

# Newborn Screening PROVIDER MANUAL



Blood Spot  
Screening



Pulse Oximetry  
Screening



Hearing  
Screening





➤ This provider manual is available to download from our website at  
**[www.health.state.mn.us/newbornscreening](http://www.health.state.mn.us/newbornscreening)**



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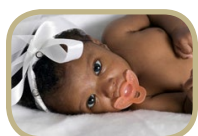
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# 1 Introduction to Newborn Screening

Healthcare providers, together with the Minnesota Department of Health (MDH), save lives and protect the health of Minnesota infants through newborn screening.

This manual is intended to serve as a reference tool for hospital personnel, physicians, out-of-hospital birth providers, and other healthcare providers who work with infants and their families. It is designed to function as a step-by-step guide to the newborn screening process.

## HISTORY OF NEWBORN SCREENING IN THE UNITED STATES

Newborn screening began in the United States over 50 years ago when Dr. Robert Guthrie devised a screening test for a rare genetic disorder, phenylketonuria (PKU), using a small amount of newborn blood dried onto filter paper. Since the early 1960s, newborn screening has grown into a critical state-based public health program that screens millions of infants every year for a number of genetic and congenital disorders.

Because newborn screening developed as a state-based program, large discrepancies arose over time, including the number of disorders screened for, follow-up practices, and educational materials available. It became clear that greater uniformity among states would benefit families, healthcare providers, and newborn screening programs. In 2002, the United States Department of Health and Human Services (DHHS) commissioned the American College of Medical Genetics (ACMG) to convene a group of experts to analyze scientific literature, gather expert opinion, and assess newborn screening systems nationwide in order to develop a Recommended Uniform Screening Panel (RUSP) of conditions for all states. The ACMG expert group developed a core



After Dr. Robert Guthrie's niece, pictured above with her mother, was diagnosed with PKU, he developed the filter paper method of testing still used today.



panel of 29 conditions that it recommends all state newborn screening programs mandate as part of routine screening. Many factors influence the decision to include a disorder on the RUSP, including the severity of the condition, the availability of effective treatment, the age of onset, and the complexity or cost of the test.

In 2003, following the original creation of the RUSP, the DHHS established the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) to provide long-term expertise and recommendations for uniform screening. In April 2013, the Public Health Service Act (PHS) changed the name of the SACHDNC to the [Discretionary Advisory Committee on Heritable Disorders in Newborns and Children \(DACHDNC\)](#), whose mission is to reduce morbidity and mortality in newborns and children who have, or are at risk for, heritable disorders. The DACHDNC reviews and makes final decisions on conditions nominated for inclusion on the RUSP.

With the help of national recommendations from the DACHDNC, each state ultimately determines which disorders to screen for and how its program will function. Disorders may be added to an individual state's newborn screening panel via its legislature with or without approval from the DACHDNC.

## NEWBORN SCREENING IN MINNESOTA

Newborn screening in Minnesota is mandated by Minnesota Statutes [144.125](#), [144.128](#), [144.966](#), and [144.1251](#) (refer to pages 49-50). These laws govern the responsibilities of both healthcare providers and MDH in blood spot screening, hearing screening, parent education, reporting of results, and follow-up services. They also require that all infants born in Minnesota are screened for the disorders listed on the newborn screening panel unless a parent refuses in writing.

Minnesota's [current disorder panel](#) can be found on the Newborn Screening Program website. Disorders are added to this panel by the Commissioner of Health with advice and recommendations from the Minnesota Newborn Screening Advisory Committee (refer to pages 51-52).

Minnesota's Newborn Screening Program, together with hospitals, laboratories, and medical professionals across the state, screens infants for critical congenital heart disease, hearing loss, and over 50 disorders that may affect their metabolism, hormones, hemoglobin, breathing, digestion, and immune system. If left untreated, these disorders can lead to illness, physical disability, developmental delay, or death. By identifying these disorders early, however, changes in diet, medications, or other interventions can help prevent most health problems caused by the disorders on the newborn screening panel.



In 2013, the Minnesota Newborn Screening Program celebrated 50 years with local families whose lives were changed by screening. Evan, pictured above with his metabolic physician, Dr. Sue Berry, was identified with galactosemia through screening in Minnesota.

# 2

## Parent Education

The Newborn Screening Program relies on healthcare providers to educate parents about newborn screening and its benefits. All parents must be informed about the newborn screening process and the options available to them. Parent awareness about the newborn screening process plays an important role in alleviating anxiety about positive, borderline, or unsatisfactory newborn screening results. The Newborn Screening Program has developed a variety of education materials to help guide discussions with parents.

### PRENATAL EDUCATION

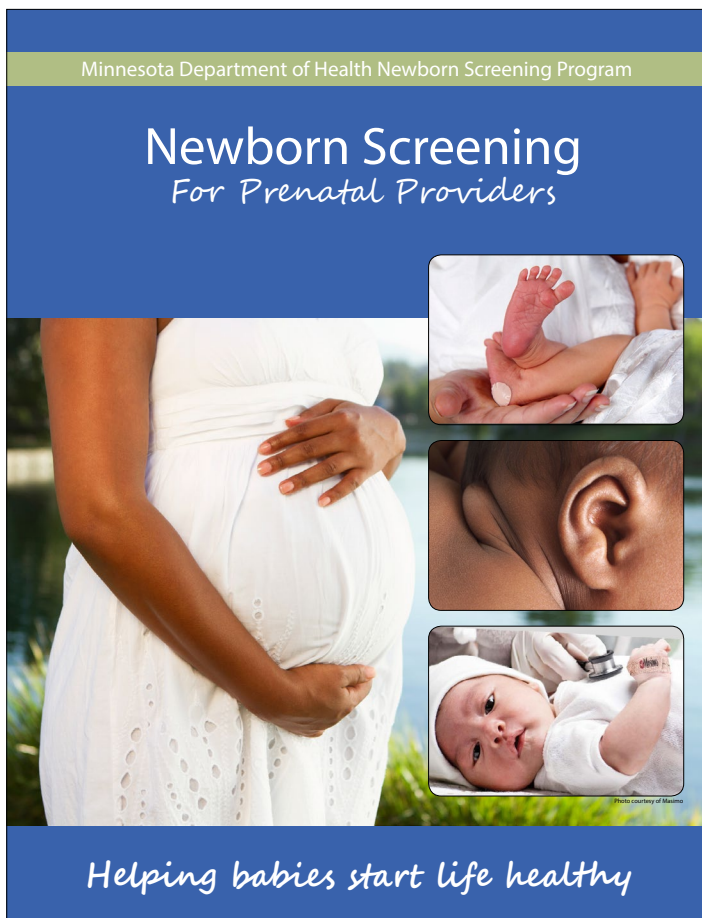
Prenatal educators and providers are in a unique position to educate parents about newborn screening before labor and delivery, allowing them time to understand the newborn screening process and their options. Studies have shown that parents prefer to learn about newborn screening during the prenatal period rather than after delivery. The importance of educating parents about newborn screening prenatally is recognized and encouraged by multiple professional associations, including the American College of Obstetricians and Gynecologists (ACOG), the American College of Medical Genetics (ACMG), the American Academy of Pediatrics (AAP), the Health Resources and Services Administration (HRSA), and the March of Dimes.

In 2012, Minnesota Statute [144.125](#) was revised to direct MDH to make information and forms available to aid prenatal care providers in educating expectant parents about the newborn screening program.



Below are some resources available to prenatal care providers:

- [Prenatal Education page](#) on the Newborn Screening Program website
- [Newborn Screening for Parents-to-be](#) handout – available in multiple languages; visit the [Education Materials and Forms page](#) on the Newborn Screening Program website for the most up-to-date list of languages available and to order copies free-of-charge
- [Newborn Screening for Prenatal Providers](#) folder – visit the [Education Materials and Forms page](#) on the Newborn Screening Program website to order a folder free-of-charge



The *Newborn Screening for Prenatal Providers* folder is designed to give prenatal care providers the information they need for introductory discussions with expectant parents.

## Newborn Screening For Parents-to-be



### Helping babies start life healthy

Every parent-to-be wants a healthy baby. Newborn screening checks babies for serious disorders that often cannot be seen at birth. These disorders can be found through blood spot, hearing, and pulse oximetry screening. If a disorder is found early through one of these screens, early interventions can help give these babies a healthy start to life.



**Blood spot screening** checks for over 50 rare but treatable disorders that can affect the immune system, how the body makes energy, or other important processes. Early detection can help prevent serious health problems or even death.



**Hearing screening** checks for hearing loss in the range where speech is heard. Identifying hearing loss early improves a baby's ability to access language and develop on track with their hearing peers.



**Pulse oximetry screening** checks for critical congenital heart disease (CCHD). If detected early, babies with CCHD can often be treated with surgery or other medical interventions.

Newborn screening makes early detection, diagnosis, and interventions possible that help give affected babies a healthy start to life.

The *Newborn Screening for Parents-to-be* handout is designed for prenatal care providers to give to expectant parents during a discussion about newborn screening at least once during the third trimester. It is available to order free-of-charge in multiple languages on the program website.

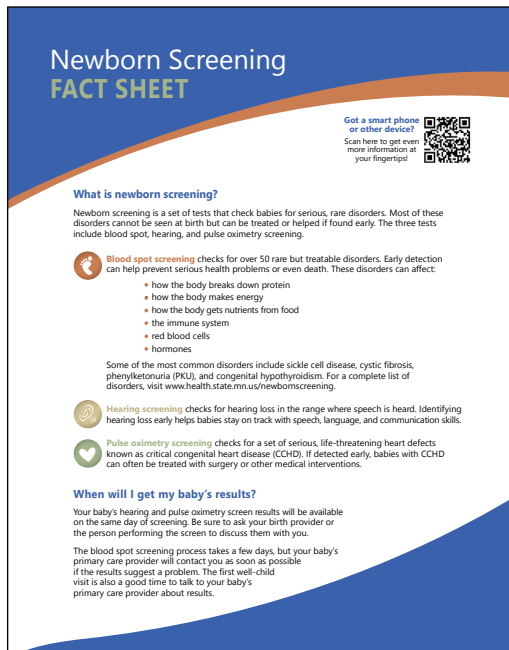


## POSTNATAL EDUCATION

Minnesota Statutes [144.125](#) and [144.966](#) require birth hospital staff and healthcare providers to inform parents about the benefits and risks of newborn screening, as well as the specific benefits and risks associated with choosing to opt-out of any part of newborn screening. The law also requires providers to document in the infant's medical record that the parents received information about newborn screening and had an opportunity to ask questions.

The Newborn Screening Program recommends the following to meet the legal requirements:

- ✓ Provide and review the [Newborn Screening Fact Sheet](#) with parents. This fact sheet is automatically sent out with every newborn screening card ordered.



limited to: confirmatory testing, quality control and improvement, evaluating and improving the accuracy of newborn screening tests, and the development of new tests and studies related to newborn screening.

- ✓ Inform parents that they may give written [consent](#) allowing their infant's blood spots and test results to be used for public health studies or research not necessarily related to newborn screening.

### *The use of blood spots and test results in public health studies and research makes advancements in testing and treatment options possible.*

Access to blood spots and test results will be granted only to researchers whose public health studies are approved by both the MDH Institutional Review Board (IRB) and the researcher's IRB. They will not be granted to law enforcement, insurance companies, or others unless required by law or a court order.

- ✓ Inform parents that they may request that their infant's blood spots be returned to them at any time — as long as a [Directive to Destroy](#) form has not already been received — by contacting the Newborn Screening Program.
- ✓ Inform parents that they may arrange for testing to be done by a private laboratory if they choose. Ideally these arrangements are made prior to birth. Parents and providers should be aware that:

- » Private testing must be arranged by the parent through their primary care provider and the specific private laboratory they choose.
- » The specific disorders screened for by private laboratories may vary from those screened for by Minnesota's Newborn Screening Program.
- » Testing performed by a private laboratory is more expensive, results may take longer than MDH screening, and follow-up will not be tailored to Minnesota's medical system.
- » The birth facility must provide documentation to the Newborn Screening Program that the parents refused to have their newborn screened by MDH.

- ✓ Inform parents that their infant's blood spots, pulse oximetry results, and hearing results will be sent to the Newborn Screening Program. Any remaining dried blood spots and all test results will be retained by the program as required by law. Visit the Newborn Screening Program [Retention Practices page](#) for more information.
- ✓ Inform parents that, in addition to screening for the disorders on the newborn screening panel, de-identified blood spots may be used for newborn screening program operations, which may include but is not

✓ Inform parents that they may decline to have their infant screened. Parents who choose this option must sign the [Parental Refusal of Newborn Screening](#) form. It is important to review the following points with parents who choose to decline screening:

- » Infants affected by the disorders on the newborn screening panel often appear healthy at birth and have no family history of the disorder.
- » By the time symptoms appear, damage can be irreversible.
- » An affected infant who is not screened may not receive treatment in time to prevent serious developmental delay, illness, or death.
- » The decision to refuse screening will be recorded and documented in their infant's medical record and at MDH.

## EDUCATION FOR LIMITED ENGLISH PROFICIENCY FAMILIES

The Newborn Screening Program has translated educational materials for limited English proficiency families and continues to explore additional resource needs. Please contact program staff to request copies of these materials or to offer suggestions for additional resources.

The following non-English resources are currently available:



- The [Newborn Screening Fact Sheet](#), which gives a general overview and introduction to newborn screening in Minnesota, is available in English, Hmong, Karen, Somali, Spanish, and Russian. A culturally-appropriate Amish version is also available.
- The [PASS Result: Hearing Screen Result Notification](#) sheet for families of infants who pass the newborn hearing screen includes information about the result and a brief hearing milestone checklist for parents. This form is available in English, Hmong, Karen, Somali, Spanish, and Russian.
- The [REFER Result: Hearing Screen Result Notification](#) sheet for families of infants who do not pass the newborn hearing screen includes information about the result and the importance of follow-up testing. This form is available in English, Hmong, Karen, Somali, Spanish, and Russian.
- The [Pass Result: Pulse Oximetry Screen Result Notification](#) sheet for families of infants who pass the pulse oximetry screen includes information about the result and how to watch for signs of CCHD. This form is available in English, Hmong, Karen, Somali, Spanish, and Russian.
- The [Did Not Pass Result: Pulse Oximetry Screen Result Notification](#) sheet for families of infants who do not pass the pulse oximetry screen includes information about the result and follow-up testing/evaluation needed. This form is available in English, Hmong, Karen, Somali, Spanish, and Russian.

### Note:

Other non-English fact sheets about newborn screening are available at the following sites:

- [New England Newborn Screening Program: Brochures](#)
- [California Department of Public Health](#)

Please note that state guidelines regarding screening may vary. Please contact the Newborn Screening Program with any questions.

# 3

## Ordering Newborn Screening Cards, Education Materials, and Forms

Providers and parents can order newborn screening cards, education materials, and forms through the Minnesota Newborn Screening Program. All education materials are provided free of charge and can be ordered online through the program website.

### NEWBORN SCREENING CARDS

The Newborn Screening Program revised the screening cards in November 2014. The new screening cards have only a single filter paper layer with all five blood spot circles.

The Newborn Screening Program automatically ships screening cards to facilities who regularly submit specimens for testing. For clinics, out-of-hospital birth providers, and parents who do not regularly submit specimens, contact program staff to arrange shipment. Submitters will be billed for the screening card once it is received by the Newborn Screening Program for testing.

The price of the newborn screening card occasionally changes as new disorders and tests are added to the newborn screening panel. For the most up-to-date price, please visit the Newborn Screening Program [website](#) or call program staff.

Newborn screening cards are regulated by the Food and Drug Administration (FDA) as Class II medical devices. Due to FDA regulations, newborn screening cards are printed with expiration dates. The cards can be used for blood spot collection up to and including the last day of the month of the expiration date printed on the card. Expired newborn screening cards submitted for testing

will be considered unsatisfactory and another specimen will be requested, which can delay diagnosis and treatment. Therefore, it is recommended that newborn screening card expiration dates are reviewed regularly.

The image shows a cover sheet for a Minnesota Newborn Screening Card. At the top left is the Minnesota Department of Health (MDH) logo. To the right of the logo, the text reads: "Newborn Screening Program", "601 Robert Street North", "St. Paul, MN 55155-2531", "Phone: (800) 664-7772", "Phone: (651) 201-5466", "Fax: (651) 215-6285", and "Email: [health.newbornscreening@state.mn.us](mailto:health.newbornscreening@state.mn.us)". To the right of this text is a red "SN" label with the number "0408255212". Below this information, it says "This Screening Card Expires 08/2017". Underneath that, it says "Remove this cover sheet before sending the card to the Newborn Screening Program". At the bottom, there is a box titled "DON'T FORGET TO:" containing two checkboxes: "Give the parent(s) educational information about newborn screening and offer the opportunity to ask questions BEFORE collecting the blood spots." and "Indicate in the infant's medical record that the parent(s) received educational information and were able to ask questions."

Screening card expiration dates should be reviewed regularly to help manage inventory. Cards may be used for blood spot collection up to and including the last day of the month of the expiration date printed on the card.

## Types of Screening Cards

There are two types of newborn screening cards that can be ordered:

1. **White**—Used for newborns weighing more than 1800 grams at the time of birth. White newborn screening cards should always be used for infants born in out-of-hospital birth settings, regardless of weight.
2. **Yellow**—Used only for newborns born in a hospital weighing less than or equal to 1800 grams at the time of birth.

Institutions and providers caring for newborns should maintain a supply of screening cards adequate to cover unexpected events such as a sudden increase in birth rate or damage to cards. If there are not enough screening cards on hand to cover immediate needs, please call the Newborn Screening Program immediately.

## Out-of-Hospital Births

Out-of-hospital birth providers have several options to ensure all of the infants in their care have access to newborn screening. Providers may order newborn screening cards from the Newborn Screening Program for each expected birth or ask the parent to order the card. If the parent will be responsible for ordering the newborn screening card, the provider should make sure the parents are familiar with the ordering procedure and obtain the card in a timely fashion. Some providers may choose to refer the family to another provider to collect the blood spots and/or perform the hearing screen. In these cases, the Newborn Screening Program recommends that the birth attendant provides educational materials to the family and follows up to make sure the infant is screened.

The Newborn Screening Program also recommends that out-of-hospital birth providers who choose to provide newborn screening cards have at least one card available for back-up in case a problem with blood spot collection occurs.

## Void or Expired Cards

If there is a problem with blood spot collection, the card is expired or damaged (e.g., the card layers separate), and/or the collected specimen is determined to be unsatisfactory, please take the following actions:

- new screening cards - do not send to MDH; simply discard them
- old screening cards - write "VOID" on the face of the card, remove the filter paper portion of the card (if it contains blood), mail the void card to MDH Newborn Form Orders, P.O. Box 64496, St. Paul, MN 55164-0496, and you will be given a credit toward new cards

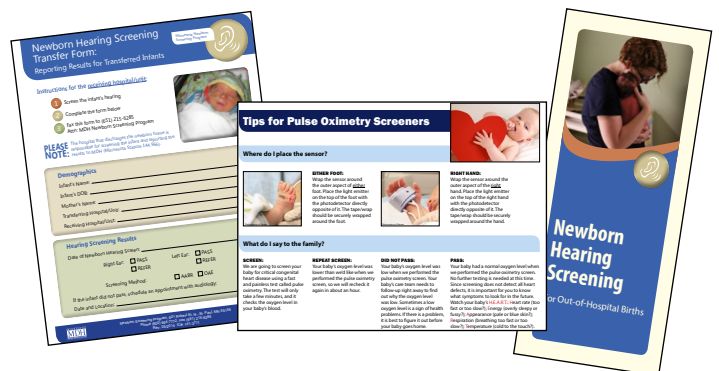
Credit for expired or damaged cards will only be available until August 31, 2015. All expired or void screening cards should be discarded after this date.

## EDUCATION MATERIALS AND FORMS

The Newborn Screening Program provides education materials and forms for parents and providers free of charge. Materials can be ordered through the [online ordering form](http://www.health.state.mn.us/newbornscreening/orderingform) or by printing the [Education Materials Ordering Form](http://www.health.state.mn.us/newbornscreening/educationmaterials) and faxing or mailing it to the Newborn Screening Program.

A list and description of available education materials and forms can be found on the Newborn Screening Program [website](http://www.health.state.mn.us/newbornscreening). Please contact program staff with any questions about available materials or how to place an order.

*Education materials can be ordered  
free-of-charge online at  
[www.health.state.mn.us/newbornscreening/  
materials/education.html](http://www.health.state.mn.us/newbornscreening/materials/education.html)*





# 4

## Blood Spot Screening

All hospitals and out-of-hospital birth providers are required by law to inform and educate parents about newborn screening and to collect and submit blood spots for every newborn unless parents decline in writing.

### WHY IS BLOOD SPOT SCREENING IMPORTANT?

The disorders on the newborn screening panel can lead to illness, physical disability, developmental delay, or death without prompt diagnosis and early intervention. Identifying and treating affected infants early can help prevent significant health complications.

*Every year more than 150 Minnesota newborns are found to have one of the disorders on the newborn screening panel.*

Every year more than 150 Minnesota newborns are found to have one of the disorders on the newborn screening panel. For the most up-to-date list of disorders included on the [newborn screening panel](#) and to view [disorder fact sheets](#), visit the Newborn Screening Program website.



## BLOOD SPOT SCREENING PROCESS

The Newborn Screening Program expects blood spots to be collected in accordance with standards developed by the Clinical and Laboratory Standards Institute (CLSI). The goal of these standards is to ensure the quality, consistency, and timeliness of both blood spot collection and screening tests.

### Personnel Performing Blood Spot Collection

Blood spot collection can be performed by trained personnel such as hospital nursery staff, laboratory staff, or out-of-hospital birth providers.

### Filling Out and Handling Newborn Screening Cards

Prior to collecting blood spots, the newborn screening card should be thoroughly checked to make sure it has not expired and is not damaged. Please discard any expired or damaged cards. You will only be billed for the screening cards that arrive at MDH for testing.

The healthcare professional collecting the blood spots should avoid touching the filter paper before, during, and after collection. Oils and other substances on hands can contaminate the card or the specimen itself. Additionally, water, infant formulas, antiseptic solutions, glove powder, hand lotion, and other materials should not come in contact with the newborn screening card at any time through the screening process.

**All demographic information requested on the newborn screening card should be completed before submission.**

All demographic information requested on the newborn screening card should be completed before submission; **all fields are required**. Accurate and complete information is essential for interpreting test results and locating the infant's healthcare provider if additional testing is needed. Refer to the [specimen card instructions](#) for details on filling out the newborn screening card. If an unusual situation arises and the best way to complete the newborn screening card is unclear, fill out as many fields as possible and contact the Newborn Screening Program with specific questions.

The form is a comprehensive newborn screening card. It includes sections for:
 

- Baby:** Last Name, First Name, Birth Date, Birth Time (military), Birth Weight (grams), Multiple Births (Yes/No), Gestational Weeks, Specimen Date of Collection, Collection Time, Type of Feeding (Milk Formula, Breast, TPN, Soy Formula), Sex (Male/Female), Collected By (initials), Clinical Information (Antibiotics/Transfused), Date of Transfusion.
- Mother:** Last Name, First Name, Mother's Birth Date, Address, City, Zip Code, Alternate Contact for Family (name and phone number), State, Mother's Phone Number.
- Physician:** Physician/Clinic Responsible for Infant Follow-Up after Discharge, Physician/Clinic Phone Number.
- Submitter:** Submitter Name, Submitter's Phone Number, Submitter City, Submitter #, Notes.
- Risk Factors:** NICU patient, Birth defects, Deceased siblings, Family history of disorder on MN screening panel, Cause of death.
- HEARING SCREENING:** Final Screen Date, Right Ear (Pass/Refer), Left Ear (Pass/Refer), Screening Method (ABR/OAE).

 The form also features a barcode, a 'Do NOT use this space' warning, and contact information for the Minnesota Department of Health, Newborn Screening Program.

Accurate and complete information is essential for interpreting test results and locating the infant's healthcare provider if additional testing is needed.

Special circumstances that may affect how the newborn screening card is completed:

- If an infant is going to a foster home or shelter, include the birth mother's information in the mother section and list the foster home or social worker as the alternate contact.
- If an infant's birth parents have relinquished custody and an adoptive parent has been identified, use the infant's adoptive name and list the adoptive parent on the newborn screening card.
- If an infant was born via surrogacy, use the name of the parent who will be caring for the child after delivery.
- If an infant was found at the hospital under the Safe Place for Newborns law, supply as much information as possible and indicate on the card why no further information is available.

## Timing of Blood Spot Collection

Timing of blood spot collection is important for accurately interpreting test results. Tests for some of the disorders on the newborn screening panel have different cutoff values based on the infant's age (in hours) at the time of blood spot collection. As a result, blood drawn too early or too late may increase the chance of false positive or false negative results.

**Blood spots are best collected between 24 and 48 hours of age.** Blood spots collected before 24 hours of age cannot be fully interpreted, which means some test results will be marked "unsatisfactory" on the newborn screening report. An unsatisfactory result will require another blood spot collection. However, special circumstances may arise that require blood spot collection at earlier or later times.

# <24 hrs

### **Situations requiring blood spot collection prior to 24 hours:**

- If an infant is going home prior to 24 hours of life, collect the blood spots before the family leaves and make arrangements to collect a subsequent specimen between the optimal time of 24 and 48 hours.
- If an infant is to be transferred to a different unit or hospital, collect the blood spots before the transport team leaves.
- If an infant requires any type of blood transfusion, collect the blood spots before blood products are administered. If the pre-transfusion specimen was collected prior to 24 hours of life, a subsequent specimen should be collected after 24 hours. The first specimen will allow for accurate interpretation for the disorders affected by transfusion, and the second specimen will be used to screen for the remaining disorders that are affected by timing of collection.
- If an infant requires surgery or another major procedure, collect the blood spots before the procedure and make arrangements to collect a subsequent specimen between the optimal time of 24 and 48 hours.
- If an infant requires ECMO or ECLS before 24 hours of life, collect the blood spots before the pump is started and make arrangements to collect a subsequent specimen at a later time.
- If an infant is unlikely to survive the first 24 hours of life, collect the blood spots immediately. Results from the screening tests may contribute to an understanding of the newborn's condition or provide important information to the parents that could benefit future children. If the infant survives past 24 hours, a repeat specimen should be collected.

# >48 hrs

## Situations requiring blood spot collection after 48 hours:

- If an infant never received an initial screen or if a newborn screening report cannot be found in the infant's medical record, at the Minnesota Department of Health Newborn Screening Program, or at another state's department of health, collect a specimen as soon as possible.
- If an infant is transfused and a prior specimen was not collected, a specimen should be collected 90 days after the last transfusion.
- If the Newborn Screening Program has requested a repeat specimen, collect the repeat specimen as soon as possible. Repeat specimens are necessary if the initial specimen was unsatisfactory or if the infant has a borderline result. Repeat testing will clarify the infant's true risk for a disorder.
- If an infant was found under the Safe Place for Newborns law, collect the blood spots immediately. It should not be assumed that a specimen was previously collected.
- If an infant or child was born in a country where newborn screening was not available, the collection of a specimen can be considered. Although newborn screening can be performed at any age, test cutoffs are normalized for infants who are less than a week old, so results may be difficult or impossible to interpret for older children. While the Newborn Screening Program accepts specimens from older children, newborn screening is not a diagnostic tool. If the child is symptomatic, pursue clinical testing.
- If the infant's birth weight was less than or equal to 1800 grams and the infant is still an inpatient, additional screens should be collected at 14 and 30 days. Refer to pages 39-43 for more information.

## Blood Spot Collection Technique

Quality collection techniques and blood spots are vital to the Newborn Screening Program's testing and result interpretation. If the collection techniques are not properly followed, the screening tests may be difficult to interpret, which can delay the diagnosis and treatment of a potentially affected infant resulting in serious health consequences or death. [Step-by-step instructions](#) for proper blood spot collection and handling procedures, including examples of a satisfactory specimen, several unsatisfactory specimens, and the possible causes for each, are available on the Newborn Screening Program website.

***Blood spots should always be collected by heel-stick for optimal results.***

Blood spots should always be collected by heel-stick for optimal laboratory results. If extenuating circumstances arise that prohibit collection by heel-stick, please contact the Newborn Screening Program to discuss the best alternative collection method.

Prior to collection, the infant's identity should be confirmed and appropriate precautions should be taken, including the use of powder-free gloves. In preparation



The puncture site should be made within the shaded area as pictured above.



for collection, the heel should be warmed with a commercially-available heel warmer or a warm, damp cloth, and the leg should be positioned lower than the heart to increase venous pressure. The infant should be swaddled in a blanket with only one foot exposed. The infant's heel should be cleaned with an alcohol wipe and the area should be allowed to thoroughly air dry.

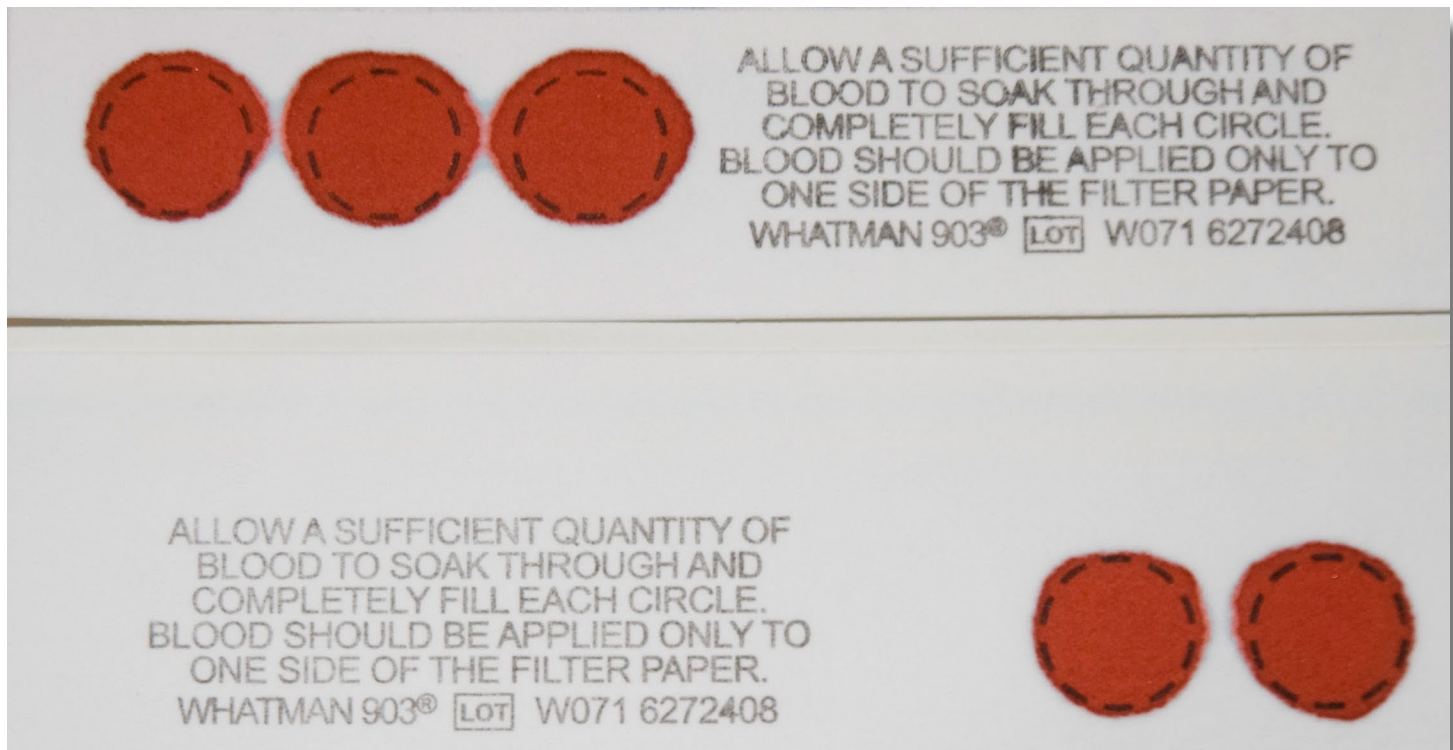
To collect the blood spots, a puncture should be made on the side of the heel using a sterile lancet with a 2.0 mm tip or a retractable incision device. The puncture should be 1 mm deep and 2.5 mm long (a shallower puncture can be made for small, premature infants). The first drop of blood should be wiped away with a sterile gauze pad. Once a large drop of blood has formed on the heel, the filter paper should be lightly touched to the drop of blood but should not touch the heel. Apply blood to one side of the filter paper only. It does not matter whether the blood is applied to the front or back of the filter paper. The blood should be allowed to soak completely through to fill the circle. After collection, examine the filter paper to ensure blood has soaked through to fill both sides.

All circles should be filled in this manner. If there is a problem with blood flow, the application of intermittent pressure to the area surrounding the puncture site can help.



The puncture should be made using a sterile lancet with a 2.0 mm tip or a retractable incision device.

Once all circles are filled, elevate the newborn's foot and, using sterile gauze, gently apply pressure to the puncture site until the bleeding stops.



All circles on the screening card should be filled completely, allowing blood to soak completely through to the other side.

Proper drying of the blood spots is important for maintaining the integrity of the specimens. Below are tips for proper drying:

- Dry the newborn screening card on a clean, flat, non-absorbent surface for at least three hours.
- Do not dry the newborn screening card next to a sink.
- Keep the newborn screening card away from direct sunlight or other heat sources.
- Do not allow the drying blood to touch other surfaces or specimens.
- Avoid stacking multiple newborn screening cards while they are drying.
- Do not close the biohazard flap over the blood spots until they are completely dry.
- There is no need to dry the newborn screening card in the dark.

Once the blood spots have completely dried, the biohazard flap can be closed and the newborn screening card can be placed in an approved container for transport to the Newborn Screening Program. The top instruction page should be removed prior to mailing the card.

## Shipping & Handling

Institutions that regularly submit specimens should have a procedure in place for pick-up by courier or other shipper established through the Newborn Screening Program. The Newborn Screening Laboratory accepts specimens Monday through Saturday at the address below. Deliveries are accepted from 7:00 AM - 4:30 PM Monday through Friday and 8:00 AM - 12:00 PM on Saturdays. Specimens must be received by 8:00 AM on Saturday in order to be tested that same day. ***The Newborn Screening Program accepts deliveries even during weather emergencies, outbreaks, and government shutdowns; therefore blood spots should continue to be collected and delivered during these times.*** For questions about holiday deliveries or if special delivery plans are needed, contact Newborn Screening Program staff.

Delivery Address:  
Newborn Screening Program  
601 Robert St. N  
St. Paul, MN 55155

For clinics, out-of-hospital birth attendants, and parents who submit specimens infrequently, specimens can be brought to the delivery address above or mailed to the following address. Since high heat and humidity can affect some of the tests, leaving specimens in hot mailboxes or other warm locations should be avoided.

Mailing Address:  
Newborn Screening Program  
P.O. Box 64899  
St. Paul, MN 55164

Multiple newborn screening specimens may be sent together; however, a shipment should never be delayed or "batched" to wait for more specimens. ***All specimens should be sent to the Public Health Laboratory no later than 24 hours after collection.*** Newborn Screening Program staff are available to consult with institutions about improving shipping time. Please contact the program with any questions or concerns about timing of shipping and delivery. Additionally, newborn screening specimens should never be placed in the same container as other specimen types traveling to the Public Health Laboratory.

Once an infant's specimen arrives at the Public Health Laboratory, staff enters the demographic information listed on the newborn screening card into a secure database. Following data entry, the specimens are ready for screening.

## Blood Spot Screening Tests

The testing performed on newborn blood spots is a high-throughput process; the Minnesota Newborn Screening Program generally screens the blood spots of nearly 70,000 newborns every year. Clinical circumstances such as an ill infant or a positive family history for a disorder on the newborn screening panel may prompt a provider to request that blood spot screening tests be run "stat." Although the testing itself cannot be expedited, the reporting of results can be expedited by contacting the Newborn Screening Program before or shortly after the blood spots have been sent.



Blood spots are hole-punched to create smaller spots used for each test performed as part of screening.



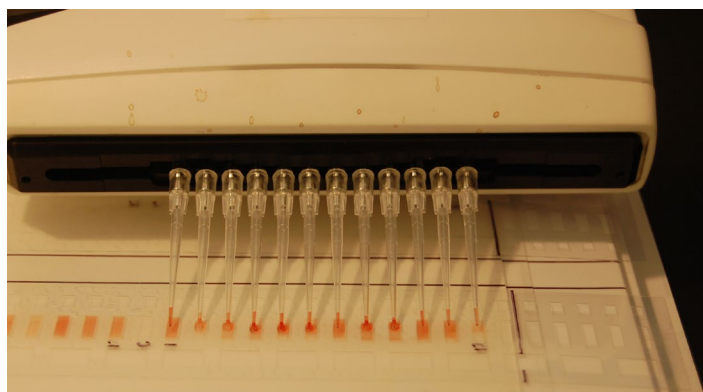
Once the blood spots are received by the laboratory, they are hole-punched to create even smaller blood spots that are used for each test performed as part of screening.

The following tests are performed on the blood spots:

- ▶ **Time-resolved fluoroimmunoassays** are used to test for endocrine disorders and for cystic fibrosis. In Minnesota, they are used to screen infants for congenital adrenal hyperplasia, congenital hypothyroidism, and first-tier testing for cystic fibrosis.
- ▶ If first-tier testing by fluoroimmunoassay for cystic fibrosis shows an elevation of immunoreactive trypsinogen (IRT), then **second-tier molecular (targeted mutation analysis) testing** for cystic fibrosis is performed on the blood spots. The Newborn Screening Program laboratory tests only for the most common mutations known in the cystic fibrosis transmembrane regulator (CFTR) gene.
- ▶ **Fluorometry and photometry** are used to screen infants for galactosemia by determining the total galactose and galactose-1-phosphate uridylyltransferase (GALT) activity in the blood spots. Fluorometry is also used to screen for biotinidase deficiency by measuring the level of biotinidase enzyme activity in the blood spots.
- ▶ **Isoelectric focusing and high-performance liquid chromatography** are performed to identify newborns with hemoglobinopathies.
- ▶ **Real-time quantitative polymerase chain reaction (qPCR)** is used to screen infants for severe combined immunodeficiency (SCID) and other primary T-cell lymphopenias.
- ▶ **Tandem mass spectrometry (MS/MS)** allows for screening of multiple metabolic disorders with a single test. In newborn screening, MS/MS is used to test infants for amino acid disorders by analyzing the amino acids present in the blood spots. It also analyzes acylcarnitines present in the blood spots to test for organic acid disorders and fatty acid oxidation disorders. Minnesota's Newborn Screening Program contracts with PerkinElmer Genetics to perform MS/MS screening.



A staff member prepares primers and probes into a master mix solution to amplify DNA and look for mutations in the CFTR gene.



Eluted hemoglobin is dispensed onto a gel for isoelectric focusing to help identify potential hemoglobinopathies.



Extracted DNA from dried blood spots is prepared for molecular SCID testing.

## RESULTS

When testing is complete, results are entered into the secure database and a newborn screening report is sent to the individual or facility who submitted the specimen; typically within three to seven days of birth. The following paragraphs provide a brief explanation of results that may appear on an infant's newborn screening report:

### Negative

A "negative" result means that the screen was normal for that particular disorder and no additional follow-up is required.

**Note:** Newborn screening is not diagnostic testing; false negative results may occur. Should a child display symptoms of a disorder for which the screen was negative, evaluate the child immediately. Newborn screening should not replace diagnostic testing in any circumstances. If the child is found to be affected, please contact the Newborn Screening Program regarding the false negative result.



Excess blood on the filter paper or blood applied to both sides of the paper are frequent causes of unsatisfactory results.



An insufficient quantity of blood on the filter paper does not allow for complete and accurate testing and is a common cause of unsatisfactory results.



If the specimen appears scratched or abraded because blood was applied with capillary tube, results will be marked as unsatisfactory and a repeat specimen will be requested.

### Unsatisfactory

An "unsatisfactory" result means that screening results cannot be accurately interpreted because of a problem with blood spot collection, inaccurate information on the newborn screening card, or a problem with the infant's age.

Most unsatisfactory results occur because of problems with blood spot collection, such as blood collected on an expired card, blood spots that reach the laboratory more than 14 days after collection, or poor quality blood spots. The [Simple Spot Check](#) document on the program website provides a complete description of possible reasons why a blood spot may be considered invalid. If an infant's blood spots are deemed unsatisfactory, Newborn Screening Program staff will call the original submitter and request the collection of another specimen. The collection of a subsequent specimen is required unless the parent refuses in writing.

Another reason laboratory staff may not be able to accurately interpret results involves the infant's age. Some of the newborn screening tests have age cut-offs,

meaning results cannot be accurately interpreted if a child does not meet the minimum age requirement or exceeds the maximum age for that particular disorder. For example, if an infant is less than 24 hours of age when the specimen was collected, results will not be valid for amino acidemias, fatty acid oxidation disorders, organic acidemias, and endocrinopathies. If a specimen was collected when the infant was less than 24 hours of age, a repeat specimen will be requested.

On the other hand, test results for cystic fibrosis and severe combined immune deficiency cannot be accurately interpreted when the infant exceeds the maximum age for those disorders (two months and 12 months, respectively). In this case, results will be documented on the newborn screening report as unsatisfactory and no additional specimens will be requested. If a previous specimen was negative, no further testing is required. However, if the child was not previously screened, the child should be regarded as unscreened for the disorder and the clinician should monitor the child for clinical symptoms.



## Inconclusive

An “inconclusive” result means that a specific amino acid or acylcarnitine profile was detected that can be produced if the infant was given supplemental intravenous nutrition. The report will ask for collection of a repeat specimen.

## Pending

A “pending” result means that screening is in progress, but a preliminary report has been released to the infant’s provider to facilitate follow-up for any abnormal or positive results. A final report will be sent to the submitting facility/provider once all tests have been completed. If a mailed report indicates that a result is still pending, please contact the Newborn Screening Program.

## A>F

An “A>F” result means that there was more adult (“A”) hemoglobin than fetal (“F”) hemoglobin identified in the infant’s blood spots. The source of this result affects how the result should be interpreted by the provider.

One possible reason for an A>F result is a transfusion prior to blood spot collection. If an infant receives donor blood prior to blood spot collection, some screening tests may reflect the status of the adult donor rather than the infant. Collecting a specimen too soon after a transfusion can affect the result interpretation for the following conditions: galactosemia, hemoglobinopathies, biotinidase deficiency, severe combined immune deficiency, and cystic fibrosis. If the infant demonstrates symptoms of any of these conditions, evaluation and consultation with the appropriate specialists should occur.

Another possible reason for an A>F result is that the infant’s fetal hemoglobin made the normal, biological switch to adult hemoglobin prior to blood spot collection. If the infant was not transfused, the result should be interpreted as negative/normal for all conditions listed as A>F and no further testing is required.

## Borderline

A “borderline” result means test results were between normal and abnormal. In these circumstances, Newborn Screening Program staff will call and request a subsequent specimen or follow-up labs. If the subsequent specimen remains borderline or becomes a positive result, Newborn Screening Program staff will contact the infant’s care provider and recommend diagnostic evaluation.

## Trait

A “trait” result indicates that the infant is likely a carrier of a particular hemoglobinopathy. If additional testing is necessary, it will be indicated on the newborn screening report. Even though the Newborn Screening Program does not directly contact the infant’s care provider with this result, the provider should discuss the result with the infant’s parents.

## Abnormal

“Abnormal” results appear on the newborn screening report for hemoglobinopathies. If an infant receives an abnormal result, Newborn Screening Program staff will contact the infant’s care provider to discuss the abnormal result and fax the information needed to notify the parents and properly follow-up on the result (refer to pages 20-21). Newborn Screening Program staff can also connect the provider to medical specialists experienced in diagnosing and treating children with hemoglobinopathies.

## Positive

All “positive” results require follow-up diagnostic testing with the exception of some positive results for newborns in the Neonatal Intensive Care Unit (NICU). Depending on the NICU infant’s condition and the disorder, Newborn Screening Program staff may request a repeat specimen prior to pursuing follow-up diagnostic testing.

In the event of a positive result, Newborn Screening Program staff will contact the infant’s care provider to discuss the result and fax the information needed to notify the parents and properly follow-up on the result (refer to pages 20-21). Newborn Screening Program staff can also connect the provider to medical specialists experienced in diagnosing and treating children with the particular disorder.

**Note:** Because newborn screening is not diagnostic testing, children may receive an abnormal or positive result but later be found to be unaffected by the disorder. Although false positives do occur, it is crucial that these results receive attention and appropriate follow-up in a timely manner. Like all screening tests, newborn screening inherently generates false positive results in order to avoid missing affected infants.

## THE NEWBORN SCREENING PROGRAM PROCESS FOR COMMUNICATING RESULTS

If an infant receives results that do not require immediate clinical follow-up, the Newborn Screening Program staff will not call the infant's care provider. The final newborn screen report will be mailed to the individual or facility who submitted the specimen.

If an infant receives a result requiring immediate clinical follow-up, Newborn Screening Program staff will contact the infant's care provider to explain the results and necessary follow-up steps. Accurate documentation on the newborn screening card of the provider or clinic where the newborn will receive care is vital to the notification process; for certain disorders, irreversible health consequences may occur within days of birth if the affected infant does not receive medical attention. Newborn Screening Program staff *rarely* calls parents to notify them of the newborn screening results. Only in emergent situations when the infant's provider cannot be determined will staff call parents.

***For certain disorders, irreversible health consequences may occur within days of birth if the affected infant does not receive medical attention.***

Newborn Screening Program staff understands that it can be unsettling for providers to receive abnormal or positive results for unfamiliar disorders for infants who appear to be in good health. However, the role of newborn screening is to identify affected infants *before they become symptomatic* so that serious – and sometimes irreversible – health consequences can be avoided. In the notification call to the infant's care provider, Newborn Screening Program staff will include an explanation of the screening result and specialists available for consult. Additionally, Newborn Screening Program staff will fax information to the clinic immediately following the notification call. The fax generally includes the newborn screening report with recommended follow-up, a "Provider Fact Sheet" on the disorder for the provider's reference, contact information for specialists with expertise for that particular disorder, a

## Positive/Abnormal Results:

**The Newborn Screening Program will contact providers in three ways:**

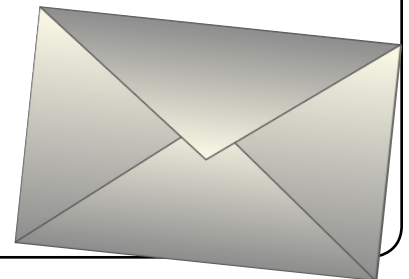
**1**  
Call the infant's care provider to explain abnormal/positive results and recommended follow-up steps



**2**  
Fax information to primary care clinic including: screening report, medical and family fact sheets on the disorder, and contact information of specialists

**3**  
Mail the final screening report to the provider or facility who submitted the specimen.

**Note:** Final screening reports are mailed to submitters for all newborn screens, regardless of screening results.



“Family Fact Sheet” explaining the disorder, and a form for the care provider to fax back to the Newborn Screening Program confirming that the report was received and that follow-up evaluation has begun.

Newborn Screening Program staff members and genetic counselors are available to address any questions or concerns the parent or provider may have throughout the newborn screening and follow-up process.

*Timely follow-up, thorough documentation, and effective communication between the Newborn Screening Program, providers, specialists, and families are key steps in the newborn screening process.*

## **FOLLOW-UP/DOCUMENTATION**

Timely follow-up, thorough documentation, and effective communication between the Newborn Screening Program, providers, specialists, and families are key steps in the newborn screening process.

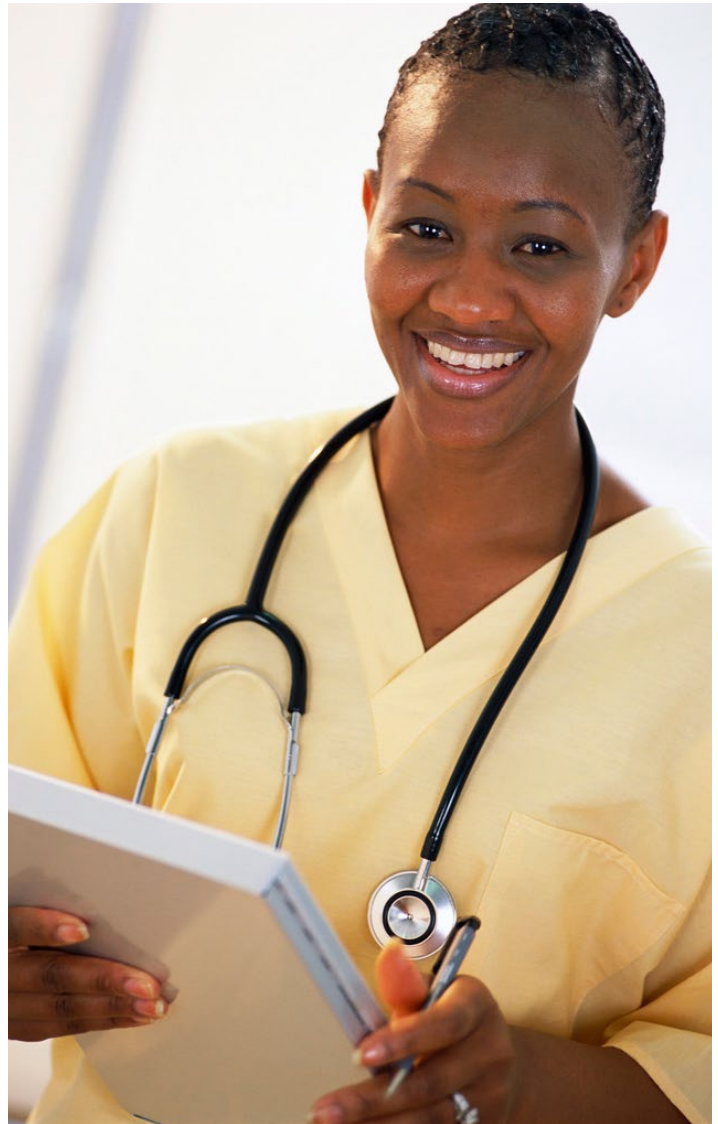
### **Primary Care Provider Follow-up**

In cases of positive or abnormal results requiring clinical follow-up, providers should contact specialists for guidance when needed. Newborn Screening Program staff will fax providers the contact information of specialists who have indicated their willingness to provide consultation. Consulting with a specialist before clinical testing begins will help target the evaluation process and identify those infants that are truly affected by the disorder, while excluding false positive results.

Because Newborn Screening Program staff does not contact parents regarding their infant’s newborn screen results, providers should share the results with the family. Providers are encouraged to give parents the “Family Fact Sheet” that is included in the packet of faxed information from Newborn Screening Program staff. This information sheet is designed to explain to the family what a positive newborn screen means, to emphasize the need for follow-up testing, and to provide a brief description of the disorder. If the diagnosis is confirmed, more in-depth information should be shared with the family.

Newborn Screening Program staff follows up with providers on all positive and abnormal results requiring clinical-follow-up to confirm that screening recommendations were followed and to track whether the result was confirmed or was found to be a false positive. Providers should complete the “Fax Back Form” as soon as possible and fax it to the Newborn Screening Program to facilitate the follow-up process.

Primary care providers have multiple resources available to



Because Newborn Screening Program staff does not contact parents regarding their infant’s newborn screen results, providers should share the results with the family.



support their infant patients with a confirmed disorder on the newborn screening panel. The MDH Children and Youth with Special Health Needs (CYSHN) program provides long-term follow-up services, including connecting families to services that may improve health and development outcomes for the infant or child. In addition, parent organizations, such as PACER's Family-to-Family Health Information Center, Family Voices of Minnesota, and disorder-specific organizations, can provide ongoing social and emotional support to families as they explore educational and medical options for their child.

## Newborn Screening Program Documentation

Once all screening tests and provider notifications are complete, a final report will be mailed to the individual or facility who submitted the specimen. All reports are mailed from the Newborn Screening Program and are generally received by the submitter between 10 and 14 days after the specimen was collected. If a report does not arrive when expected, contact Newborn Screening Program staff by phone, fax, or email. Staff will check to see if the specimen was received and processed. If the specimen was received and screening is complete, results will be mailed or faxed upon request. If the specimen was

not received, a repeat specimen will be requested.

## Discharging Facility/Out-of-Hospital Birth Provider Documentation

Final reports, once received, should be filed in the infant's medical record and a copy should be sent to the infant's primary care provider. For facilities who share an electronic medical record system, providers may scan the newborn screening report into the system to satisfy this requirement. Simply indicating in the infant's medical record that the newborn screen was abnormal or positive is not sufficient; the full report should always be readily accessible.

***The newborn screening report—regardless of screening results—must always be sent to the infant's primary care provider as soon as possible to enable timely follow-up.***





# 5

## Hearing Screening

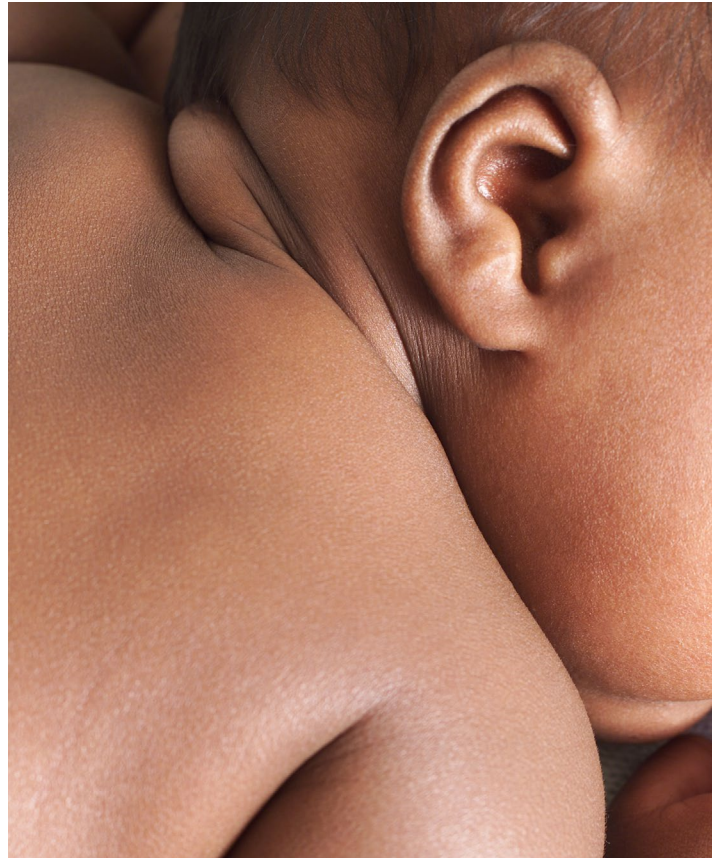
All Minnesota newborns should have their hearing screened prior to hospital discharge or at no later than one month of age unless parents decline in writing. Providers caring for newborns are expected to educate parents about newborn hearing screening and to report hearing screening results to the family, primary care provider, and to the Newborn Screening Program.

### WHY IS HEARING SCREENING IMPORTANT?

Hearing loss is one of the most common birth defects in the United States. In Minnesota alone, approximately one in 300 newborns is born with a hearing loss that can be identified through newborn hearing screening.

Without early detection and intervention, children with hearing loss often fall behind in speech and language, academics, and social and emotional development. Infants with hearing loss may startle to loud sounds and even appear to hear; therefore, hearing loss is often not evident to parents or providers without objective testing. Identifying infants with hearing loss and offering intervention early can make a significant difference in language and development. Early intervention, regardless of the communication option chosen (i.e., oral, sign, or bimodal), has proven successful in improving a child's ability to access language.

National standards recommend that hearing screening for all infants should be complete by one month of age, hearing loss should be clinically diagnosed at no later than three months of age, and intervention should be initiated by six months of age. When screening, diagnosis,



and intervention meet these goals, children with hearing loss can often develop on track with their hearing peers.

For a detailed description of the location, type, degree, and risk factors associated with hearing loss, refer to Appendix A. Some types of hearing loss, if identified early, can be successfully addressed medically or surgically.

## HEARING SCREENING PROCESS

The Newborn Screening Program adheres to hearing screening guidelines developed by local experts and based on nationally accepted guidelines put forth by the Joint Committee on Infant Hearing (JCIH). These best practice guidelines have been tailored to fit Minnesota's system of care to help ensure that every infant receives quality screening and follow-up throughout the state.

Refer to the Minnesota Early Hearing Detection and Intervention (EHDI) program [Guidelines for the Organization and Administration of Universal Newborn Hearing Screening Programs in the Well-Baby Nursery](#).

## Personnel Performing Hearing Screening

Newborn hearing screening can be performed by volunteers, nurses, midwives, audiological technicians, audiologists, and other trained personnel.

Initial training for those who perform newborn hearing screenings, as well as refresher trainings and periodic monitoring of staff performance, are essential to ensuring quality screening. A [sample competency checklist](#) has been created that can help assess staff performance and identify areas for improvement. Studies have shown that ongoing experience with screening is an important factor in maintaining low and accurate REFER rates in hearing screening. Therefore, the Newborn Screening Program recommends designating specific staff members to conduct hearing screens for all newborns at a given facility. A trained screener should be available at all times to ensure that every newborn is screened.

For infants born outside of a birthing hospital, there are several options available to ensure that newborn hearing screening is performed before one month of age. There are many midwives throughout the state of Minnesota with access to screening equipment who have been trained by Newborn Screening Program audiologists to perform newborn hearing screening. The [Minnesota Council of Certified Professional Midwives \(MCCPM\)](#), for

example, has distributed hearing screening equipment to trained members practicing across the state to screen newborns for hearing loss. MCCPM members also offer newborn hearing screening to families who are not clients in their practice. Visit the [Hearing Screening for Out-of-Hospital Births](#) page on the Newborn Screening website for the current list of Midwives Offering Newborn Hearing Screening.

Midwives who do not have access to screening equipment should educate parents about newborn hearing screening and set up a hearing screening appointment with another provider before one month of age. Midwives who refer families to other providers for hearing screenings are encouraged to fill out the [Notification of Newborn Hearing Screening Appointment](#) form and fax or mail it to the Newborn Screening Program.

## Filling Out and Handling Screening Cards

Accurate patient information is crucial for timely follow-up. For a detailed explanation of the newborn screening card and how to complete the demographic fields, please refer to pages 12-13.

The form is a rectangular card with various fields for data entry. At the top, there are fields for 'City' and 'Zip Code'. Below these are fields for 'State' and 'Mother's Phone Number'. A section labeled 'After Discharge' contains a date field. To the right of this is a box titled 'HEARING SCREENING' which includes a 'Final Screen Date' field, checkboxes for 'Right Ear' (Pass/Refer) and 'Left Ear' (Pass/Refer), and a 'Screening Method' section with checkboxes for 'ABR' and 'OAE'. At the bottom left, there are fields for 'Submitter City' and 'Submitter #'. A 'Notes' section is located at the bottom right.

All demographic information requested on the newborn screening card should be completed before submission.

## Timing of Hearing Screening

For hospital births, the staff members who discharge the newborn home are responsible for ensuring that a newborn hearing screening is complete. Initial hearing screening is best performed after 12 hours of age but at no later than one month of age. Although screening can be done before 12 hours of age, very early testing is more likely to yield a false positive result, depending on the equipment used.

**Initial screening is best performed after**

**12 hrs**  
**of age, and should be complete**  
**at no later than**  
**1 month**  
**of age.**

Special circumstances may arise that affect the timing of newborn hearing screening:

- If an infant never received newborn hearing screening, the screening should be scheduled and performed as soon as possible but at no later than one month of age.
  - If an infant is to be transferred to a different hospital, unit, or state, conduct the newborn hearing screening before transfer, if possible, and communicate the results with the receiving facility. If newborn hearing screening cannot occur before the transfer but a blood spot specimen has been collected, note the infant's transfer status and location on the newborn screening card. If a blood spot specimen has not been collected, alert the receiving facility of the need to perform newborn screening and notify the Newborn Screening Program of the infant's transfer using the [Hearing Screening Form for Transferred Infants](#). The transferring hospital/unit should also provide this form to the receiving facility. If the infant was transferred from another hospital/unit or state and the infant's screening status cannot be determined, initiate screening as soon as possible.
  - If an infant is sick, premature, or in the NICU or special care nursery and is expected to remain in the hospital for a prolonged period of time, screening should be performed prior to three months corrected age or when medically feasible. Refer to pages 44-46 for more information on screening in the NICU.
- If an infant/child was adopted and it is unclear whether or not newborn hearing screening was performed, the child should receive a hearing screen regardless of age.

## Hearing Screening Technologies

Newborn hearing screening must be performed using objective physiological screening methods that do not require behavioral responses from the infant. Otoacoustic emissions (OAE) and automated auditory brainstem response (AABR) are the two types of technology proven to be effective in screening for hearing loss in newborns. Each has its advantages and disadvantages. Either technology, or a combination of the two, is considered appropriate for screening. The following paragraphs provide a brief description of these two tests. Refer to the [Newborn Hearing Screening Technologies](#) sheet for more information.

OAE equipment (pictured below) measures the sound the cochlea produces in response to external stimuli. There are two types of OAEs: transient and distortion product. Transient OAEs emit sound in the frequency range found in speech. Distortion product OAEs emit sound in specific frequency ranges. Refer to the [Newborn Hearing Screening: OAE Testing Steps](#) for screening instructions.

***Newborn hearing screening must be performed using objective physiological screening methods that do not require behavioral responses from the infant.***



Otoacoustic emissions (OAE) equipment measures the sound the cochlea produces in response to external stimuli.





Automated auditory brainstem response (ABR) equipment measures electrical currents that are generated by the brain when the auditory system is excited by a stimulus.

ABR equipment (pictured above) measures electrical currents that are generated when the auditory system is excited by a stimulus. A computer records the infant's brainwave activity and indicates whether the auditory system is appropriately responding to sound. Refer to [Screening ABR Tips & Tricks](#) for instructions on how to use ABR technology.

Circumstances may arise, such as a lack of supplies or an equipment failure, which affect the ability to conduct a hearing screen. To avoid these situations, the Newborn Screening Program recommends that facilities maintain a generous supply of required disposable supplies and have a protocol in place for checking and re-ordering supplies. All practices/facilities should also have a written protocol for screeners to follow in case of equipment malfunction. If a newborn hearing screening is not performed or "missed," the infant must return for screening or be scheduled to have a screening performed elsewhere as soon as possible.

## Hearing Screening Policies and Procedures

Accurate hearing screening and result communication is vital to the Newborn Screening Program. If hearing screening is not performed correctly, or if the results of the hearing screening do not reach the Newborn Screening Program in a timely manner, the period of time before diagnosis may be prolonged, delaying the initiation of critical intervention services.

Every nursery and out-of-hospital birth provider performing newborn hearing screening should have a written policy and procedure for staff to follow when screening infants for hearing loss. For sample policies and procedures, contact the Newborn Screening Program.

### *Screening Protocol for the Well-Baby Nursery and Out-of-Hospital Births*

Prior to performing a hearing screen, providers should:

- ☒ give parents information about newborn hearing screening;
- ☒ enter the infant's information into a tracking and management system.

If an infant is born with a missing or anomalous ear or some other obvious abnormality of one or both ears, no screening is necessary and the infant should be referred directly for full audiological evaluation. Providers should indicate a REFER result on the newborn screening card for the anomalous ear(s) and write the type of anomaly in the "Notes" section, if known.

Newborn hearing screening is best performed when the infant is asleep, well-fed, and comfortable. It should take place in a quiet environment away from conversation, fans, loudspeakers, and other sources of noise.

Screeners should follow infection control procedures and prepare the newborn for hearing screening using the step-by-step instructions included with the screening equipment. These instructions should be kept with the screening equipment at all times and should be easily accessible for reference as needed.

Once these preparations have been made, the infant is ready to be screened. Both ears should be screened. If the infant does not pass in both ears, the infant's hearing should be screened again immediately. If the infant passes this initial screen, the results should be documented and communicated appropriately to the parents, the infant's primary care provider, and the Newborn Screening Program (refer to pages 29-31). If the infant does not pass the initial screen, the infant should be rescreened at a later time.

For hospital births, the rescreen should be performed before discharge. For out-of-hospital births, the rescreen should be performed at no later than two weeks



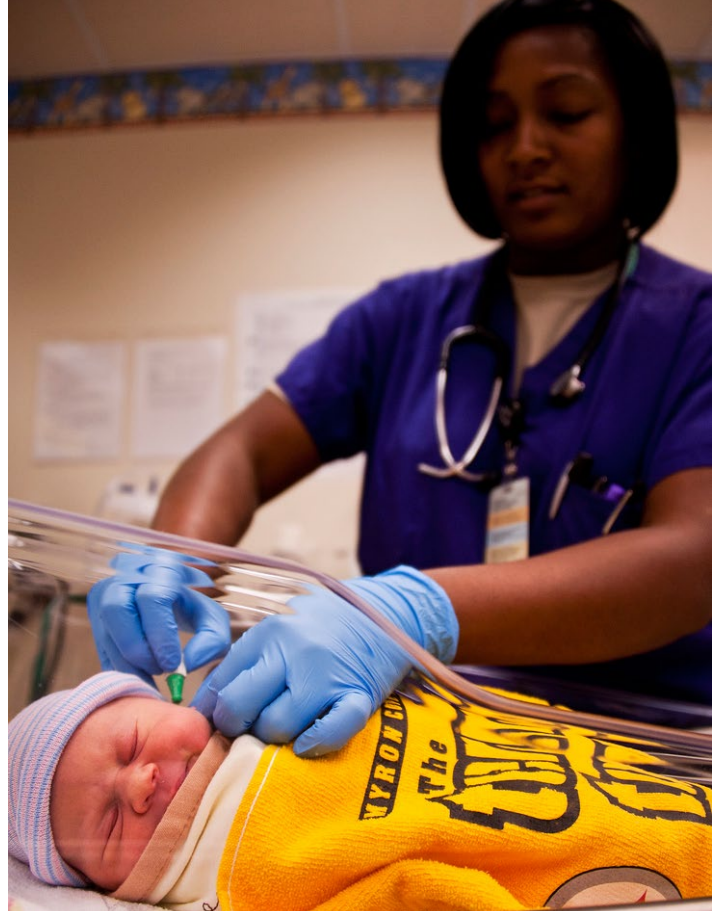


*Newborn hearing screening is best performed when the infant is asleep, well-fed, and comfortable.*

postpartum. During the rescreen, both ears should once again be checked for hearing loss regardless of past results. If the infant passes this final rescreen in both ears, no further testing is needed. If the infant does not pass the final screen in both ears, an appointment for outpatient rescreening or audiological evaluation should be scheduled for the family. Outpatient rescreening should take place at no later than two weeks of life. If the infant is referred directly for a diagnostic audiological evaluation, this appointment should take place at no later than six weeks of life. No infant should undergo more than three screens before one of these follow-up appointments is scheduled.

The results of the final screen (whether PASS or REFER) and any scheduled follow-up arrangements should be documented and communicated appropriately to the parents, the infant's primary care provider, and the Newborn Screening Program (refer to pages 29-31).

Refer to the [Newborn Hearing Screening Flowchart for the Well-Baby Nursery](#) and the [Newborn Hearing Screening Flowchart for Out-of-Hospital Births](#) for visual representations of this process.



For OAE testing, probe fit is the most important step. A good probe fit ensures a strong signal is sent to the infant's ear and reduces the chance of a false positive result.



For OAE testing, use firm pressure to insert the probe into the ear far enough to obtain a good seal. Twisting the probe slightly can help ensure a tight fit.

## Protocol for Outpatient Rescreening

Prior to performing a hearing rescreen, providers should:

- ☒ give parents information about newborn hearing screening;
- ☒ enter the infant's information into a tracking and management system.

Hearing screening is best performed when the infant is asleep, well-fed, and comfortable. It should take place in a quiet environment away from conversation, fans, loudspeakers, and other sources of noise.

Screeners should follow infection control procedures and prepare the newborn for hearing screening using the step-by-step instructions included with the screening equipment. These instructions should be kept with the screening equipment at all times and should be easily accessible for reference as needed.

*Both ears should be rescreened regardless of previous results.* If the infant passes the rescreen in both ears, the results should be documented and communicated appropriately to the parents, the infant's primary care provider, and the Newborn Screening Program (refer to pages 29-31). If the infant does not pass in both ears, further testing is necessary and an appointment for a diagnostic audiological evaluation should be scheduled as soon as possible. The Newborn Screening Program recommends that providers schedule the appointment to encourage timely follow-up and share the [Preparing for Your Baby's Audiology Visit](#) form with families. The hospital outpatient results indicating that the child did not pass and any follow-up arrangements should be documented and communicated appropriately to the parents, the infant's primary care provider, and the Newborn Screening Program (refer to pages 29-31).

*If the infant/family does not attend the outpatient rescreen appointment, call the parents to reschedule before one month of age.*

If the infant/family does not attend the outpatient rescreen appointment, call the parents to reschedule before one month of age. If the infant is older than one month of age, refer to and schedule an appointment for them with audiology. If the infant is scheduled to be seen at his/her primary care clinic or audiology site for rescreening, it becomes the responsibility of the primary care provider to reschedule the appointment. Timely follow-up is important so that the audiological evaluation can be performed without sedation. Sedation may be necessary to help older infants sleep throughout the complete hearing evaluation.

## RESULTS

Infants screened for hearing loss receive either a PASS, Incomplete/Inconclusive, or REFER result. PASS/REFER criteria vary by equipment manufacturer and should be reviewed by a consulting audiologist or a Newborn Screening Program audiologist to ensure the criteria are appropriate. Adjustments may need to be made to the equipment by an audiologist in order for it to comply with clinically accepted national practices. The following paragraphs explain possible results and the immediate follow-up needed for each.

### PASS

Newborn hearing screening indicated that the infant exhibited normal hearing function in both ears. Document the result in the hearing screening tracking and management system and in the infant's medical record.

Hearing loss can occur at any time throughout a person's life. Refer to the [Hearing and Speech Milestones](#) document for typical hearing and speech behaviors. Should a child display symptoms of hearing loss or a parent express concerns about their child's hearing, the child should be evaluated immediately by the primary care provider.

### Incomplete/Inconclusive

Newborn hearing screening did not yield a PASS or REFER result. An incomplete/inconclusive result can happen for several reasons, including too much background noise, excess myogenic activity, debris in the ear canal, testing errors, or an uncooperative infant. Document the result in the hearing screening tracking and management system and in the infant's medical record, and arrange for the infant to have another screen at a later time. If incomplete/inconclusive again, document the result in

the hearing screening tracking and management system and arrange for a rescreen at a later time but at no later than two weeks of age.

## REFER

Newborn hearing screening indicated that the infant is at risk for hearing loss and requires follow-up. Document the result in the hearing screening tracking and management system and in the infant's medical record and make appropriate arrangements according to the policies and procedures described on pages 26-28.

Because newborn hearing screening is not a diagnostic test, children may receive a REFER result but later be found to have normal hearing. Although false positives occur, it is crucial that all REFER results receive attention and appropriate follow-up in a timely manner. Like all screening tests, newborn hearing screening inherently generates false positive results in order to avoid missing infants with a hearing loss.

Providers should inform parents of screening results the

**same day** of screening.

## To Parents

Providers are encouraged to inform the infant's parents of the hearing screening results the same day the screen takes place. This information should be provided to them both verbally and in writing. Refer to the [Communicating "REFER" or "DID NOT PASS" Results to Families](#) sheet for sample messages. The Newborn Screening Program has also created [PASS Result: Hearing Screen Result Notification](#) and [REFER Result: Hearing Screen Result Notification](#) sheets to assist providers in communicating hearing screening results to families. These forms have been translated into Hmong, Karen, Russian, Somali, and Spanish and are available on the [Newborn Screening Program website](#).

If the infant receives a PASS result, the family should be informed that the infant passed his or her newborn hearing screening, but that changes in hearing can occur at any time. Encourage them to contact their infant's primary care provider should concerns arise.

If an infant receives an incomplete/inconclusive or REFER result in one or both ears, a plan for follow-up needs to be arranged and effectively communicated to the parents. The discussion should include verifying the infant's primary care provider, the reason the infant needs to be referred, and the importance of timely follow-up. Assist the family in scheduling the necessary follow-up appointment as soon as possible and encourage the family to discuss hearing results with the infant's primary care provider at the first appointment.

## PASS Result Notification REFER Result Notification

**PASS Result:**  
Hearing Screen Result Notification

Your baby **passed** the hearing screen.  
Please bring this sheet to your baby's primary care provider at your first well-child visit.

ATTN: Primary Care Provider: \_\_\_\_\_  
Clinic: \_\_\_\_\_

Baby's Name: \_\_\_\_\_  
Baby's Date of Birth: \_\_\_\_\_  
Hospital/Birth Site: \_\_\_\_\_  
Date of Last Hearing Screen: \_\_\_\_\_

Right Ear: ☐ PASS Left Ear: ☐ PASS

It is unlikely that your baby has hearing loss at this time. However, here are a few things to keep in mind!

- 1 Your baby passed the hearing screen, but it is important to be aware that there can be changes in hearing at any time throughout childhood.
- 2 Speech and language begin to develop at birth, even though babies don't usually talk until about one year of age. Identifying hearing loss early is important to make sure babies have the interventions and support they need for healthy development.
- 3 If you think your baby is not hearing well in the future, contact your doctor or primary care provider. The information on the other side of this sheet will help you know how to watch your baby's hearing and speech behaviors for progress.

Minnesota Screening Program (MSP) Contact Us: 1-800-644-7772, Fax (651) 215-6285  
Minnesota Early Hearing Detection and Intervention (EHDI) website: [www.mnearlyehdi.org/mn](http://www.mnearlyehdi.org/mn)

**REFER Result:**  
Hearing Screen Result Notification

Your baby **did not pass** the hearing screen.  
This means that your baby needs further testing to make sure he or she is hearing everything well. Please bring this sheet to your baby's primary care provider at your first well-child visit.

ATTN: Primary Care Provider: \_\_\_\_\_  
Clinic: \_\_\_\_\_

Baby's Name: \_\_\_\_\_  
Baby's Date of Birth: \_\_\_\_\_  
Hospital/Birth Site: \_\_\_\_\_  
Date of Last Hearing Screen: \_\_\_\_\_

Right Ear: ☐ PASS ☐ REFER Left Ear: ☐ PASS ☐ REFER

An appointment for hearing follow-up testing/rescreening was made.  
Date and time: \_\_\_\_\_  
Location: \_\_\_\_\_

**Next steps:**

- 1 Attend the follow-up appointment listed above. If you are unable to attend or if there is no appointment listed above, talk with your provider about making alternative arrangements—ideally within 2 to 4 weeks of birth (or as medically feasible for NICU graduates).
- 2 Bring this result notification with you to your baby's first clinic visit and discuss it with your baby's primary care provider. If no follow-up appointment has been scheduled at this time, your baby's provider can help you schedule an appointment with an audiologist.
- 3 Make sure to ask both your primary care provider and audiologist any questions you may have about your baby's hearing. The sooner hearing loss is identified, the sooner babies with hearing loss can receive help and begin developing critical speech and language skills.

Minnesota Screening Program (MSP) Contact Us: 1-800-644-7772, Fax (651) 215-6285  
Minnesota Early Hearing Detection and Intervention (EHDI) website: [www.mnearlyehdi.org/mn](http://www.mnearlyehdi.org/mn)

Hearing Result Notification sheets should be given to parents immediately following screening.

## COMMUNICATING RESULTS

In accordance with Minnesota statute, all newborn hearing screening and follow-up results should be conveyed to the newborn's parents, the infant's primary care provider, and the Newborn Screening Program.



Within

**10 days**  
of screening,

**results and scheduled follow-up  
arrangements should be communicated to:**

- 1. The infant's primary care provider**
- 2. The Newborn Screening Program**

## To the Primary Care Provider

Final results from the newborn hearing screen and any scheduled follow-up arrangements should be communicated in writing to the infant's primary care provider within 10 days of screening. Newborn hearing screening final results can be sent using the same [Hearing PASS Sheet](#) or [Hearing REFER Sheet](#) that was given to the infant's parents. Alternatively, results stored in the infant's medical record can be faxed or sent electronically to the primary care provider.

## To the Newborn Screening Program

Minnesota law requires that final results from the initial newborn hearing screen (regardless of test outcome) and any rescreening results be sent to the Newborn Screening Program. For all infants with REFER results requiring further testing, the Newborn Screening Program should be notified when and where follow-up testing will take place. Hearing screening results and follow-up plans should be communicated to the Newborn Screening Program within 10 days of screening.

The newborn screening cards used for blood spot collection are also designed to facilitate the reporting of hearing screening results to the Newborn Screening Program. Because the blood spots are used to screen for disorders that can be serious or even fatal, submission

should never be delayed in order to wait for the newborn hearing screening results.

If hearing screening is complete before the submission of blood spots, send the results to the Newborn Screening Program on the newborn screening card. Simply fill in the area in the lower right-hand corner of the card; there is no need to detach the "Hearing Screening Copy" in this situation.

If hearing screening is not complete until after the submission of blood spots, but the "Hearing Screening Copy" from the newborn screening card is still available, send results to the Newborn Screening Program separately on that form. Complete the demographic information according to the [Instructions for Properly Completing Newborn Screening Cards](#), fill in the results, and send the form to the Newborn Screening Program using the same courier or transport service used for sending blood spots.

Mailing Address:  
Newborn Screening Program  
P.O. Box 64899  
St. Paul, MN 55164

If hearing screening is not complete until after the submission of blood spots, and the "Hearing Screening Copy" from the newborn screening card is not available, there is no need to use an additional newborn screening card. The hearing screening results can be faxed to the Newborn Screening Program at 651-215-6285 using another form such as a discharge summary or the equipment printout with the complete identifying information of both the infant and the submitter.

When reporting outpatient rescreening results to the Newborn Screening Program, it is best to use the [Hearing Report for the Newborn Screening Program](#) form.

Reporting of hearing screening results will soon be required through the Newborn Screening Program's new electronic reporting system, MNScreen. For information on MNScreen and electronic reporting of results, contact program staff at 651-201-5466.



## FOLLOW-UP/DOCUMENTATION

Timely follow-up, thorough documentation, and effective communication among the Newborn Screening Program, providers, specialists, and families are key steps in the newborn hearing screening process that help facilitate prompt diagnosis, family support, and implementation of early intervention services.

### Discharging Facility and Out-of-Hospital Birth Provider Documentation

All newborn hearing screening results should be documented in a hearing screening tracking and management system and in the infant's medical record. Record keeping is essential for tracking infants who are "missed," who require rescreening, and who may need to return for screening due to equipment failure. The hearing screening tracking and management system should also serve as a tool for tracking staff performance,

for tracking which individuals were notified of the results, and for documenting follow-up plans.

### Primary Care Provider Follow-up

Infants whose final hearing screening result is a PASS do not require follow-up. However, changes in hearing can occur at any time. Primary care providers should continue to monitor hearing and discuss any parental concerns. Providers should notify the Newborn Screening Program as soon as possible if a child of up to 10 years of age develops late-onset permanent hearing loss to ensure that appropriate program evaluation, follow-up, and access to support are achieved.

Infants whose final hearing screen result is a REFER require immediate follow-up. The primary care provider should refer the family to audiology for follow-up as soon as possible. To find an Audiologist near the family, visit the [Minnesota Early Hearing Detection and Intervention \(EHDI\) website](#). Providers are encouraged to share

the [Preparing for Your Baby's Audiology Visit](#) form with families, which outlines what families can expect during the audiology appointment. A diagnostic evaluation should be complete before three months of age. The [Hearing Screening Follow-up Process](#) flowchart illustrates best practice timelines and when referrals are needed.

Primary care providers have multiple resources available to support their infant patients with confirmed hearing loss. The MDH [Children and Youth with Special Health Needs \(CYSHN\)](#) program supports primary care providers by providing just-in-time information regarding recommended care for children who are deaf or hard of hearing. The program also provides families with information about community support and resources. Connecting families as soon as possible to resources such as [Help Me Grow](#) or other early intervention programs is essential. In addition, parent organizations, such as [Minnesota](#)



[Hands & Voices](#) and PACER's Family-to-Family Health Information Center, can provide ongoing social and emotional support to families as they explore educational and medical options for their child.

## Newborn Screening Program Follow-up

The role of the Newborn Screening Program is to ensure that every infant born in Minnesota undergoes a hearing screen and receives appropriate follow-up when necessary.

It is expected that the birth hospital staff or out-of-hospital birth provider send the final hearing screening results to the Newborn Screening Program. However, if Newborn Screening Program staff does not receive a newborn's final hearing screening results *within 14 days of birth*, a staff member will contact the birth hospital or out-of-hospital birth provider to make sure the infant underwent a newborn hearing screen. If the screen was performed, a copy of the results will be requested. If the screen was not performed, Newborn Screening Program staff will contact the infant's primary care provider to request that newborn hearing screening be performed as soon as possible.

When a newborn receives a REFER result on the initial hearing screen and the Newborn Screening Program does not receive rescreen results, a staff member will contact the infant's primary care provider and request a copy of the rescreen results. If the child was never rescreened, Newborn Screening Program staff will make sure that the primary care provider is aware of the REFER result and request that follow-up is initiated as soon as possible.

***The role of the Newborn Screening Program is to ensure that every infant born in Minnesota undergoes a hearing screen and receives appropriate follow-up when necessary.***

When a newborn receives a PASS on the initial hearing screen, the Newborn Screening Program does not provide any additional follow-up. If a child passes their hearing screen(s) but later develops hearing loss, the [CYSHN](#) program is available to provide families with information about community support and resources.



# 6

## Pulse Oximetry Screening

All Minnesota newborns should have pulse oximetry screening. The goal of this screening is to decrease the morbidity and mortality from unrecognized critical congenital heart disease.

### WHY IS PULSE OXIMETRY SCREENING IMPORTANT?

Congenital heart disease is the most common type of birth defect and accounts for nearly 30 percent of infant deaths nationwide. Critical congenital heart disease (CCHD) are those heart defects requiring surgery or catheter intervention within the first year of life. On average, the Minnesota Newborn Screening Program expects to identify at least 125 infants each year with a CCHD.

Without screening shortly after birth, infants with CCHD are sometimes sent home without care because they appear healthy. At home, affected newborns can go into shock, become cyanotic, and often require emergency care. If CCHD is detected early, however, infants can be treated and lead healthier lives.

Newborn screening for CCHD is performed using a pulse oximeter. Pulse oximetry screening targets seven specific anomalies although secondary targets may also be detected. For a definition of the primary and secondary targets of pulse oximetry screening, refer to Appendix B and C.



*Detection of heart problems increases by 25 percent with pulse oximetry screening*



# PULSE OXIMETRY SCREENING PROCESS

The Newborn Screening Program recommends using a slightly modified protocol from the one endorsed by the U.S. Secretary of Health and Human Services and the American Academy of Pediatrics. The updated approach was piloted with Fariview Health System and is currently employed by several states. The modified algorithm has been shown to increase the detection rate of CCHD.

## Personnel Performing Pulse Oximetry Screening

Pulse oximetry screening should be performed by qualified personnel who have been trained in both newborn pulse oximetry monitoring and Minnesota's recommended screening algorithm.

The Newborn Screening Program has multiple resources available that can be used for training screeners, including:

- » [Pulse Oximetry Screening Protocol for CCHD and Tips for Pulse Oximetry Screeners](#)
- » [Dos & Don'ts of Pulse Oximetry Screening](#)
- » Screener Knowledge Assessment (Appendix D)
- » [Newborn Foundation Screening](#) video that the Newborn Foundation made in collaboration with the University of Minnesota Children's Hospital.

Screeners should provide parents with education materials about newborn screening and give them an opportunity to ask questions.

**Fewer than**  
**half**  
**of CCHDs are detected by prenatal ultrasounds.**

## Filling Out and Handling Screening Cards

Accurate patient information is crucial for timely follow-up. For a detailed explanation of the newborn screening card and how to complete the demographic fields, please refer to pages 12-13.

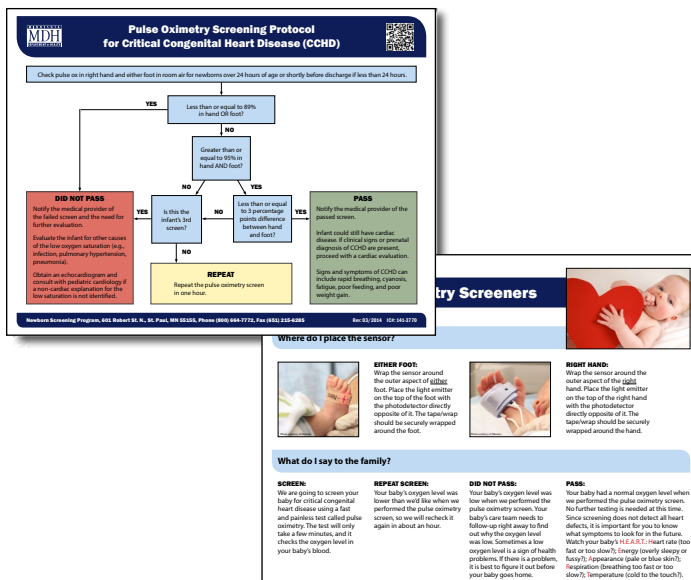
## Timing of Pulse Oximetry Screening

Screening is best performed between 24 and 48 hours of life for healthy term newborns. Earlier screening may produce false positive results due to the newborn's transition from fetal to neonatal circulation and the stabilization of systemic oxygen saturation levels.

Special circumstances may arise that affect the timing of pulse oximetry screening:

- If an infant is going home prior to 24 hours of life, the screening must occur as close as possible to the time of discharge.
- If an infant is premature or in the NICU or special care nursery, screening should be performed when medically feasible. Refer to pages 44-46 for more information on screening in the NICU.

If an infant is symptomatic or appears to have a genetic syndrome with known associated cardiac issues, do not perform the screen. In these situations, immediately refer to pediatric cardiology.





## Pulse Oximetry Screening Equipment

Screening should be performed using a motion tolerant pulse oximeter. A variety of pulse oximeters are available for use with newborns. It is important that the equipment used is compliant with national standards, including:

- » Approval by the Food and Drug Administration (FDA) for use in newborns
- » Validation in low-perfusion conditions and provides accurate readings with movement
- » Two percent root, mean-square accuracy
- » Reporting of functional oxygen saturation

Hospitals should choose a probe recommended by the pulse oximeter manufacturer for use with the device and with newborns. Both disposable and reusable probes with a disposable foam wrap are acceptable for screening.

Circumstances may arise, such as a lack of supplies or an equipment failure, which affect the ability to conduct a pulse oximetry screen. To avoid these situations, the Newborn Screening Program recommends that facilities maintain a generous supply of required supplies and have a protocol in place for checking and re-ordering supplies. All practices/facilities should also have a written protocol for screeners to follow in case of equipment malfunction. If the pulse oximetry screen is not performed (missed), the infant must return for screening or be scheduled to have a screening performed elsewhere as soon as possible.



Photo courtesy of Masimo

Both disposable and reusable probes with a disposable foam wrap are acceptable for screening.

## Pulse Oximetry Screening Policies and Procedures

Accurate pulse oximetry screening and result communication is vital to the Newborn Screening Program. If pulse oximetry screening is not performed correctly, or if the results of the screening do not reach the Newborn Screening Program in a timely manner, the period of time before diagnosis may be prolonged, delaying the initiation of critical intervention services.

Every nursery and out-of-hospital birth provider performing newborn pulse oximetry screening should have a written policy and procedure for staff to follow when screening infants for CCHD.

### *Screening Protocol for the Well-Baby Nursery and Out-of-Hospital Births*

Pulse oximetry screening is best performed when the infant is awake and comfortable. It may be best to screen while the newborn is being held or is lying calm in a bassinet.

Prior to placing the sensor, make sure the skin is warm and dry. The screening should not take place in bright or infrared light. It is acceptable to cover the sensor with a blanket to block the light in order to ensure accuracy.



Pulse oximetry equipment measures the amount of oxygen in the newborn's blood.

Once these preparations have been made, the infant is ready to be screened. A new, clean sensor should be used for each newborn. Oxygen saturation readings should be collected from either foot and the right hand either in parallel or in sequence.

- Either foot - wrap the sensor around the outer aspect of either foot. Place the emitter on the top of the foot with the photodetector directly opposite of it. The tape/wrap should be securely wrapped around the foot.
- Right hand - wrap the sensor around the outer aspect of the right hand. Place the emitter on the top of the right hand with the photodetector directly opposite of it. The tape/wrap should be securely wrapped around the hand.

The [Pulse Oximetry Screening Protocol for Critical Congenital Heart Disease \(CCHD\)](#) should be used to interpret the results.



Photo courtesy of Masimo

## RESULTS

Infants screened receive either a pass, rescreen, or did not pass result. The following sections explain the possible results and the immediate follow-up needed for each.

### Pass

If the infant receives a pass result, no immediate follow-up is needed.

### Rescreen

If the infant needs to be rescreened, repeat the screen an hour after the previous screen was performed. Each newborn can receive up to three screens. If the

infant does not pass on the third attempt, then further evaluation is needed (refer to pages 37-38).

### Did not pass

If the infant receives a non-passing result, further evaluation is needed (refer to pages 37-38).

## COMMUNICATING RESULTS

In accordance with Minnesota statute, all newborn pulse oximetry results should be conveyed to the newborn's parents, the infant's primary care provider, and the Newborn Screening Program.

### To Parents

Providers are encouraged to inform the infant's parents of the pulse oximetry screening results the same day the screen takes place. This information should be provided to them both verbally and in writing. The Newborn Screening Program has created [Pass Result: Pulse Oximetry Screen Result Notification](#) and [Did Not Pass Result: Pulse Oximetry Screen Result Notification](#) sheets to assist providers in communicating the final pulse oximetry screening results to families. These forms have been translated into Hmong, Karen, Russian, Somali, and Spanish and are available on the [Newborn Screening Program website](#).

If the infant receives a pass result, the family should be informed that the infant passed his or her newborn pulse oximetry screening, but that not all cases of CCHD can be detected. Encourage them to contact their infant's primary care provider should concerns arise.

If an infant receives a did not pass result, a plan for follow-up needs to be arranged and effectively communicated to the parents.

### To the Primary Care Provider

Final results from the newborn pulse oximetry screen and any scheduled follow-up arrangements should be communicated in writing to the infant's primary care provider within 10 days of screening. Results stored in the infant's medical record can be faxed or sent electronically to the primary care provider to meet this expectation.

## To the Newborn Screening Program

Minnesota law requires that all pulse oximetry screening results be reported to the Minnesota Department of Health (MDH).

Reporting of pulse oximetry screening results will soon be required through the Newborn Screening Program's new electronic reporting system, MNScreen. Until then, MDH does not have the capacity to receive pulse oximetry screening results but all Minnesota birth facilities should continue screening to comply with Minnesota State Law. For information on MNScreen and electronic reporting of results, contact program staff at 651-201-5466.

## FOLLOW-UP/DOCUMENTATION

Timely follow-up, thorough documentation, and effective communication among the Newborn Screening Program, providers, specialists, and families are key steps in the newborn pulse oximetry screening process that help facilitate prompt diagnosis, family support, and initiation of medical and surgical interventions.

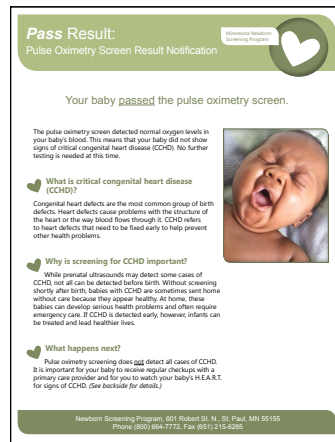
### Discharging Facility and Out-of-Hospital Birth Provider Follow-up/Documentation

For infants whose final pulse oximetry screen is a passing result, notify the parents and medical provider of the passed screen. No immediate follow-up is needed; however, the newborn could still have cardiac disease. Signs and symptoms of CCHD can include rapid breathing, cyanosis, fatigue, poor feeding, and poor weight gain. Encourage parents to contact their infant's primary care provider should concerns arise.

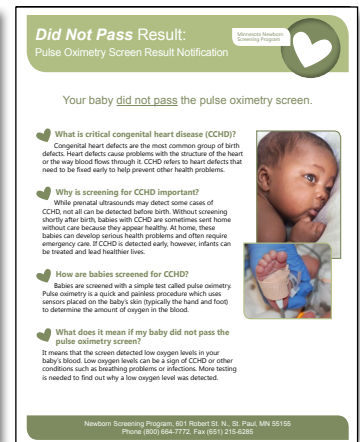
***Infants whose final pulse oximetry screen result is a non-passing result require immediate follow-up.***

For infants whose final pulse oximetry screen is a non-passing result, notify the parents and medical provider of the failed screen. The Newborn Screening Program has created a [Provider Fact Sheet: Did Not Pass Pulse Oximetry Screen](#) sheet that can be given to the provider. Prompt

### Pass



### Did Not Pass



Pulse oximetry result notification sheets should be given to parents immediately following the final screen.

follow-up is vital and evaluation should be initiated immediately and should be resolved prior to discharge.

The newborn should receive a comprehensive evaluation for causes of hypoxemia (e.g., CCHD, infection, pulmonary hypertension, and pneumonia).

If a non-cardiac explanation for hypoxemia is not identified, CCHD must be excluded. A cardiac evaluation may include:

- » Echocardiogram
- » Perfusion check (blood pressure and pulses x4 extremities)
- » Arterial blood gases
- » Electrocardiogram

If the evaluation is of concern for CCHD, the infant should be immediately referred to pediatric cardiology and transferred to a neonatal intensive care unit (NICU). In smaller communities and more rural hospitals, hospital staff may need to discuss with a neonatologist or pediatric cardiologist about transferring the newborn to another facility so that a neonatal echocardiogram can be performed. Depending on the circumstances, additional testing or further observation at the local hospital may be appropriate.

If CCHD is identified, newborns should be followed by pediatric cardiologists. Most infants with CCHD will need surgery or cardiac catheterization; however, the type of treatment recommended will depend on the type of CCHD.



If CCHD is not identified, the newborn should have a sepsis/respiratory evaluation. Sepsis/respiratory evaluation may include:

- » Axillary temperature
- » Blood culture
- » CBC with differential
- » Chest x-ray
- » C-reactive protein
- » Blood glucose
- » Lumbar puncture

All newborn pulse oximetry screening results should be documented in the infant's medical record. Record keeping is essential for tracking infants whose screen is not performed (missed), who require rescreening, and who may need to return for screening due to equipment failure.

---

**When diagnosed early,**

**95%**

**of newborns with heart defects survive and thrive.**

---

## Primary Care Provider Follow-up

If the infant passes the pulse oximetry screen, no follow-up is needed. However, not all cases of CCHD can be detected. Primary care providers should continue to monitor for symptoms of CCHD, which can include rapid breathing, cyanosis, fatigue, poor feeding, and poor weight gain. Failure to detect or late detection of CCHD may lead to significant morbidity or death. Primary care providers should pay attention to and discuss any parental concerns.

If the infant did not pass the pulse oximetry screen, follow-up diagnosis occurs at the hospital. Assist the family in making any necessary follow-up appointments. If the newborn is identified as having a CCHD, a pediatric

cardiologist will develop a unique treatment plan for the infant's particular heart defect. Primary care providers should continue to monitor for symptoms and ensure the infant receives continued follow-up care.

***Approximately 18 per 10,000 live births have CCHD, and the condition affects all ethnic groups.***

Primary care providers have multiple resources available to support their infant patients with a confirmed disorder on the newborn screening panel. The [MDH Children and Youth with Special Health Needs \(CYSHN\)](#) program provides long-term follow-up services, including connecting families to services that may improve health and development outcomes for the infant or child. In addition, parent organizations, such as [Lasting Imprint](#), [Mended Little Hearts](#), [Parents for Heart](#), and [The Children's Heart Foundation](#), can provide ongoing social and emotional support to families as they explore educational and medical options for their child.

## Newborn Screening Program Follow-up

The role of the Newborn Screening Program is to ensure that every infant born in Minnesota undergoes a pulse oximetry screen and receives appropriate follow-up when necessary.

When a newborn receives a pass on the pulse oximetry screen, the Newborn Screening Program does not provide any additional follow-up.

When a newborn receives a rescreen result on the initial or second pulse oximetry screen and the Newborn Screening Program does not receive rescreen results within seven days, a staff member will contact the provider who performed the initial screen or the primary care provider and request that a rescreen be performed.

When a newborn does not pass the pulse oximetry screen, the Newborn Screening Program will work with the screening provider and pediatric cardiology to confirm that screening recommendations were followed and to track the final outcome of the screen.

# 7

## Screening in the Neonatal Intensive Care Unit (NICU)

Premature and sick infants require unique methods and procedures when it comes to newborn screening. The following outlines the protocol for blood spot, hearing, and pulse oximetry screening for newborns in the NICU.

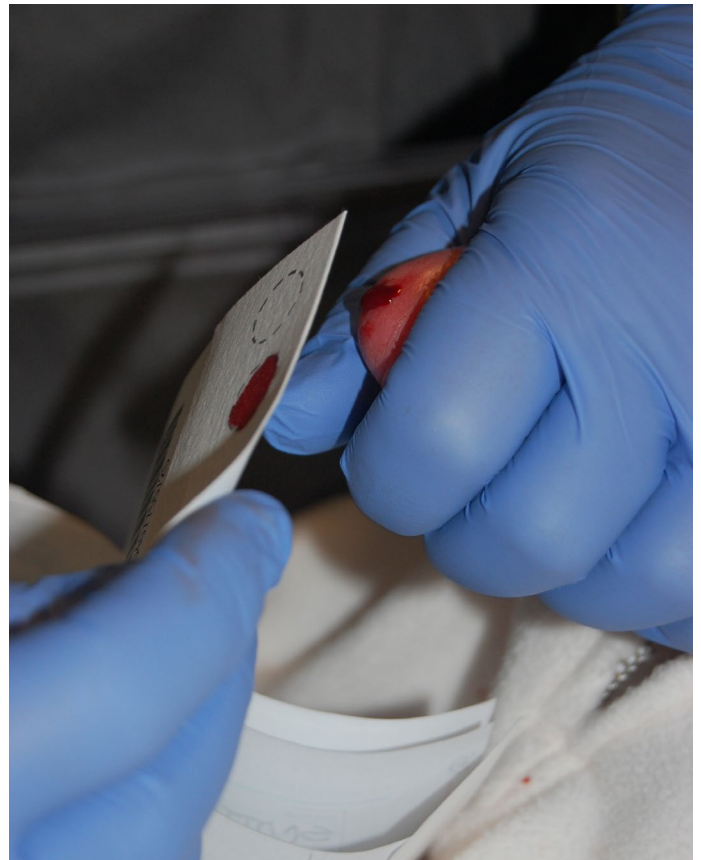
### BLOOD SPOT SCREENING IN THE NICU

Most infants in the NICU are hospitalized for reasons not associated with one of the disorders on the newborn screening panel. However, all infants in the NICU are more likely to have false positive results due to confounding factors such as immaturity, birth defects, drug side-effects, or non-standard feeding needs. Depending on their health status, infants in the NICU also require special attention when it comes to screening. For these reasons, it is critical that all medical staff members that play a role in newborn screening – including neonatologists, neonatal nurse practitioners, nurse clinicians, nurses, laboratory professionals, and support staff members – understand these nuances and are prepared to follow alternative screening protocols.

### Personnel Performing Blood Spot Collection

Within Minnesota, birth hospitals are legally responsible for ensuring that a valid specimen is collected for every infant born at the facility and for sending the specimen to the Newborn Screening Program.

If transferring an infant to another hospital/unit, the birth hospital should collect the newborn screening specimen



before the infant leaves with the transport team – even if the infant is less than 24 hours old. The transferring hospital/unit should also notify the receiving hospital/unit of the newborn's screening status. The receiving hospital/unit should verify that every admitted infant has been screened. If the receiving hospital/unit cannot verify that a newborn has been screened, or if the screen took place prior to 24 hours, collect a specimen after 24 hours of life. It is preferable for an infant to be screened twice than to not be screened at all. The Newborn Screening Program encourages providers to reference the [Newborn Screening: Pre-Transfer Checklist](#) before transferring an infant to another hospital/unit.

Each state has different newborn screening policies and screening cards. If an infant born in another state is admitted to a Minnesota NICU, the receiving hospital should verify the infant's screening status with the birth hospital. If the receiving hospital cannot verify that the

infant has been screened, collect the blood spots after 24 hours of life on a Minnesota screening card. Infants born in Minnesota who are transferred to another state should be screened before the transfer occurs – even if the infant is less than 24 hours old. Do not send a Minnesota screening card with the infant. The blood spots should be collected by the receiving facility using their state's screening card. Results for blood spots collected in the NICU are reported to the unit; results for blood spots collected pre-transfer are reported to the birth hospital.

## Filling Out and Handling the Newborn Screening Cards

Accurate patient information is essential for interpreting test results and promptly locating the infant's primary care provider to notify them of any results requiring follow-up. For a detailed discussion of how to properly fill

**Do NOT use this space**

Infant Medical Record Number

**Baby**

Last Name First Name

Birth Date Birth Time (military) Birth Weight (grams) Multiple Births Gestational Weeks

Specimen Date of Collection Collection Time Type of Feeding Sex

Collected By (initials) Clinical Information Date of Transfusion

Risk Factors

NICU patient Birth defects

Deceased siblings Family history of disorder on MN screening panel

Cause of death:

**Mother**

Last Name First Name Mother's Birth Date

Address City Zip Code

Alternate Contact for Family (name and phone number) State Mother's Phone Number

**Physician**

Physician/Clinic Responsible for Infant Follow-Up after Discharge

Physician/Clinic Phone Number

**Submitter**

Submitter Name Submitter City

Submitter's Phone Number Submitter #

Notes

HEARING SCREENING

Final Screen Date

Right Ear

Left Ear

Screening Method

Pass Refer

Pass Refer

ABR OAE

90405623792

Minnesota Department of Health, Newborn Screening Program, 601 Robert St. N., St. Paul, MN 55155-2531, Phone: (800) 664-7772 or (651) 201-5466, Fax: (651) 215-6285

Special care should be taken when completing the fields highlighted above, as they often require NICU staff to enter unique information. Yellow newborn screening cards should be used for infants weighing less than or equal to 1800 grams at birth.



out and handle the newborn screening cards, refer to pages 12-13.

Below are demographic fields that often require NICU staff to enter unique information.

- **Birth Weight:** Birth weight should be recorded in grams. If an infant weighs less than or equal to 1800 grams, a yellow newborn screening card should be used. These infants should have repeat specimens collected at 14 days and 30 days if still in the NICU. Please enter the infant's birth weight (not current weight) on the 14 and 30 day specimens.
- **Physician/Clinic Responsible for Infant Follow-up after Discharge:** List neonatal staff as physician unless the newborn's discharge is imminent.
- Be sure to check the relevant boxes and enter information to provide the clinical status of the newborn, including *NICU patient*, *Type of Feeding*, *Clinical Information*, and *Date of Transfusion*.

## Timing of Blood Spot Collection

Timing of blood spot collection is important for accurately interpreting test results. Tests for some of the disorders on the newborn screening panel have different cutoff values based on the infant's age (in hours) at the time of blood spot collection. As a result, specimens drawn too early or too late may increase the chance of false positive or false negative results.

Blood spots are best collected between **24 and 48 hours of age**. For a detailed discussion about the timing of blood spot collection, refer to pages 13-14. Special circumstances may arise that require blood spot collection at earlier or later times.

*Specimens drawn too early or too late may increase the chance of false positive or false negative results.*

In all instances where a specimen was collected prior to 24 hours of life from an infant weighing less than or equal to 1800 grams, the subsequent specimen can be collected at 14 days of age instead of collecting between 24 and 48 hours.

# <24 hrs

## Situations requiring blood spot collection prior to 24 hours:

- If an infant requires any type of blood transfusion, collect the blood spots before blood products are administered. If the pre-transfusion specimen was collected prior to 24 hours of life, a subsequent specimen should be collected after 24 hours. The first specimen will allow for accurate interpretation for the disorders affected by transfusion, and the second specimen will be used to screen for the remaining disorders that are affected by timing of collection.
- If an infant requires surgery or another major procedure, collect the blood spots in advance and make arrangements to collect a subsequent specimen between the optimal time of 24 and 48 hours.
- If an infant is going to be transferred to a different unit or hospital, collect the blood spots before the transport team leaves.
- If an infant is unlikely to survive the first 24 hours of life, collect the blood spots immediately. Results from the screening tests may contribute to an understanding of the newborn's condition or provide important information to the parents that could benefit future children. If the infant survives past 24 hours, a repeat specimen should be collected.
- If an infant requires ECMO or ECLS, collect the blood spots before the pump is started and make arrangements to collect a subsequent specimen after ECMO or ECLS is complete.

# >48 hrs

## Situations requiring blood spot collection after 48 hours:

- If an infant weighs less than or equal to 1800 grams and remains in the NICU, repeat specimens should be collected at 14 days and 30 days of life. If the infant is ready for discharge before either subsequent screen, collect a specimen on the day of discharge. If the infant is scheduled to be discharged shortly after the 14-day specimen was collected, use medical judgment to determine whether a subsequent specimen is warranted. Reviewing the results of multiple screens provides a more accurate risk assessment for the infant, which helps reduce the need for diagnostic labs, as well as false positive and false negative results.
- If an infant is transfused and a pre-transfusion specimen was not collected, a specimen should be collected 90 days after the last transfusion. This repeat specimen may need to be collected post-discharge and require alerting the primary physician to this recommendation.
- If the Newborn Screening Program has requested a repeat specimen, collect the repeat specimen as soon as possible. Repeat specimens are necessary if the initial specimen was unsatisfactory or if the infant has a borderline result. Repeat testing will clarify the infant's true risk for a disorder.
- If an infant never received an initial screen or an initial screen cannot be verified, collect the blood spots as soon as possible.
- If a newborn screening report cannot be found in the infant's medical record, at the Minnesota Department of Health Newborn Screening Program, or at another state's department of health, collect a specimen as soon as possible.
- If an infant was found under the Safe Place for Newborns law, collect the blood spots immediately. It should not be assumed that a specimen was previously collected.

## Blood Spot Collection

Blood spots should always be collected by heel-stick for optimal laboratory results. For detailed information on specimen collection, refer to pages 14-15. If extenuating circumstances arise that prohibit collection by heel-stick, please contact the Newborn Screening Program to discuss the best alternative collection method.

For detailed information on proper drying of the newborn screening card after specimen collection, refer to page 16.

*Blood spots should always be collected by heel-stick for optimal laboratory results.*



## Shipping & Handling

The Newborn Screening Program laboratory accepts specimens Monday through Saturday at the address below.

Newborn Screening Program  
601 Robert St. N  
St. Paul, MN 55155

For detailed information on shipping and handling, refer to page 16.

## Blood Spot Screening Tests

For a description of the tests performed on the newborn blood spots, refer to pages 16-17. Clinical circumstances such as an ill infant or a positive family history for a disorder on the newborn screening panel may prompt a provider to request that blood

spot screening tests be run “stat.” Although the testing itself cannot be expedited, the reporting of results can be expedited by contacting the Newborn Screening Program before or shortly after the blood spots have been sent.

## Results

For a brief explanation of results that may appear on an infant’s newborn screening report, refer to pages 18-19.

NICU staff members are more likely to encounter false positive screening results because the clinical state (e.g., prematurity, severe illness) of the newborns in their care and the modalities necessary to treat them can significantly affect result interpretation. Normal reference ranges for newborn screening tests are based on the infant population as a whole rather than on the premature and ill infants found in the NICU. The Newborn Screening Program continually strives to reduce false positive results in this special population. Even though false positive results are more common in NICU infants, positive results should never be dismissed. Newborns in the NICU are just as likely to be affected by disorders on the screening panel as full-term neonates.

*Newborns in the NICU are just as likely to be affected by disorders on the screening panel as full-term neonates.*

Because newborn screening is not diagnostic testing, false negative results may also occur. For example, therapeutic steroids given at delivery could suppress adrenal function and lead to a false negative result for congenital adrenal hyperplasia. False negative results can also occur for some of the disorders on the newborn screening panel as a result of collecting blood spots after transfusion. Should an infant display symptoms of a disorder for which the screen was negative, evaluate the infant immediately. If the infant is found to be affected, please contact the Newborn Screening Program to report the false negative result.

## The Newborn Screening Program Process for Communicating Results

If an infant has a negative newborn screen, the final report will be mailed to the submitting hospital. If an infant’s newborn screen is abnormal or positive, the

Newborn Screening Program will contact the neonatal staff caring for the infant by phone and fax to discuss the result and follow-up recommendations. Newborn Screening Program staff will also assist in establishing a connection between NICU staff and appropriate specialists when necessary.

## Follow-up/Documentation

It is the responsibility of NICU staff to follow-up on the recommendations made by the Newborn Screening Program. Additionally, NICU staff members are responsible for relaying the results and follow-up recommendations to the family and to the professionals who will care for the infant after discharge.

Documentation that newborn screening specimens have been collected should be available for every infant in the NICU. Tracking whether repeat specimens are required is also important. The NICU provider is responsible for facilitating subsequent testing.

If staff members are unable to locate an infant’s newborn screening results, please verify that screening was performed. If it is confirmed that blood spots were collected and results have not been received within two weeks following sample submission, contact the Newborn Screening Program to obtain a copy of the results. Hospital staff should keep in mind that the infant may have been known by a different name at the time the initial screen was submitted.

Newborn screening results should be included in all NICU discharge summaries. If results are not yet available, include information on the date of collection and how the primary care provider can obtain results from the hospital or from the Newborn Screening Program.

For infants born weighing less than or equal to 1800 grams, the results of all screenings should be included in the discharge summary. If a result is still pending, it is important to communicate that to the primary care provider who may not be familiar with the screening procedure for infants weighing less than or equal to 1800 grams.

The Newborn Screening Program follows up on all positive results to confirm that screening recommendations were followed and to track whether the result was confirmed or found to be a false positive. If diagnostic evaluation results are requested, please fax them to program staff in a timely manner.



## HEARING SCREENING IN THE NICU

The risk of hearing loss is reported to be 10 times greater among infants in the NICU than for healthy infants. Therefore, special attention must be given to screen infants in the NICU appropriately. Refer to the Minnesota Early Hearing Detection and Intervention (EHDI) program [Guidelines for Organization and Administration of Special Care Nursery and Neonatal Intensive Care Unit \(NICU\) Universal Newborn Hearing Screening Programs](#).

Screening infants that are premature, ill, or who have congenital anomalies generally requires a unique screening protocol due to confounding factors presented by their conditions and the treatments they require.

National standards recommend that hearing screening for all infants should be complete by one month of age, hearing loss should be clinically diagnosed by three months of age, and intervention should be initiated by six months of age or as soon as medically feasible for infants with a prolonged stay in the NICU. Corrected gestational age should be used for significantly premature infants.

The rest of this section discusses the appropriate methods and procedures for performing newborn hearing screening in the NICU. For complete details regarding newborn hearing screening in general, refer to pages 23-32.

### Timing of Hearing Screening

The hospital staff members who discharge the newborn home are responsible for ensuring that a newborn hearing screening is complete. Initial hearing screening is best performed after 12 hours of age.

If an infant's health status changes (e.g., infant requires an exchange transfusion, ECMO, assisted ventilation, etc.) after the initial newborn hearing screening, a rescreen should be performed prior to discharge.

### Transferred Infants

Hearing screens may be "missed" when infants are transferred from one hospital/unit to another. The receiving hospital/unit should always verify that the infant's hearing was screened before transfer and that results were sent to the Newborn Screening Program. If it cannot be verified that an infant has been screened, arrangements should be made for the infant to be screened as soon as possible. It is preferable for an infant to be screened twice than to not be screened at all.



*The risk of hearing loss is reported to be 10 times greater among infants in the NICU than for infants in the well-baby nursery.*

The Newborn Screening Program recommends that birth hospitals preparing for transfer include the [Hearing Screening Form for Transferred Infants](#) with the transport team to alert the receiving hospital/unit that a hearing screen has not yet been performed. The receiving hospital/unit should screen the infant's hearing, complete the form, and fax it to the Newborn Screening Program as soon as possible.

### Re-Admitted Infants

All infants re-admitted to the hospital during the first month of life with conditions associated with potential hearing loss (e.g., significant hyperbilirubinemia, meningitis, sepsis) need to have a hearing screen repeated prior to discharge. Screening results should be reported to the Newborn Screening Program as soon as possible.

### Hearing Screening Technologies

Newborn hearing screening must be performed using objective physiological screening methods that do not require behavioral responses from the infant. The two

recommended newborn hearing screening technologies are otoacoustic emissions (OAE) and automated auditory brainstem response (AABR).

If nurseries have both OAE and AABR equipment available, the Newborn Screening Program recommends screening each infant in the NICU using both technologies to ensure all types of hearing loss are detected. OAE effectively identifies cochlear or conductive hearing loss but cannot detect hearing loss of neural origin. Because infants who have been in the NICU for more than five days have a higher risk for neural hearing loss, these infants must be screened using AABR in order to be effectively screened.

If it is not possible to screen with both technologies, the Joint Commission on Infant Hearing 2007 Guideline and the Newborn Screening Program recommend the use of AABR technology for infants in the NICU.

## Hearing Screening Policies and Procedures

Accurate hearing screening and result communication is vital. If hearing screening is not performed correctly, or if the results of the hearing screening do not reach the Newborn Screening Program or the primary care provider in a timely manner, the period of time before diagnosis may be prolonged, delaying the initiation of critical intervention services.

Every special care nursery or NICU performing newborn hearing screening should have a written policy and procedure for staff to follow when screening infants for hearing loss. For sample policies and procedures, contact the Newborn Screening Program.

Prior to performing a hearing screen, providers should:

- ☒ give parents information about newborn hearing screening;
- ☒ enter the infant's information into a tracking and management system.

If an infant is born with a missing or anomalous ear or some other obvious abnormality of one or both ears, no screening is necessary and the infant should be referred directly for full audiological evaluation. Providers should indicate a REFER result on the newborn screening card for the anomalous ear(s) and write the type of anomaly in the "Notes" section on the screening card, if known.

Newborn hearing screening is best performed when the infant is asleep, well-fed, and comfortable. It should take place in a quiet environment away from conversation, fans, loudspeakers, and other sources of noise.

Screeners should follow their infection control procedure and prepare the newborn for hearing screening using the step-by-step instructions included with the screening equipment. These instructions should be kept with the screening equipment at all times and should be easily accessible for reference as needed.

Once these preparations have been made, the infant is ready to be screened. Both ears should be screened. If the infant does not pass in both ears, the infant's hearing should be immediately screened again. If the infant passes this initial screen, the results should be documented and communicated appropriately to the parents, the infant's primary care provider, and the Newborn Screening Program (refer to *Communicating Results and Follow-up/Documentation* below). If the infant



Newborns who have stayed in the NICU for more than five days must be screened using AABR technology, pictured above.

does not pass the initial screen, a rescreen of *both ears* should be completed at a later time prior to discharge.

If the infant passes the final inpatient rescreen in both ears, no further testing is needed. If the infant does not pass the final inpatient rescreen in both ears, the infant should receive a diagnostic ABR evaluation from a pediatric audiologist prior to discharge or on an outpatient basis as soon as possible. No infant should undergo more than three screens before receiving a diagnostic evaluation.

The results of the final inpatient rescreen (whether PASS or REFER), the results of the ABR evaluation (if performed), and any scheduled follow-up arrangements should be documented and communicated appropriately to the parents, the infant's primary care provider, and the Newborn Screening Program (refer to *Communicating Results* and *Follow-up/Documentation* below).

## Results

Infants screened receive either a PASS, incomplete/inconclusive, or REFER result. For complete details on hearing screening results, refer to pages 28-29.

## Communicating Results

In accordance with Minnesota statute, newborn hearing screening results should be conveyed to the infant's parents, the infant's primary care provider, and the Newborn Screening Program.

- The infant's parents should be informed of the final hearing screening results and any scheduled follow-up arrangements the same day the screen takes place. This information should be provided to them both verbally and in writing.
- Results from the final inpatient newborn hearing screen and any scheduled follow-up arrangements should be communicated in writing to the infant's primary care provider *within 10 days*.
- Minnesota law requires that results from the final inpatient newborn hearing screen (regardless of test outcome) be communicated to the Newborn Screening Program *within 10 days*. Any follow-up plans should also be communicated within this timeframe.

For complete details regarding communicating newborn hearing screening results, refer to pages 29-30.

## Follow-up/Documentation

Timely follow-up, thorough documentation, and effective communication between the Newborn Screening Program, providers, specialists, and families are key steps in the newborn hearing screening process that help facilitate prompt diagnosis, family support, and implementation of early intervention services.

*Hearing screening results should be conveyed to the infant's parents, the infant's primary care provider, and the Newborn Screening Program.*

Final newborn hearing screening results should be documented in a hearing screening tracking and management system and in the infant's medical record, including the discharge summary.

For infants who do not pass the final inpatient screen, a follow-up appointment for a pediatric audiological evaluation should be scheduled as soon as medically feasible. This diagnostic evaluation can be performed prior to discharge or on an outpatient basis. If the evaluation cannot be performed prior to discharge, the Newborn Screening Program recommends that providers assist the family in scheduling the outpatient appointment. The scheduled appointment should be communicated to the infant's primary care provider and to the Newborn Screening Program.

For complete details regarding follow-up and documentation of newborn hearing screening results, refer to pages 31-32.



## PULSE OXIMETRY SCREENING IN THE NICU

There are currently no national guidelines for performing pulse oximetry screening in the NICU population; however, screening premature infants and infants admitted to a higher-level nursery is mandated under Minnesota Statute [144.1251](#). For complete details regarding newborn pulse oximetry screening in general, refer to pages 33-38.

### Timing of Pulse Oximetry Screening

The hospital staff members who discharge the newborn home are responsible for ensuring that a newborn pulse oximetry screening is complete. Initial screening is best performed after 24 hours of age or as soon as medically feasible, but prior to discharge.

If the infant required supplemental oxygen, delay screening until the infant is stable on room air for at least 24 hours. For infants who are to be discharged home on supplemental oxygen, perform the pulse oximetry screen or an echocardiogram prior to discharge.

Infants with a known CCHD or who have had a previous echocardiogram, do not need to have pulse oximetry screening but the reason for not screening should be reported to the Newborn Screening Program.

### Pulse Oximetry Screening Equipment

Screening should be performed using a motion tolerant pulse oximeter. A variety of pulse oximeters are available for use with newborns. It is important that the equipment used is compliant with national standards. For complete details, refer to page 35.

### Pulse Oximetry Screening Policies and Procedures

Accurate pulse oximetry screening and result communication is vital to the Newborn Screening Program. If pulse oximetry screening is not performed correctly, or if the results of the screening, or the reason for not screening (e.g., prenatal diagnosis) do not reach the Newborn Screening Program in a timely manner, the period of time before diagnosis may be prolonged, delaying the initiation of critical intervention services.

Every nursery performing newborn pulse oximetry screening should have a written policy and procedure for staff to follow when screening infants for CCHD.

If the newborn never required supplemental oxygen or has since been stable in room air for at least 24 hours, proceed with the pulse oximetry screening algorithm for newborns in the well-baby nursery. For complete details regarding the pulse oximetry screening protocol, refer to pages 35-36.



### Results

Infants screened receive either a pass, rescreen, or did not pass result. If the infant receives a pass result, no immediate follow-up is needed. If the infant needs to be rescreened, repeat the screen an hour after the previous screen was performed. Each newborn can receive up to three screens. If the infant does not pass on the third attempt or receives a non-passing result at any time, further evaluation is needed (refer to page 48).

### Communicating Results

In accordance with Minnesota statute, newborn pulse oximetry screening results should be conveyed to the infant's parents, the infant's primary care provider, and the Newborn Screening Program.

- The infant's parents should be informed of the results and any scheduled follow-up arrangements the same day the screen takes place. This information should be provided to them both verbally and in writing.
- Final results from the newborn pulse oximetry screen and any scheduled follow-up arrangements should be communicated to the infant's primary care provider within 10 days of screening.

- Minnesota law requires that all pulse oximetry screening results be reported to the Newborn Screening Program. All results should be reported electronically using the direct reporting system established by MDH. Please note: as of September 2014, MDH is in the process of implementing an electronic reporting system for both pulse oximetry and hearing screening results. All birth facilities will be contacted by MDH once this system is in place and ready for use. Until then, MDH does not have the capacity to receive pulse oximetry screening results, but all Minnesota birth facilities should continue screening to comply with Minnesota State Law.

## Follow-up/Documentation

Timely follow-up, thorough documentation, and effective communication among the Newborn Screening Program, providers, specialists, and families are key steps in the newborn pulse oximetry screening process that help facilitate prompt diagnosis, family support, and initiation of medical and surgical interventions, if needed.

For infants whose final pulse oximetry screen is a passing result, notify the parents and medical provider of the passed screen. No immediate follow-up is needed; however, the newborn could still have cardiac disease. Signs and symptoms of CCHD can include rapid breathing, cyanosis, fatigue, poor feeding, and poor weight gain. Encourage parents to contact their infant's primary care provider should concerns arise.

For infants whose final pulse oximetry screen is a non-passing result, notify the parents and medical provider of the failed screen. Prompt follow-up is vital and evaluation should be initiated immediately and should be resolved prior to discharge.

The newborn should receive a comprehensive evaluation for causes of hypoxemia (e.g., CCHD, infection, pulmonary hypertension, and pneumonia).

If a non-cardiac explanation for hypoxemia is not identified, CCHD must be excluded. A cardiac evaluation may include:

- » Echocardiogram
- » Perfusion check (blood pressure and pulses x4 extremities)
- » Arterial blood gases
- » Electrocardiogram

If the evaluation is of concern for CCHD, the infant should be immediately referred to pediatric cardiology. In smaller communities and more rural hospitals, hospital staff may need to discuss with a neonatologist or pediatric cardiologist about transferring the newborn to a NICU so that a neonatal echocardiogram can be performed. These specialists may ask if Alprostadil (PGE1) is available as this medication is often used to stabilize these infants for transfer. Depending on the circumstances, additional testing or further observation at the local hospital may be appropriate.

If CCHD is identified, newborns should be followed by pediatric cardiologists. Most infants with CCHD will need surgery or cardiac catheterization; however, the type of treatment recommended will depend on the type of CCHD.

If CCHD is not suspected, the newborn should have a sepsis/respiratory evaluation. Sepsis/respiratory evaluation may include:

- » Axillary temperature
- » Blood culture
- » CBC with differential
- » Chest x-ray
- » C-reactive protein
- » Blood glucose
- » Lumbar puncture

All newborn pulse oximetry screening results should be documented in the infant's medical record. Record keeping is essential for tracking infants whose screen is not performed (missed), who require rescreening, and who may need to return for screening due to equipment failure.

For complete details regarding follow-up and documentation of newborn pulse oximetry screening results, refer to pages 37-38.



# 8

## Minnesota Newborn Screening Laws

Newborn screening operates within a state-run public health system in order to ensure that all Minnesota-born infants have access to screening and diagnosis of the disorders on the screening panel. The state-run system also works to reduce health disparities, offer equal access to care and assistance, reduce time between screening, diagnosis, and intervention, and coordinate communication among multiple care providers.

### NEWBORN SCREENING STATUTES

In Minnesota, newborn blood spot screening is mandated by Minnesota Statutes [144.125](#) and [144.128](#), newborn hearing screening is mandated by Minnesota Statute [144.966](#), and pulse oximetry screening is mandated by Minnesota Statute [144.1251](#). The statutes govern the responsibilities of healthcare providers and the Minnesota Department of Health (MDH) in newborn screening, specimen collection, distribution of results, and follow-up services. These statutes also govern the Newborn Screening Program's storage policy. Visit the Newborn Screening Program's [Retention Practices page](#) for more information.

Minnesota law requires the Newborn Screening Program to make information and forms available to healthcare providers that describe the newborn screening program for use in discussions with expectant parents and parents of newborns. These discussions should include a review of parental options.





## PARENTAL OPTIONS

Newborn screening is performed for every Minnesota newborn and blood spots and test results are retained by the program unless parents choose an alternative option.

### Destruction of Blood Spots and Test Results

Parents who want screening through MDH but do not want the blood spots and/or test results retained may request that they be destroyed by filling out the [Directive to Destroy](#) form.

### Return of Blood Spots to Parents or Guardians

Parents who want screening through MDH but do not want the blood spots to be retained may request that their infant's blood spots be returned to them at any time as long as a [Directive to Destroy](#) form has not already been received. In order to ensure that a child's blood spots are released only to his or her parent or guardian, program staff will work with the child's healthcare provider to return requested blood spots. Instructions for how to make these arrangements can be obtained by contacting the Newborn Screening Program.

### Private Testing

Parents who want their infant to have blood spot screening but prefer that testing be performed outside of MDH may choose to arrange for testing through a private laboratory. Parents should be made aware that the specific disorders screened for by private testing laboratories may vary from those screened for by MDH.

Private testing must be arranged by parents through a primary care provider and the specific private laboratory the parents choose prior to the infant's birth. Should this option be pursued, the birth provider must provide documentation to the Newborn Screening Program that the parents refused to have their child screened by Minnesota's state-run program.

### Refusal of Newborn Screening

If parents choose to refuse newborn screening, they must indicate their refusal in writing on the [Parental Refusal of Newborn Screening Form](#). The signed original must be kept in the infant's medical record, and copies of the signed form must be given to the family and to the Newborn Screening Program. By signing the [Parental](#)

[Refusal of Newborn Screening Form](#), parents acknowledge that they are informed of the risks of refusing screening and that they accept legal responsibility for any consequences (death or permanent and severe health problems) of not screening their infant.

### Consent for Research or Public Health Study

Parents of infants who had blood spots collected on or after August 1, 2014 may choose to provide written consent allowing the blood spots and test results to be used for public health studies or research not necessarily related to newborn screening.

***The use of blood spots and test results in public health studies and research makes advancements in testing and treatment options possible.***

Access to blood spots and test results will be granted only to researchers whose public health studies are approved by both the MDH Institutional Review Board (IRB) and the researcher's IRB. In the past, research has been granted to external partners such as the University of Minnesota and the Mayo Clinic. Access will not be granted to law enforcement, insurance companies, or others unless required by law or a court order.

No personal identifying information is attached to the blood spots or test results if used for research. If a parent wishes to authorize that a child's blood spots and test results be used for research or public health studies, they must sign a [consent form](#). Parents who choose this option may revoke their consent at any time.

# 9

## Newborn Screening Advisory Committees

The Minnesota Statutes [144.125](#), [144.128](#) and [144.966](#) that mandate newborn screening also created and maintain two advisory committees to provide advice and guidance for the Newborn Screening Program.

### NEWBORN SCREENING ADVISORY COMMITTEE

The Newborn Screening Advisory Committee meets on a semi-annual basis. These meetings are open to the public. To suggest a topic of discussion for the committee meeting agenda or to be added to the mailing list for alerts about upcoming meeting dates and times, email the Newborn Screening Program at [health.newbornscreening@state.mn.us](mailto:health.newbornscreening@state.mn.us).

According to Minnesota Statute [144.1255](#), membership of the Newborn Screening Advisory Committee includes, but is not limited to: parents and other newborn screening consumers, healthcare providers, hospital representatives, laboratory professionals, and other medical and educational experts.

To become a member of the Newborn Screening Advisory Committee, view the list of vacancies and submit an application through the [Office of the Secretary of State](#). For a current list of [Newborn Screening Advisory Committee members](#), visit the Newborn Screening Program website.

The committee's activities include, but are not limited to:

- collection of information on the efficacy and reliability of various tests for heritable and congenital disorders;
- collection of information on the availability and efficacy of treatments for heritable and congenital disorders;
- collection of information on the severity of medical conditions caused by heritable and congenital disorders;
- discussion and assessment of the benefits of performing tests for heritable and congenital disorders as compared to the costs, treatment limitations, or other potential disadvantages of requiring the tests;
- discussion and assessment of ethical considerations surrounding the testing, treatment, and handling of data and specimens generated by the testing requirements;
- providing advice and recommendations to the commissioner concerning tests and treatments for heritable and congenital disorders found in newborn children.

## NEWBORN HEARING SCREENING ADVISORY COMMITTEE

The Newborn Hearing Screening Advisory Committee meets four times per year. These meetings are open to the public. See [Minnesota's Early Hearing Detection and Intervention website](#) to view meeting dates, locations, and agendas. To suggest a topic of discussion for the committee meeting agenda, email the Newborn Hearing Screening Advisory Committee chairpersons at [ehdi@state.mn.us](mailto:ehdi@state.mn.us).

By law, membership of the Newborn Hearing Screening Advisory Committee includes, but is not limited to: parents of children with hearing loss, advocates with expertise in issues affecting people who are deaf and hard of hearing, a representative from a consumer organization representing culturally deaf persons, healthcare providers, hospital representatives, and other medical and educational experts. For a full list of qualifying members appointed to the Newborn Hearing Screening Advisory Committee, see Minnesota Statute [144.966](#).

To become a member of the Newborn Hearing Screening Advisory Committee, view the list of vacancies and submit an application through the [Office of the Secretary of State](#). For a current list of [Newborn Hearing Screening Advisory Committee members](#), visit the Newborn Screening Program website.

This committee's role is to advise and assist the Minnesota Department of Health and the Minnesota Department of Education in:

- developing protocols and timelines for screening, rescreening, and diagnostic audiological assessment and early medical, audiological, and educational intervention services for children who are deaf or hard-of-hearing;
- designing protocols for tracking children from birth through age three that may have passed newborn screening but are at risk for delayed or late onset of permanent hearing loss;
- designing a technical assistance program to support facilities implementing the screening program and facilities conducting rescreening and diagnostic audiological assessment;
- designing implementation and evaluation of a system of follow-up and tracking; and
- evaluating program outcomes to increase effectiveness and efficiency and ensure culturally appropriate services for children with a confirmed hearing loss and their families.





# 10 Quality Assurance

Monitoring quality is an important part of every step in the newborn screening process in order to ensure the best possible outcomes for every Minnesota newborn.

## QA REPORTS

To help improve the newborn screening process, the Newborn Screening Program sends quality assurance (QA) reports to submitting facilities on their performance twice a year. Please contact Newborn Screening Program staff with any questions about the information on the QA report.

## QA ASSESSMENT TOOL

The following assessment tool is designed to guide submitting facilities in ensuring that every infant in their care receives proper screening and prompt follow-up.

### Delayed or Missed Screening

- ☒ Have all infants been screened except those whose parents refused screening?
- ☒ Are blood spots collected between 24-48 hours?
- ☒ Have all infants had hearing and pulse oximetry screening completed before discharge?



***“There is little margin for error in newborn screening. Accurate analysis and assiduous follow-up are required to protect the health of potentially affected babies.”***

*-Association of Public Health Laboratories*

## Screening Techniques

- ✓ Is staff properly trained and up-to-date in performing blood spot, hearing, and pulse oximetry screening?
- ✓ Is a policy and procedure in place for blood spot collection as well as operation of the hearing equipment and pulse oximeters?

## Storage

- ✓ Are the newborn screening cards kept in a clean, dry place?
- ✓ Is there a sufficient supply of newborn screening cards on hand relative to the birth rate of infants at the practice/facility?
- ✓ Are the expiration dates on the newborn screening cards monitored and checked before use?
- ✓ Is there a generous supply of hearing screening pulse oximetry screening supplies and is there a protocol in place for checking and re-ordering supplies?

## Submitting Specimens

- ✓ Has the newborn screening card been inspected to ensure a satisfactory specimen has been collected and all written information is complete, accurate, and legible?
- ✓ Are newborn screening cards sent to the Minnesota Department of Health separately from clinical specimens?
- ✓ Are yellow specimen cards used for infants weighing less than or equal to 1800 grams?

## Results


- ✓ Have the hearing and pulse oximetry screening results been communicated to the parents, the infant's primary care provider, and MDH?
- ✓ Has the blood spot screening report been mailed or faxed to the infant's primary care clinic?

## Documentation

- ✓ Does someone track the specimens until test results are received?
- ✓ Are hearing and pulse oximetry screening results documented in the infant's medical record?
- ✓ When applicable, has the [Parental Refusal of Newborn Screening](#) form been signed? Are the signed originals kept in the infant's medical record, and copies of the signed form given to the family and to the Newborn Screening Program?

If unusual situations arise or if providers have questions regarding procedures for appropriate screening, shipment, tracking, or reporting of newborn screening specimens and results, please contact Newborn Screening Program staff.

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**Newborn Screening  
Quality Assurance Report**

Submitter Name \_\_\_\_\_  
Submitter Address \_\_\_\_\_

**Reporting periods**

<b>Current:</b> 01-JAN-14 - 30-JUN-14	<b>Previous:</b> 01-JUL-13 - 31-DEC-13
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**Summary data**

	Your hospital		All hospitals	
	Current	Previous	Current	Previous
Specimens received	1344	1448	33772	34737
Birth certificates filed	1643	1724	32975	34198

**Infant age at time of collection**

	Your hospital		All hospitals	
	Current	Previous	Current	Previous
Specimens collected between 24 & 48 hours	1341	99.8%	1443	99.7%
Specimens <i>not</i> collected between 24 & 48 hours	3	0.2%	5	0.3%

**Days between collection and date received by MDH - (Goal is 1 - 2 days)**

Note: Sundays are not counted.

	Your hospital		All hospitals	
	Current	Previous	Current	Previous
2 or fewer days	1317	98.0%	1434	99.0%
3 days	26	1.9%	14	1.0%
4 or more days	1	0.1%	0	--

**Delivery information**

Courier used for delivery?	Y	Courier used for Saturday delivery?	Y
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**Amending**

	Your hospital		All hospitals	
	Current	Previous	Current	Previous
Reports requiring amending by MDH staff	0	0.0%	0	0.0%

Newborn Screening Program, Minnesota Department of Health  
601 Robert Street North, St. Paul, MN 55155-2531

Quality assurance reports are sent to submitting facilities twice a year.

# APPENDIX A

## Hearing Loss: Types, Locations, Degrees, and Risk Factors

### TYPES

Conductive hearing loss occurs when sound is not conducted efficiently through the outer ear or middle ear to the sensory cells of the inner ear. Temporary conductive hearing loss may result from fluid in the middle ear, a punctured eardrum, or infection. Permanent/long-term conductive hearing loss results if the condition cannot be corrected (e.g. abnormalities of the middle ear ossicles or by congenital anomalies such as atresia or microtia).

Sensorineural hearing loss occurs when there are abnormalities of the auditory nerve or hair cells of the inner ear. Sensorineural hearing loss is permanent and can be caused by infection, head trauma, toxic medications, genetic syndromes, or may be inherited on its own (nonsyndromic).

Mixed hearing loss occurs when conductive and sensorineural hearing losses are both present. Abnormalities of the outer or middle ear and the inner ear or auditory nerve results in mixed hearing loss.

Auditory Neuropathy/Dyssynchrony describes disorders which affect auditory nerve timing in the presence of normal cochlear function.

### LOCATIONS

Hearing loss is either unilateral or bilateral. Unilateral hearing loss occurs when hearing loss exists in only one ear. Bilateral hearing loss occurs when hearing loss exists in both ears.

### DEGREES

The general classifications for degrees of hearing loss are mild, moderate, severe, and profound. Hearing loss can border between two classifications and is typically described as a combination of the two, such as severe-to-profound. The degree of hearing loss is measured in decibels with the softest sounds being made around zero and the loudest around 120. Normal speech is around 50 decibels. The table below shows the decibel range for each classification of hearing loss:

Degree of Hearing Loss	Hearing Loss Range (softest intensity at which sound is heard)
Mild	25-40 dB
Moderate	41-69 dB
Severe	70-90 dB
Profound or Severe-Profound	>91 dB



## RISK FACTORS

There are a variety of causes of hearing loss including genetic, environmental, and reasons yet to be determined. Fifty percent of the time, hearing loss results because of genetics. There are both syndromic and non-syndromic forms of hearing loss caused by genetic changes. The most common cause of non-syndromic hearing loss is due to changes to the GJB2 gene, also known as connexin 26. Environmental causes, on the other hand, account for ~25% of cases of hearing loss. The environmental exposure that causes the hearing loss can occur either before or after birth. The remaining 25% of cases of hearing loss are presently unknown and their causes are yet to be determined.

Risk factors for late-onset or progressive hearing loss are listed below:

- Assisted ventilation or extracorporeal membrane oxygenation (ECMO)
- Caregiver concern regarding hearing, speech, language, or developmental delay
- Chemotherapy
- Craniofacial anomalies, including those that involve the pinna, ear canal, ear tags, ear pits, and temporal bone anomalies
- Family history of permanent childhood hearing loss
- Head trauma (especially basal skull/temporal bone fracture requiring hospitalization)
- Hyperbilirubinemia requiring exchange transfusion
- In utero infections, such as CMV, herpes, rubella, syphilis, and toxoplasmosis
- Neonatal intensive care stay for greater than five days
- Neurodegenerative disorders (e.g., Hunter syndrome, Friedrich's Ataxia, Charcot-Marie-Tooth)
- Ototoxic medications (e.g., gentamycin, vancomycin, kanamycin, streptomycin)
- Physical findings (e.g. white forelock) that are associated with a syndrome known to include a sensorineural or permanent conductive hearing loss
- Postnatal infections associated with sensorineural hearing loss (e.g., meningitis, herpes, and varicella)
- Syndromes associated with hearing loss (e.g., neurofibromatosis, osteopetrosis, Usher syndrome Alport, Pendred, and Jervell and Lange-Nielsen)

## APPENDIX B

# Primary Targets of Pulse Oximetry Screening

### HYPOPLASTIC LEFT HEART SYNDROME

The left side of the heart didn't develop properly (either too small or absent). Because of this, the oxygen-rich blood cannot be pumped to the body in the normal way.

### PULMONARY ATRESIA

The pulmonary valve that lets blood out of the heart to the rest of the body didn't form correctly. This prevents the blood from going to the lungs to be oxygenated.

### TETRALOGY OF FALLOT

Consists of four defects: a hole between the lower chambers (ventricles) of the heart, a narrowing of the pulmonary valve and main pulmonary artery, the aortic valve is enlarged and seems to open from both ventricles instead of just the left ventricle, and the muscle surrounding the right ventricle becomes overly thickened. These defects cause the body to receive reduced oxygen levels.

### TOTAL ANOMALOUS PULMONARY VENOUS RETURN

A defect in the veins leading from the lungs to the heart. As a result, oxygen-rich blood enters the right side of the heart instead of the left. This causes oxygen-rich blood to mix with oxygen-poor blood. This mixing results in the baby getting less oxygen to the body than is needed.

### TRANSPOSITION OF THE GREAT ARTERIES

The pulmonary artery and aorta are reversed. This causes oxygen-poor blood to be pumped directly back to the body while oxygen-rich blood from the lungs is pumped back in to the lungs.

### TRICUSPID ATRESIA

The tricuspid valve didn't form correctly. Because of this, the oxygen-rich blood cannot be pumped to the body in the normal way.

### TRUNCUS ARTERIOSUS

Results in one large artery instead of two separate ones to carry blood to the lungs and the body. This causes oxygen-poor blood that should go to the lungs and oxygen-rich blood that should go to the body to be mixed together.

**Note:** Primary targets are those heart defects that are most likely to be detected by pulse oximetry screening.

# Secondary Targets of Pulse Oximetry Screening

## DOUBLE OUTLET RIGHT VENTRICLE (DORV)

The aorta arises from the right ventricle instead of the left ventricle. This means that both the pulmonary artery and the aorta come from the same ventricle, and no arteries arise from the left ventricle. This causes the aorta to deliver oxygen-poor blood to the rest of the body instead of oxygen-rich blood.

## EBSTEIN'S ANOMALY

The tricuspid valve doesn't work properly and causes blood to leak back through the valve, which makes the heart work less efficiently. This defect can lead to enlargement of the heart or heart failure.

## COARCTATION OF THE AORTIC ARCH

The aorta is narrowed, which can cause increased work on the heart and high blood pressure. If severe, it can result in heart failure in infancy as the heart works too hard to get blood through the area of narrowing.

## INTERRUPTION OF THE AORTIC ARCH

There is an absence or disconnection between the top part of the aortic arch and the lower, descending aorta. This prevents oxygen-rich blood from getting to the rest of the body.

## HYPOPLASIA OF THE AORTIC ARCH

Aortic arch is small. Commonly seen in conjunction with coarctation of the aortic arch.

## AORTIC ATRESIA

There is no opening from the left ventricle into the aorta. Because of this, the blood cannot move from the left ventricle to the rest of the body.

## SINGLE VENTRICLE

Is a group of cardiac defects that share the common feature of having only one of the two ventricles that are of adequate size and function. Additional defects distinguish one single ventricle defect from another.

**Note:** Secondary targets are those heart defects that are potentially detected by pulse oximetry screening. Pulse oximetry screening may detect other hypoxic cardiac or non-cardiac associated conditions (e.g., persistent pulmonary hypertension and bacterial infection).



# APPENDIX D

## Pulse Oximetry Screener Knowledge Assessment

1. Pulse oximetry screening will detect all forms of congenital heart disease:

- a. True
- b. False

2. The following can affect the accuracy of a pulse oximetry reading:

- a. Movement
- b. Cold extremities or shivering
- c. Crying
- d. Bilirubin lamps or surgical lights
- e. All of the above

3. One clean, disposable pulse oximetry probe can be used on up to five newborns:

- a. True
- b. False

4. To ensure the accuracy of a pulse oximetry reading, screeners should:

- a. Look at the waveform displayed on the monitor; if the waveform is asymmetrical and choppy or is a flat line, the pulse oximetry reading is most likely accurate
- b. Look at the waveform displayed on the monitor; if the waveform is symmetrical and does not have motion artifact (i.e., is not jumping up and down), the reading is most likely accurate
- c. Both a and b are correct
- d. Neither a or b are correct

5. All of the following can affect the accuracy of the pulse oximetry reading except:

- a. Placing the pulse oximetry probe on the same extremity from which you are taking the newborn's blood pressure
- b. Performing the pulse oximetry screen while the infant is crying
- c. Using a clip on the finger of the infant
- d. Infant skin color or jaundice

6. The following criteria would exclude an infant from being screened:

- a. Gestation age greater than 35 weeks
- b. Presence of dysmorphism or a known genetic syndrome that requires cardiac evaluation
- c. Normal vital signs while in the newborn nursery
- d. Age greater than 24 hours

7. The screening guidelines outlined in the protocol state that pulse oximetry should be performed on:

- a. The right hand
- b. The left hand
- c. Either foot
- d. Both a and c
- e. Both b and c

8. Pulse oximetry screening should be performed when the infant is what age?

- a. Less than 8 hours
- b. Between 8 hours and 24 hours
- c. At least 24 hours

# ANSWERS

## TO THE PULSE OXIMETRY SCREENER KNOWLEDGE ASSESSMENT:

1. B — Some CCHDs may not be detected through screening. Therefore, it is important to educate families about monitoring their baby's H.E.A.R.T. (heart rate, energy, appearance, respiration, and temperature) for possible signs of undetected CCHD.
2. E — Movement, cold extremities or shivering, crying, bilirubin lamps, and surgical lights can all affect the accuracy of a pulse oximetry reading.
3. B — A clean, disposable pulse oximetry probe can only be used on one newborn before it is discarded.
4. B — To ensure the pulse oximetry reading is accurate, screeners should reference the waveform displayed on the monitor; if the waveform is symmetrical and does not have motion artifact (i.e., is not jumping up and down), the reading is most likely accurate.
5. D — Infant skin color or jaundice cannot affect the accuracy of the pulse oximetry reading. However, other factors such as placing the pulse oximetry probe on the same extremity as a blood pressure cuff, performing the screen while the infant is crying, or using a clip on the infant's finger can cause inaccurate results.
6. B — Newborns with dysmorphic features or known genetic syndromes that require cardiac evaluation do not require pulse oximetry screening.
7. D — Screening sensors should be placed on both the right hand and either foot.
8. C — Pulse oximetry screening should be performed when the infant is at least 24 hours old.





Newborn Screening Program  
Minnesota Department of Health

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