

# LabLink

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## Bureau Vision

The Bureau of Laboratories is a stronger, more diverse team within an integrated public health system. We utilize advanced technology and innovative leadership to provide comprehensive public health services in our dynamic global community.

## Bureau Mission

We are dedicated to continuing leadership in providing quality laboratory science for healthier people and communities through partnerships, communication and technical innovation.

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# ***Adding New Disorders to the Newborn Screening Panel***

***by Shelby Heppe, MPH— Newborn Screening Follow-up Section Manager  
and Heather Wood, M.S.— Operations and Analytics Unit Manager, Newborn Screening***

## **What is Newborn Screening?**

Newborn screening (NBS) is a lifesaving public health program mandated by Michigan law. The Michigan (MI) NBS program began screening babies in 1965 for phenylketonuria (PKU). The program has expanded significantly since then, with nearly 60 disorders on the panel. The newborn screen panel includes dried blood spot (DBS) testing and point-of-care screening tests for hearing loss and critical congenital heart disease, see [Newborn Screening - List of Disorders](#). The NBS program encompasses the NBS laboratory section in the Bureau of Laboratories (BOL), the short-term follow-up group in the Bureau of Epidemiology and Population Health, Early Hearing Detection and Intervention group in the Bureau of Health and Wellness, and contracted clinical partners.

The expansion of the NBS panel has primarily occurred through the addition of new disorders for the dried blood spot testing. DBS is a blood sample collected by a heel stick and applied to special filter paper between 24 and 36 hours of life. Specimens are transported to the BOL via courier six days a week. The NBS laboratory tests over 100,000 specimens yearly. Every year more than 300 babies are diagnosed with a disorder detected by the NBS panel.

## **How the decision is made to add new disorders to NBS panel?**

The NBS program has an advisory committee structure to assist with the decision-making process for the inclusion of additional newborn screening tests. The committee structure is composed of multiple disease-specific committees, the Technical Advisory Committee (TAC), and the legislatively mandated NBS Quality Assurance Advisory Committee (QAAC). The committee's responsibility includes, but is not limited to, providing a final

review and commentary on the recommendations for new disorder additions.

Recommendations from the disease-specific committees and the TAC are forwarded to the QAAC for final review and approval. Once the QAAC has formalized a recommendation, it is routed to the Public Health Administration, the MDHHS director, and finally to the Michigan legislature health policy committees. If there is no action from the legislature, the disorder is automatically added to the NBS panel.

There are two routes to nominate a condition for the NBS panel. Any additions to the NBS panel must be approved by the advisory committee structure and legislature as outlined above. These processes include 1) Addition to the Recommended Uniform Screening Panel (RUSP) by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) or 2) Review using the Michigan Condition Readiness Tool following a formal request for addition.

## **The addition to the RUSP by ACHDNC**

The ACHDNC serves as an advisory committee to the secretary of the U.S. Department of Health and Human Services, see [Advisory Committee on Heritable Disorders in Newborns and Children | HRSA](#). Their mission is to reduce morbidity and mortality in newborns and children who either have or are at risk for heritable disorders. Disorders on the RUSP are chosen based on evidentiary review to ensure screening supports a net benefit, feasibility to screen for the disorder, and the availability of effective treatments. The committee recommends every NBS program to screen for the core 38 disorders.

# ***Adding New Disorders to the Newborn Screening Panel***

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## **The Michigan Condition Readiness Tool**

The Michigan condition readiness tool was designed to assist decision-making processes for adding conditions to the screening panel not on the RUSP. The tool is used by MDHHS, with input from clinical stakeholders, and serves as a basis for discussion and recommendations. Required criteria is incorporated into the MI condition readiness tool to assess the appropriateness of screening for the proposed disorder is listed below:

- Support from screening facility (MDHHS lab or birth hospitals).
- Support from appropriate follow-up program (NBS follow-up or other maternal child health program).
- Support from Michigan specialists.
- Identifiable condition in the newborn period when it would not ordinarily be detected clinically.
- Available within the next 12 months or a screening test with appropriate sensitivity and specificity.
- Established benefits of early detection, timely intervention, and safe, efficacious treatment with a significant improvement in the quality of life for identified newborns.
- The condition does not have a known late-onset form (if yes, additional criteria must be met).

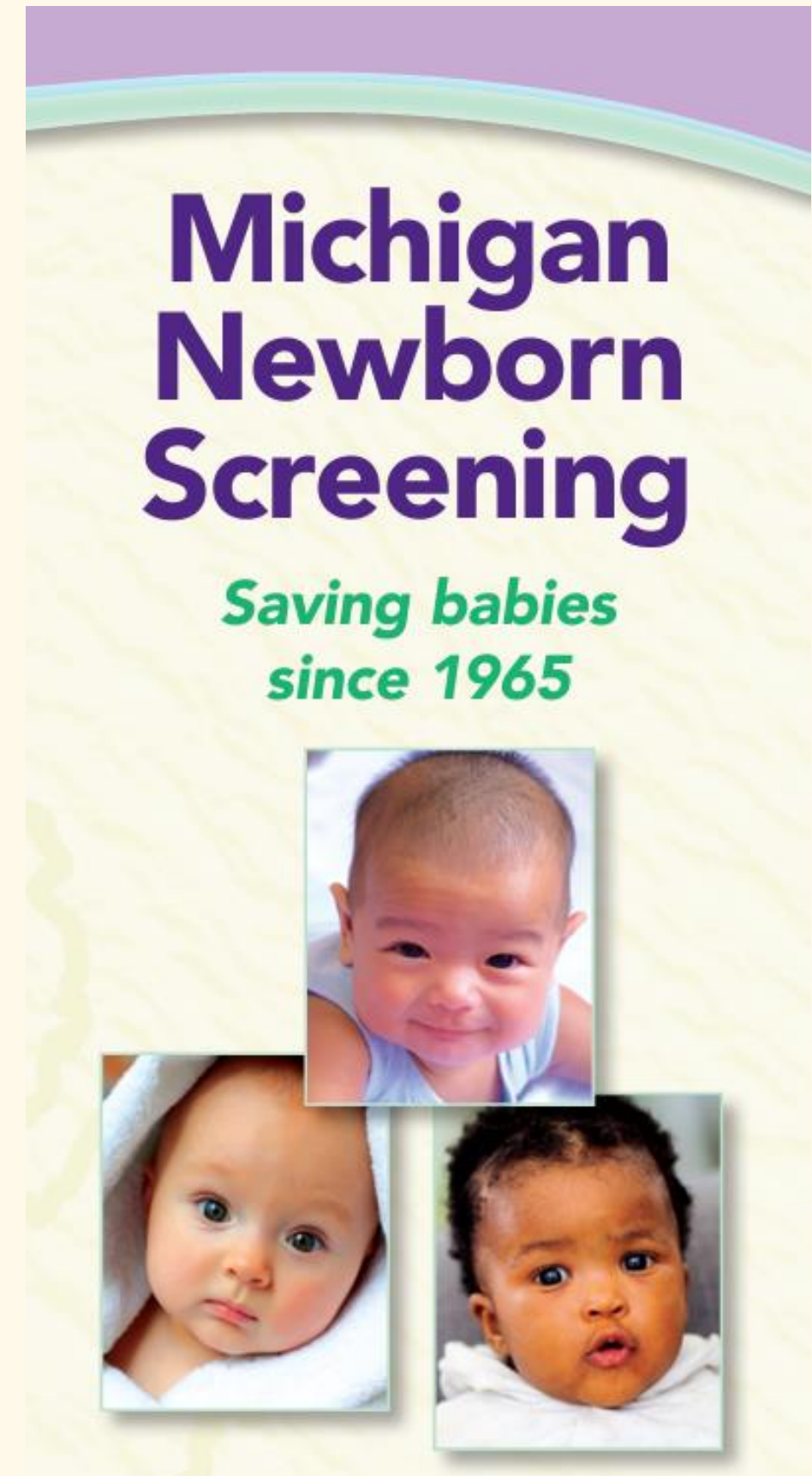
The level of readiness is classified as either ready, developmental, or unprepared for screening.

Conditions meeting the ready or developmental stage can be recommended to QAAC for inclusion on the NBS panel.

## **Summary**

The NBS panel contains nearly 60 disorders with more disorders being added each year. All disorders added to the recommended uniform screening panel are added to the Michigan newborn screening panel. It takes a considerable amount of effort and coordination of the laboratory, short-term follow-up, committees, and clinical partners to add a new disorder.

However, Michigan has two established routes to systematically add a new disorder to the NBS panel.



# The Importance of the Specimen Collection and Submission Process

*By Mary Bonifas, Quality Assurance Section Manager*

While collection and submission are often referred to, in general conversation, as part of the testing process, they are distinct processes separate from laboratory testing.

The importance of proper specimen collection and submission on the laboratory testing process, however, cannot be overstated. Collection and submission processes result in the input for laboratory testing and, as with any process, the result is only as good as the initial input.

Collection processes for clinical diagnostic testing must include:

- Positive identification of the patient using two separate and unique identifiers (e.g., asking to confirm first and last name and date of birth).
- Labeling the specimen container in the presence of the patient.
- Labeling the specimen container with at least 2 unique identifiers such as:
  - ⇒ First and last name (together these are a single identifier, one without the other is not an acceptable identifier).
  - ⇒ Date of birth.
  - ⇒ Requisition number.
  - ⇒ Unique random number.
  - ⇒ Note: A location, such as a room number, is not considered unique and cannot be used.
- Other applicable items such as:
  - ⇒ Patient preparation (e.g., fasting).
  - ⇒ The correct specimen container.
  - ⇒ Storage conditions prior to transport to the laboratory (e.g., time, temperature).

Submission processes include:

- Proper packaging:
  - ⇒ Primary and secondary containers.

- ⇒ Packaging that supports transit temperature requirements (e.g., Styrofoam inserts, ice packs).
- ⇒ Package labeling that meets transportation regulations (e.g., UN3373 labels for category B biological substances).
- ⇒ Absorbent capable of absorbing the amount of liquid being shipped (BOL absorbent strips can absorb up to 50mL).
- The completed test requisition form in the outside pouch of the biohazard bag.
- Using a transport method that will get the package to the lab in time.

Collection and submission requirements for testing offered by the Bureau of Laboratories are available in the test A-Z forms as well as in the specimen collection and shipping instructions.

These forms and instructions do change and should be periodically checked for updates.

A-Z forms for testing offered at the BOL are available here:

<https://www.michigan.gov/mdhhs/doing-business/providers/labservices/a-z-test-listing>

Specimen collection and shipping instructions are available here:

<https://www.michigan.gov/mdhhs/doing-business/providers/labservices/labservicesguide/specimen-collection-and-shipping-instructions>

Test requisition forms are available here:

<https://www.michigan.gov/mdhhs/doing-business/providers/labservices/test-request-forms>

If a question arises regarding collection or submission for testing at the Bureau of Laboratories, please contact MDHHS Lab@michigan.gov