Why

Meet Marvin Redfern

Q: What is your official title?

A: Public Health Lab Scientist General Lead

Q: What are your principal duties at MDH?

A: My general lab responsibilities include receiving, accessioning, quality-checking, punching, and storing of patient samples collected from infants throughout the state. As the Lead in the Mass Spectrometry section in NBS I am responsible for providing technical oversight and expertise, aiding in method development and validation, completing data analysis and interpretation, maintaining QA and QC, and performing instrumentation troubleshooting, operation, and maintenance. My duties also include specimen processing, abnormal result reporting and communication, record keeping, inventory management and auditing, and assisting with SOP development, process improvements, audit preparation, and proficiency testing.

Q: How long have you been with the NBS program?

A: A little over 6 years.

Q: What attracted you to NBS and what does NBS mean to you?

A: I kind of stumbled upon NBS. After working in the healthcare field for several years I was looking for a change of pace and career opportunity. I wanted to focus more on my background in science, and I found NBS which was a marriage of the two. To me NBS represents a lifeline for those infants and families that we provide services to. Offering early detection for serious medical conditions, preventing irreversible harm, and improving the quality of life to one of our most vulnerable populations.

Q: What is your prediction on the future of NBS?

A: I predict that NBS will continue to grow, incorporating new testing platforms and screening methods, and broadening the scope of what disorders we can screen for. As science advances I believe NBS will develop and advance in proportion to continue offering timely intervention to the infants of Maryland. It would be interesting to see how NBS programs throughout the country harmonize in the future as well as what new instrumentation will be available to enhance our screening capabilities.



Unsatisfactory Specimens: Enhancing Our Newborn Screening Process

The Newborn Screening (NBS) program is committed to streamlining its operations to align with national recommendations. Our goal is to ensure timely specimen collection and rapid reporting of time-critical disorders. We are also aligning our specimen acceptance criteria with the standards outlined in the 7th edition of the CLSI NBS01 Dried Blood Spot Specimen Collection for Newborn Screening.

To support these goals, we have implemented the following improvements:

- 1. Retrained staff to ensure they can consistently and accurately identify acceptable specimens, which will help the team make precise determinations when a specimen is unsatisfactory.
- 2. Introduced a two-person review for every specimen received.
- 3. Established a supervisory review process to assess specimen quality and assign unsatisfactory codes.

You may have noticed an increase in your facility's unsatisfactory specimen rate due to these changes. To help reduce these rates, we recommend the following steps:

- Request a site visit with our NBS follow-up team to review your specimen collection techniques.
- Ask for images of your unsatisfactory samples for targeted retraining.
- Avoid holding or batching specimens; courier or ship them to the lab within 24 hours of collection.
- Use priority or overnight shipping to prevent specimens from exceeding the 10-day transit limit, which may cause them to be deemed unsatisfactory.

Helpful Resources

Please review the following videos as a refresher on proper specimen collection techniques:

- Newborn Screening Dried Blood Spot Collection Video 1
- Newborn Screening Dried Blood Spot Collection Video 2
- NewSteps Resource Library

Useful Online Tools

Use our Cognito portal to easily access important NBS forms and requests:

https://www.cognitoforms.com/mdh3/nbslabrequests

- Lab order slip requests (NBS collection forms)
- Specimen requests (results or corrections)
- Sickle cell trait records requests

Refusal documentation for newborn screens

MyLIMS Web Portal

For quick and convenient access to your facility's NBS results, enroll in our MyLIMS web portal. To sign up for the portal or for issues accessing the portal/reports, please email the lab at mdphl.nbs@maryland.gov. You can also reach out to the NBS follow-up office for screening guidance and follow-up recommendations at mdh.newbornscreeningfollowup@maryland.gov. Thank you for your continued partnership as we work together to improve the Newborn Screening program.

Newborn Screening on Babies 6 Months of Age or Greater

Effective September 1, 2025, the Maryland Newborn Screening (NBS) program will no longer accept specimens for babies aged six months or older. Please review the latest letter from the Maryland Newborn Screening Program here.

Understanding Key Terms in Newborn Screening (NBS) Reports

Insufficient Milk Feed (IMF)

- Where it appears: Amino acids and galactose result fields.
- **Meaning:** Valid results require the infant to have been on milk feeding for at least 24 hours before blood collection.
- Why: Feeding influences amino acid and galactose levels in the blood. Without adequate feeding, these metabolites may be abnormally low or misleading, leading to inaccurate screening results.
- If the infant's feeding status or specimen collection date is not documented on the lab slip, results will be reported as **IMF** to avoid false interpretation.
- **Action:** Confirm feeding history and specimen timing to ensure accurate interpretation.

Invalid

- Where it appears: T4 and 17-OHP result fields.
- Meaning:
 - T4 and 17-OHP results are invalid if the specimen was collected before 24
 hours of age because hormone levels in newborns fluctuate significantly right
 after birth and stabilize after 24 hours. Testing too early can give misleading
 results.
- Why: Testing before 24 hours or in very low birth weight infants can produce inaccurate results due to physiological factors, leading to false positives or negatives.
- Action: Follow screening collection protocol
 - NICU <24 hours, 2-3 days of age, 10 days then 1 month.
 - Full term- 24-36 days of age, 10 -14 days of age.

Incomplete

- Where it appears: Galactose, amino acids, and IRT result fields.
- **Meaning:** Results are incomplete when critical information for accurate interpretation is missing, such as date of birth, collection date, feeding status, infant weight, or gestational age.
- Why: These clinical and specimen details are essential to contextualize and interpret lab results properly. Without them, results may be misleading or uninterpretable.
- Action: Ensure complete and accurate data accompany every specimen. If your sample is incomplete, <u>please do not collect a repeat NBS</u>, obtain the missing information and send a request to update the lab slip using https://www.cognitoforms.com/mdh3/nbslabrequests. A new report will be released using the updated clinical and specimen details.

September is National Newborn Screening & Sickle Cell Awareness Month

September is a special month dedicated to raising awareness about the life-saving power of **Newborn Screening (NBS)** and the importance of **Sickle Cell Disease (SCD)** education and early diagnosis.

National Newborn Screening Awareness Month reminds us that every baby deserves timely screening for serious but treatable conditions. Early detection through NBS saves lives, prevents disabilities, and improves health outcomes for thousands of infants each year.

Sickle Cell Awareness Month highlights the challenges faced by individuals living with sickle cell disease and promotes early diagnosis, comprehensive care, and community support. Since SCD is a core condition on newborn screening panels across the US, September is a perfect time to learn more about both.

Upcoming Webinars:

Sickle Cell Disease Webinar

Date: September 10, 2025Time: 1:00 PM – 2:00 PM ET

② Join us for an informative session on sickle cell disease screening, management, and family support.

Lysosomal Storage Disorders (LSD) Webinar

Date: September 24, 2025Time: 1:00 PM – 2:00 PM ET

2 Presented by Dr. Grant, this webinar will cover LSD conditions included in newborn screening, lab workflows, and clinical follow-up protocols.

(Registration links and details to follow)

New Programming for Sickle Cell Disease

In the spirit of Sickle Cell Awareness Month, the Office of Children and Youth with Specific Health Care Needs is excited to announce the awarding of four new grants. These grants will fund programs designed to promote health equity and improve access to care for individuals and families affected by Sickle Cell Disease and Sickle Cell Trait.

Here is a brief overview of the organizations and programs. More details will be shared in the upcoming months.

- **Howard University** will provide testing for sickle cell trait and other hemoglobinopathies, including thalassemia trait. This will include follow-up genetic counseling for those who test positive.
- Johns Hopkins University will provide notifications, education, and scheduling assistance for annual transcranial doppler (TCD) screenings for children diagnosed with sickle cell disease.
- Maryland Sickle Cell Disease Association will facilitate a statewide program offering notification, counseling, and education to families of newborns identified as having sickle cell trait or another hemoglobinopathy trait.
- SCORE (Sickle Cell Outreach Resources and Engagement) will provide social support through Community Health Workers (CHWs) to help Maryland residents with sickle cell disease navigate the health systems and access resources.

Maryland Early Hearing Detection and Intervention (MD EHDI): Reinforcing the Importance of Follow-Up Hearing Screenings

The Maryland Early Hearing Detection and Intervention (MD EHDI) program is dedicated to ensuring early identification and intervention for infants with hearing differences. Our goal is to minimize the language learning gap for children diagnosed as deaf or hard of hearing, aligning with national initiatives to provide early intervention services by 6 months of age. We recognize the crucial role of pediatricians in this process, as they are trusted professionals who can significantly influence family adherence to medical advice.

To support these goals, we emphasize the following:

- 1. **Reinforcing the Importance of Follow-Up Screenings:** Pediatricians are vital in reinforcing the necessity of follow-up hearing screenings for infants who have been flagged.
- 2. **Providing Comprehensive Resources:** Pediatricians can assist families by offering referrals for follow-up screenings, providing contact information, MD EHDI Resource Line 1-800-633-1316, for the Maryland Infant Hearing Program, and supplying materials in the family's native language about what to expect during the appointment.
- 3. Facilitating Culturally Sensitive Communication: Discussions about hearing screenings may require an interpreter, especially one familiar with the family's culture, to ensure full understanding and address all questions.

We know that infants begin to learn language from birth and specific contexts by 6 months of age; a hearing difference can impede this knowledge transfer. A personalized "warm handoff" from their pediatrician, a trusted figure, empowers families to make informed decisions that can improve language and communication outcomes for their baby. When

pediatricians prepare parents and caregivers for potential calls or letters from the MD EHDI program, they equip the family with a foundational understanding of the process and reassure them that they are not alone.



Heart Corner (CCHD)

Special Note: Please Document All CCHD Information in OZ

All pulse oximetry screening data must be thoroughly documented in **OZ**. The medical record should include the following details:

- The age of the baby at the time of screening.
- The **specific values** of each oximetry result.
- The **extremity** from which each reading was obtained.
- Whether the screening was deemed a pass or fail.
- If the screening was **not performed**, the **reason(s)** must be documented.
- Any **subsequent actions** following a failed screen (e.g., clinical exam, echocardiogram) should also be clearly documented.

Accurate and complete documentation ensures proper follow-up and supports the quality of CCHD screening.

Want something included in the next quarterly newsletter? Email mdh.cyshcn@maryland.gov

health.maryland.gov/phpa/cyshcn/Pages/home.aspx

Maryland Department of Health | 201 W. Preston St | Baltimore, MD 21201 US

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