2025

# Georgia Newborn Screening

## Policy and Procedure Manual

GEORGIA DEPARTMENT OF PUBLIC HEALTH

The purpose of this manual is to provide a structured and informative framework for the establishment and operation of the Georgia Newborn Screening (NBS) Program to help ensure the health and well-being of every newborn in the state. The manual provides information and tools for healthcare professionals and stakeholders to conduct newborn screening effectively and efficiently for early detection and intervention of congenital disorders and inherited conditions in infants.

The NBS Program is committed to the following key objectives:

**Universal Access:** Every Georgia infant receives quality and timely newborn screening for the disorders mandated by state regulations.

**Follow-up and Recommendations:** Newborns with abnormal screening test results receive timely and appropriate follow-up. These results and recommendations are shared with healthcare providers to expedite diagnostic and treatment services.

**Data for Action:** Robust data collection, analysis, and dissemination inform all aspects of the program's operations. This includes the assessment of newborn screening methods and strategies, cost-effectiveness analyses, and evaluations of health outcomes.

**Parent Education:** Parents and caregivers are empowered with information about the importance of newborn screening and the benefits it offers to Georgia's newborns.

**Technical Assistance and Education:** The NBS Program's diverse range of stakeholders, including birthing facilities, follow-up programs, healthcare professionals, families of affected children, and the public will have the information they need to ensure the early detection and intervention for congenital disorders and inherited conditions in infants.

If you have any questions about the information in this manual, please email DPH-NBS@dph.ga.gov.

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# SECTION I. INTRODUCTION TO NEWBORN SCREENING

Newborn Screening (NBS) is a public health activity aimed at early identification of conditions in infants that, without prompt detection and treatment, can result in permanent disability or death. NBS programs have saved countless lives by identifying infants with rare but serious health conditions shortly after birth. Over the years, these programs have evolved, expanding the list of screened disorders and incorporating advances in technology and medical knowledge.

Effective newborn screening involves hospitals, state newborn screening laboratories, primary care providers, follow-up programs, parents, and community agencies. Healthcare providers are on the frontline ensuring all newborns get the screenings they need and receive timely and appropriate follow-up care.

## 1.1 GEORGIA NEWBORN SCREENING PROGRAM OVERVIEW

Georgia's NBS Program is a state-mandated program within the Georgia Department of Public Health's (DPH) Public Health Laboratory and Division of Women, Children, and Nursing Services, Office of Child Health. The NBS Program in Georgia operates as a universal access, coordinated, multi-partner system dedicated to the early identification and intervention of congenital and heritable conditions through efficient screening, follow-up, consultation, tracking, data analysis, and educational initiatives.

The NBS Program includes 3 categories of health screens:

- **Metabolic and endocrine conditions:** Blood spots are collected for laboratory testing for selected endocrine and genetic metabolic conditions.
- **Critical Congenital Heart Disease (CCHD):** Pulse oximetry measures are collected to detect CCHD.
- **Congenital Hearing Loss:** Auditory measurements are collected to detect congenital hearing loss.

The Georgia Public Health Laboratory provides accurate and timely genetic testing on dried blood spots collected from all newborns in Georgia. Currently, the Georgia Public Health Laboratory conducts testing for and reports results for metabolic and endocrine conditions for approximately 125,000 Georgia newborns every year.

## 1.2 NEWBORN SCREENING PROGRAM CONTACT INFORMATION

### General Program Questions, Order Educational Brochures, or Training Resource Needs:

**Georgia Newborn Screening Program:**
Email: DPH-NBS@dph.ga.gov
Fax: (404) 657-2773
Webpage: www.dph.ga.gov/NBS

### Laboratory-Specific Questions or to Order Newborn Screening Cards:

**Georgia Public Health Laboratory:**
The Newborn Screening Section
Georgia Public Health Laboratory
1749 Clairmont Road
Decatur, GA 30033-4050
Phone: (404) 327-7950
Fax: (404) 327-7919
Webpage: www.dph.ga.gov/lab

# SECTION 2: RESPONSIBILITIES IN THE NEWBORN SCREENING PROCESS

The NBS process is a coordinated effort between the birthing facility (specimen submitter), primary care physician, Georgia Public Health Laboratory, and the NBS Follow-Up program.

## 2.1 BIRTHING FACILITY (SPECIMEN SUBMITTER)

It is the responsibility of the birthing facility, birthing center, physician's office, or other healthcare facility in which each infant is born to ensure that a newborn screening dried blood spot (NBS DBS) specimen is collected and submitted to the Georgia Public Health Laboratory for testing for select endocrine and genetic metabolic conditions. Testing for congenital hearing loss and CCHD must also be completed, and results (1) recorded in the clinical record, (2) reported to DPH, and (3) shared with the infant's parent or guardian. Newborns who have already received an echocardiogram for any reason may be excluded from CCHD screening.

If the birth occurs outside a birthing facility, birthing center, or other healthcare facility, then it is the responsibility of the attending physician or midwife to properly complete NBS DBS specimen collection and submit the NBS DBS card to Georgia Public Health Laboratory. When a live birth occurs in any hospital, birthing center, or facility that is equipped to conduct the newborn hearing screening and Critical Congenital Heart Disease (CCHD) screening, those tests shall be conducted prior to the infant's discharge.

**Newborn Dried Blood Spot Specimen Card:**
Submitters are responsible for ensuring all the fields on the NBS DBS card are completed before it is sent to Georgia Public Health Laboratory. See Section 5 for more information. The birthing facility is responsible for the recollection of specimens in the event of specimens lost in transit or submission of specimens that are inadequate for testing.

**Critical Congenital Heart Disease (CCHD) and Congenital Hearing Loss Screening:**
The results of the test shall be included in the baby's clinical record, reported to the Georgia Department of Public Health, and given to the parents or legal guardians, along with any follow-up recommendations.

### Providing Information on Newborn Screening to Parents:

The birthing facility, birthing center, or other healthcare facility in which the infant is born is responsible for ensuring parents are given a copy of "Georgia Newborn Screening Program: What Every Parent Should Know." DPH offers free brochures that will be shipped to the submitting facility quarterly. Email DPH-NBS@dph.ga.gov to place an order.

All CCHD and Hearing Screening results must be given to the parents or legal guardians along with any follow-up recommendations.

### Re-collection of NBS DBS Specimens with Unsatisfactory Results:

Submitting a specimen that is inadequate for testing leads to delays in providing results and places the newborn at risk for a delayed diagnosis. Birthing facilities must collect a second specimen if the first specimen submitted to the Georgia Public Health Laboratory was determined to be unsatisfactory for testing. The second specimen should be collected as soon as possible. It should be collected with another NBS DBS card and sent to the Georgia Public Health Laboratory. If the infant has been discharged, the birthing facility shall be responsible for contacting the pediatrician listed on the NBS DBS card or the infant's parent or legal guardian if the pediatrician's information is missing to arrange for the collection of a second specimen.

## 2.2 GEORGIA PUBLIC HEALTH LABORATORY

The Georgia Public Health Laboratory is responsible for receiving dried blood spot specimens and conducting laboratory testing. The Georgia Public Health Laboratory sends a written report of newborn screening results to the submitter and pediatrician listed on the NBS DBS card. Abnormal results are also reported by the Laboratory to the designated follow-up program.

## 2.3 NEWBORN SCREENING FOLLOW-UP PROGRAMS

Timely follow-up of an abnormal result is critical to preventing morbidity and mortality. State-designated follow-up programs locate infants with abnormal screening results, provide education to their parents/guardians, and facilitate referrals for diagnostic testing and disease management in a timely fashion.

DPH contracts with the following organizations to assist with timely follow-up:

- **Emory University Department of Human Genetics - Follow-Up Program:** Organic Acid Disorders, Fatty Acid Oxidation Disorders, Amino Acid Disorders, Lysosomal Storage Disorders, Endocrine Disorders, and Other Disorders
- **Augusta University and Children's Healthcare of Atlanta:** Sickle Cell Disease and Hemoglobin Disorders
- **Sickle Cell Foundation:** Sickle Cell Trait
- **Early Hearing Detection and Intervention (EHDI) District Coordinators:** Congenital hearing loss

For more information on follow-up procedures, see Section 9: Follow-Up Program Procedures.

## 2.4 PRIMARY CARE PROVIDERS

The provider listed on the NBS DBS card as the pediatrician after discharge will receive the results of newborn screening for metabolic and endocrine disorders and is responsible for contacting the family to arrange diagnostic testing and follow-up as indicated. If the infant is seeing a different healthcare provider than listed on the NBS DBS card, the family must inform DPH immediately (email DPH-NBS@dph.ga.gov) so the correct provider can be notified.

Birthing hospitals are responsible for informing parents about abnormal screening results for both CCHD and hearing screenings and providing referrals following the abnormal results. Primary care providers (PCP) should confirm receipt of CCHD and hearing testing results with parents and whether the results were abnormal and required referral.

See Section 3: Accessing Newborn Screening Results for more information regarding accessing newborn screening results.

### Coordination with Follow-Up Programs:

The PCP will be contacted by the relevant state-designated follow-up programs about infants with abnormal newborn screening results:

1. **Emory University Department of Human Genetics - Follow-Up Program:** Organic Acid Disorders, Fatty Acid Oxidation Disorders, Amino Acid Disorders, Lysosomal Storage Disorders, Endocrine Disorders, and Other Disorders
2. **Augusta University, Children's Healthcare of Atlanta, and The Sickle Cell Foundation of Georgia:** Sickle Cell Disease Follow-Up
3. **District Early Hearing Detection and Intervention Coordinator**: Hearing screening follow-up

The PCP will provide the family with the NBS results and education. The PCP may be asked by a state-designated follow-up program to do one or more of the following:

1. **Contact the family to bring the infant in for an assessment**. Infants should be assessed as soon as possible. The follow-up program may advise that an immediate assessment or referral to an emergency department is necessary for some infants.
2. **Repeat the newborn screen -** Many infants will need a repeat screen to confirm a diagnosis. The follow-up program will include this request in the verbal and/or faxed report.
3. **Collect diagnostic test samples** - Some infants will require diagnostic testing. The follow-up team's verbal and faxed report will include information on how to do this, details on which tests to order, and recommended labs.
4. **Refer the infant for confirmatory testing** - Some infants may need to be referred to a specialist for additional testing to confirm a diagnosis. The follow-up program will provide this guidance to the PCP.

Primary care providers confirming abnormal test results or clinical symptoms for the conditions listed in DPH Rule 511-5-5-.03 must report those findings to the appropriate follow-up provider. See Section 9: Follow-Up Program Procedures and Appendix B: Georgia Rules and Regulations Pertaining to Newborn Screening.

# SECTION 3: ACCESSING NEWBORN SCREENING RESULTS

## 3.1 PHYSICIANS

Physicians have two options for obtaining newborn screening results, as outlined below. Results are typically populated in the following databases approximately 7-10 days after birth.

1) e-Reports: Online Portal for physicians registered in Georgia to retrieve newborn screening results. The web portal address is https://ereports.ga.gov/dph/eReports. See eReports Web Portal Registration Form in Appendix H: eReports Web Portal Registration Form for instructions on registration.
   - Note: e-Reports will generate a medical report for conditions tested via NBS DBS card. If an infant is born at a hospital who reports hearing and cardiac screening outside of the DBS card, those results will not be available in e-reports.

2) State Electronic Notification Surveillance System (SendSS): Authorized providers can also access newborn screening results online through the State Electronic Notification Surveillance System (SendSS). When registering, request access to "SendSS Newborn: Newborn Screening Results"
   - Note: SendSS generates an **unofficial report** that includes all conditions (i.e., congenital hearing loss, Critical Congenital Heart Disease (CCHD), and metabolic/endocrine disorders.

## 3.2 PARENTS/GUARDIANS

Parents and guardians may request a copy of their child's newborn screening results by e-mail a completed Authorization for Release of Newborn Screening Report form (Appendix I: Authorization for Release of Newborn Screening Report Form) along with proof of identity to DPH-NBS@dph.ga.gov.

# SECTION 4: FILLING OUT THE NEWBORN SCREENING CARD

## 4.1 IMPORTANCE OF COMPLETE DEMOGRAPHIC INFORMATION ON THE NEWBORN SCREENING CARD

Submitters are responsible for ensuring all the fields on the NBS DBS card are completed before it is sent to the Georgia Public Health Laboratory. All information requested on the NBS DBS card is vital for timely and accurate screening and follow-up. The Georgia Public Health Laboratory relies on the date and time of birth, the date and time of specimen collection, and birth weight recorded on the NBS DBS card to determine whether screening results are normal or abnormal. Omitting this information or providing inaccurate, incomplete, or illegible information may result in inaccurate results, delays in reporting results, or rejection of the specimen and the need for re-collection of the specimen.

Providing the names of the (1) submitting health care provider and (2) pediatrician after discharge on the NBS DBS card is critical for ensuring rapid follow-up of the results. State-designated Follow-up Programs rely on the demographic information provided on the NBS DBS card to locate infants with abnormal results to ensure that they receive timely follow-up.

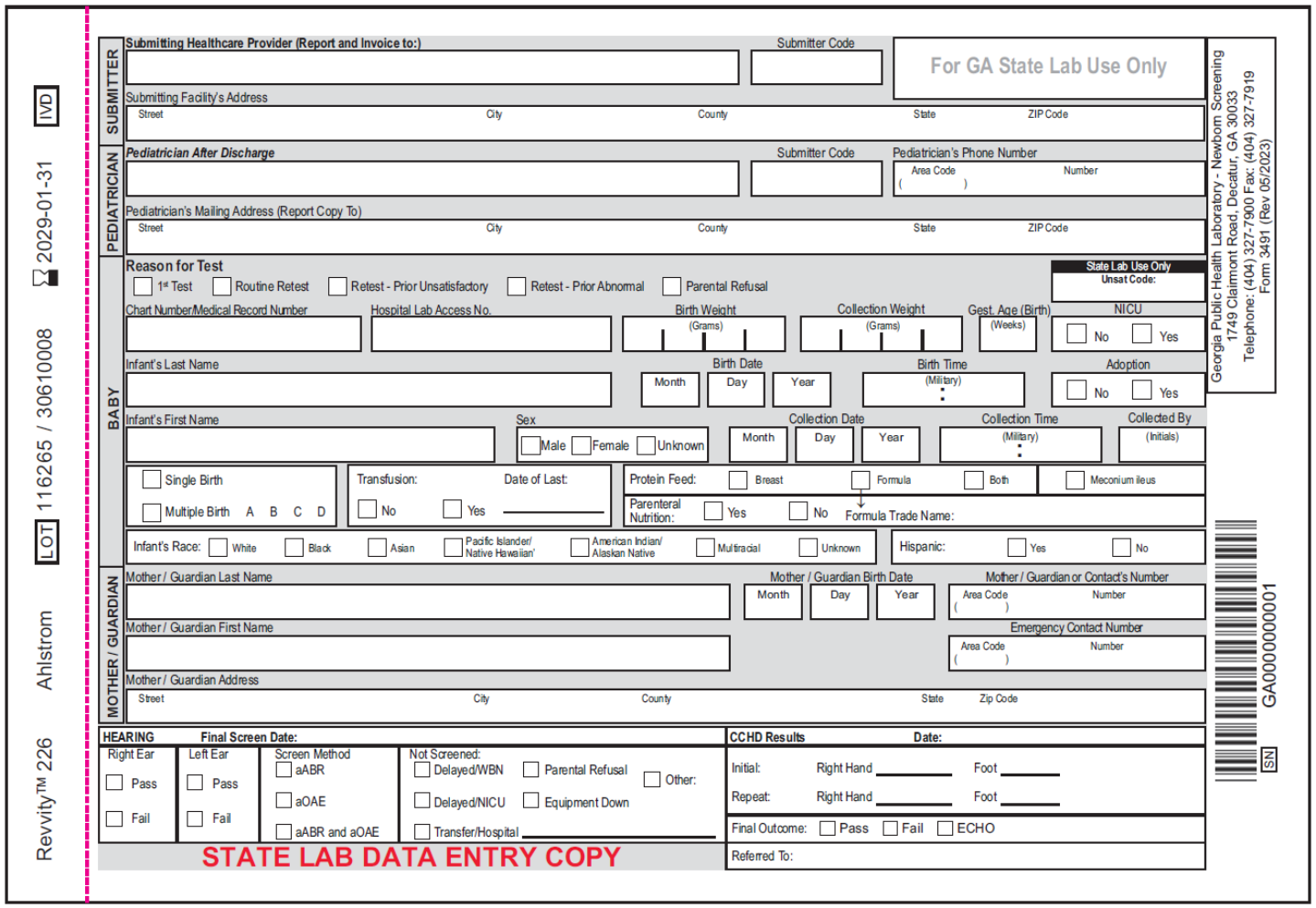
## 4.2 GUIDANCE FOR COMPLETING THE NEWBORN SCREENING CARD

Newborn screening cards are medical devices. They should be stored in a cool, dry place away from direct sunlight.

The first step in blood spot specimen collection is to check the NBS DBS card's expiration date.

- NBS DBS cards are to be used on or before the expiration date.
- Destroy all outdated cards immediately.
- Newborn screening cards can be ordered from the Georgia Public Health Laboratory by calling (404) 327-7928 or ordering from GPHL. See Appendix L: Form to Order Newborn Screen Collection Forms (Georgia Public Health Laboratory) Specimen Collection Order Form.
- Do not request more than a 6-month supply of cards.

**Figure 4.1 Georgia Newborn Screening Card Example**




**Important:** Check the newborn screening card's expiration date before collecting the specimen. The expiration date is located on the left-side of the newborn screening card.

**Figure 4.2 Georgia Newborn Screening Card Expiration Date Example**


**Table 4.1 Georgia Newborn Screening Card Data Fields and Descriptions**

| SUBMITTER SECTION | |
|---|---|
| **Data Field** | **Description** |
| Submitting Healthcare Provider (Report and Invoice to) | Name of the facility where the specimen was collected |
| Submitter Code | Unique identifier for the facility (three digits/letters) |
| Submitting Facility's Address | |

| | |
|---|---|
| • Submitting Facility's Street | Street of the Submitting Facility |
| • Submitting Facility's City | City of the Submitting Facility |
| • Submitting Facility's County | County of the Submitting Facility |
| • Submitting Facility's State | State of the Submitting Facility |
| • Submitting Facility's Zip Code | Zip Code of the Submitting Facility |
| **PEDIATRICIAN SECTION** | |
| **Data Field** | **Description** |
| Pediatrician After Discharge | Name of pediatrician given by parent or guardian who will administer care after discharge<br>**Note:** A final NBS report will be mailed to this provider |
| Submitter Code | Unique identifier for the pediatrician (i.e., six digits "123456"); Add if known |
| Pediatrician's Phone Number | Named pediatrician's phone number |
| Pediatrician's Mailing Address (Report Copy To) | |
| • Pediatrician's Street | Street of the pediatrician's facility |
| • Pediatrician's City | City of the pediatrician's facility |
| • Pediatrician's County | County of the pediatrician's facility |
| • Pediatrician's State | State of the pediatrician's facility |
| • Pediatrician's Zip Code | Zip code of the pediatrician's facility |
| **BABY SECTION** | |
| **Data Field** | **Description** |
| Reason for Test | |
| • 1st Test checkbox | Select "1st Test" if this is the initial screen for infant |
| • Routine Retest checkbox | Select "Routine Retest" for infants in NICU |
| • Retest – Prior Unsatisfactory checkbox | Select "Retest Prior Unsatisfactory" for unsatisfactory result |
| • Retest – Prior Abnormal checkbox | Select "Retest Prior Abnormal" for out-of-range result |
| • Parental Refusal checkbox | Select "Refusal" for parents who refuse NBS DBS screening |
| Chart Number/Medical Record Number | Place infant's chart number/medical record number here |
| Birthing facility Lab Access Number | If your birthing facility uses lab access number to log the specimens, lab will place that number here |
| Birth Weight (grams) | Weight taken at birth used for interpretation of results |
| Collection Weight (grams) | Current weight at time of collection if the infant is older >7 days used for interpretation of results |

| | |
|---|---|
| Gestational Age (Birth) | Gestation is determined by a physician or based on the dates of pregnancy. Report gestational age in weeks |
| NICU | Check "yes" if the infant has been admitted to a Level II or III special care nursery. Check "no" if the infant has not been admitted to a Level II or III special care nursery |
| Infant's Last Name | Last name of infant |
| Birth Date | Enter infant's birthdate (MM/DD/YR) |
| Birth Time (Military) | Infant's time of birth |
| Adoption | If adopted, check "yes", if not, select "no" |
| Infant's First Name | Infant's first name. Can be listed as Baby Boy, Baby Girl or if twins: Twin A or B if the first name is not known |
| Sex | Indicate if infant is a male, female or unknown |
| Collection Date | The date the specimen was collected |
| Collection Time (Military) | Time the specimen was collected |
| Collected By (Initials) | The initials of the nurse or lab tech who collected the specimen |
| Single Birth and Multiple Births | **Single birth**: If a mother delivered a single infant, check the "Single Birth" checkbox<br>**Multiple birth**: If a mother delivered more than one infant, check the "Multiple Birth" checkbox, and indicate in what order this infant was delivered (e.g., A=1st, B=2nd, C=3rd, D=4$^{th}$, etc.) |
| Transfusion | Did the infant have a transfusion? "Yes" or "No" |
| Date of Last (Transfusion) | If the infant had a transfusion, enter the date of the last transfusion |
| Protein Feed | Select the infant's current feeding type:<br>• Breast – breastfed only<br>• Formula – formula fed only<br>• Both – breastfed and formula fed |
| Meconium ileus | Select if the infant has a clinical diagnosis of meconium ileus, a bowel obstruction. |
| Parenteral Nutrition | If the infant is currently receiving the administration of nutrients intravenously select "yes". If the infant is not currently receiving the administration of nutrients intravenously select "no" |
| Formula Trade Name | If the infant is being fed with formula, enter the formula trade name |
| Infant's Race | Ask parent/guardian, then indicate the race of infant |
| Hispanic | Select "yes" if the infant's ethnicity is Hispanic. Select "no" if the infant's ethnicity is not Hispanic |
| **MOTHER / GUARDIAN SECTION** | |
| **Data Field** | **Description** |
| Mother/ Guardian Last Name | Last name of the birth mother or guardian |
| Mother/Guardian Birth Date | Birth date of the birth mother or guardian |

| | |
|---|---|
| Mother/Guardian or Contact's Number | Mother's / Guardian's number where she can be best reached after discharge |
| Mother/ Guardian First Name | Birth mother's or guardian's first name |
| Emergency Contact Number | Friend or relative of the mother/guardian who can be contacted if the mother/guardian cannot be reached |
| Mother/ Guardian Address | |
| • Mother/ Guardian Street | Residing street of the mother or guardian |
| • Mother/ Guardian City | Residing city of the mother or guardian |
| • Mother/ Guardian County | Residing county of the mother or guardian |
| • Mother/ Guardian State | Residing state of the mother or guardian |
| • Mother/ Guardian Zip Code | Residing zip code of the mother or guardian |
| **HEARING SECTION** | |
| **Data Field** | **Description** |
| Final Screen Date | Enter the date of the final hearing screen<br>If screened twice, use the date of the second screen |
| Right Ear | Select "Pass" if the infant passed the hearing screen in the right ear. Select "Fail" if the infant did not pass the hearing screen in the right ear. |
| Left Ear | Select "Pass" if the infant passed the hearing screen in the left ear. Select "Fail" if the infant did not pass the hearing screen in the left ear. |
| Screen Method | Check the screening instrument (aABR, aOAE, aABR and aOAE) used for the final hearing screen. |
| Not Screened | If the infant did not receive a final screen before the card was submitted indicate the reason: "Delayed/WBN" (well baby nursery), "Parental Refusal", "Delayed/NICU" (neonatal intensive care unit), "Equipment Down", "Other", "Transfer/Birthing facility" (enter the birthing facility name the infant was transferred to). |
| **CCHD RESULTS SECTION** | |
| **Data Field** | **Description** |
| Date | Enter the date the CCHD screen was completed |
| Initial (Both right hand and either foot must be tested) | |
| • Right Hand | Enter the initial pulse oximetry results (%) for the right hand. |
| • Foot | Enter the initial pulse oximetry results (%) for either foot |
| Repeat (Both right hand and either foot must be tested) | |
| • Right Hand | Enter the repeat pulse oximetry results (%) for the right hand. |
| • Foot | Enter the repeat pulse oximetry results (%) for either foot |
| Final Outcome | Select the appropriate checkbox to indicate the final outcome of CCHD screening. |

| | |
|---|---|
| | • Select "Pass" if the infant passed the CCHD screening<br>• Select "Fail" if the infant did not pass the CCHD screening<br>• Select "ECHO" if the infant had an ECHO test completed |
| Referred To | Indicate if the infant was referred to a cardiologist or birthing facility. Write the full name of the cardiologist or birthing facility without abbreviations. |

# SECTION 5: COLLECTING, HANDLING, AND SHIPPING NEWBORN SCREENING CARDS

## 5.1 TIMING OF DRIED BLOOD SPOT SPECIMEN COLLECTION

A sample of each infant's blood should be collected 24 to 48 hours after first feeding or prior to the infant's discharge from the birthing facility if the infant is discharged before 24 hours of age. It is recommended to collect an NBS DBS specimen from all infants, including those considered unlikely to survive to 24 hours of age.

See Section 5.4: Metabolic and Endocrine Screening Considerations and NBS DBS Collection Schedules for Special Populations for information about the timing of NBS DBS specimen collection from critically ill infants and infants requiring transfusion or total parenteral nutrition.

## 5.2 DRIED BLOOD SPOT SPECIMEN COLLECTION PROCEDURES

Use standard precautions when collecting and handling NBS DBS specimens.

Avoid contamination of NBS DBS cards with physical contaminants such as antiseptic solutions, powders, petroleum jelly, lotions, or other materials, which may adversely affect the testing process.

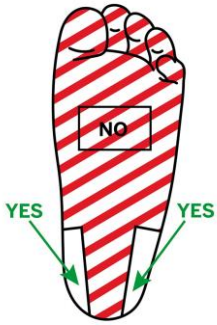
The NBS DBS specimen collection procedure can be viewed on video by using the link: https://www.youtube.com/watch?v=T-CL7dQRZ7w

Do not use capillary tubes for specimen collection. Capillary tubes contain heparin, which can result in diluted or contaminated NBS DBS specimens.

Check the expiration date prior to performing the heel stick. Every newborn screening card is printed with an expiration date. NBS cards can be used for blood spot collection through the last day of the month of the expiration date printed on the card.

**Procedure Steps:**

1. Wash hands before collecting the newborn's NBS DBS specimen. Use standard precaution practices (e.g., wear gloves and change gloves between newborns) during specimen collection and handling.
2. Fold back the cover sheet on the NBS DBS card to expose the filter paper. Do not touch or handle the preprinted circles on the filter paper before, during, or after applying blood.
3. Swaddle the infant or allow the parent to hold the infant to reduce movement and provide comfort.
4. Position the infant with feet lower than the level of the heart to improve blood flow.
5. Warm the infant's heel by applying a disposable heel-warming device to the area for three to five minutes before beginning the procedure.
6. Clean the puncture site with a sterile alcohol pad. Allow to air dry to reduce alcohol which can cause hemolysis and denature of some of the enzymes being tested.
7. Use a sterile, single-use, retractable lancet to make an incision in the areas indicated on the diagram on the right.
    - **Average weight infants and older children:** do not exceed puncture depth of 2.0 mm.
    - **Preterm and LBW:** do not exceed a puncture depth of 0.85 mm.




8. Wipe away the first drop of blood with dry sterile gauze.
9. Allow a large drop of blood to form. To enhance blood flow during collection, apply gentle intermittent pressure to the heel with the thumb.
   NOTE: Do not excessively "milk" or squeeze the puncture site. Milking can cause hemolysis of the specimen or result in a mixture of tissue fluids with the blood specimen, resulting in an unsatisfactory specimen.
10. Lightly touch the front (or back) of the filter paper card to the blood drop and fill each printed circle with one single drop, allowing the blood to saturate through completely to the other side of the card.
11. Apply blood to one side of the filter paper only. Fill all circle areas. Do not layer successive small drops of blood in the same circle. Avoid touching or smearing the blood spots.
12. If blood flow is diminished, repeat steps three through nine with a new sterile lancet.

If there is inadequate blood from the heel to complete specimen collection, alternative methods of collection can be used. Venous, arterial, or umbilical catheter blood may be used. If one of these methods is used, the drops should be applied to the DBS card in a similar manner to the traditional procedure. Allow the blood drop to pool at the tip of the syringe or catheter and apply one drop to the center of the spot.

## 5.3 NEWBORN SCREENING CARD DRYING, HANDLING, AND SHIPPING

Allow the NBS DBS card to thoroughly air dry for at least three hours at an ambient temperature of 18-25°C on a flat, nonabsorbent surface, away from direct heat and sunlight. Do not allow the protective flap to encounter blood spots until the spots are thoroughly dry. Do not stack or allow the blood spots to touch anything during drying.

Avoid contamination of NBS DBS cards with physical contaminants such as antiseptic solutions, powders, petroleum jelly, lotions, or other materials, which may adversely affect the testing process.

After drying, NBS DBS cards should be stored in a cool, dry place. Do not refrigerate.

Send NBS DBS cards to the Georgia Public Health Laboratory within 24 hours of collection.

- Delayed submission to the laboratory may result in a significant delay in the identification of an infant with a disorder.
- Do not accumulate or "batch" specimens before shipping since this may result in specimens too old to test.

**Send NBS DBS cards to:**

**Georgia Public Health Laboratory**
**1749 Clairmont Road**
**Decatur, GA 30033-4053**

The Georgia Public Health Laboratory has a contractual agreement with United Parcel Service (UPS) to pick up and transport specimens from birthing facilities in Georgia to the Georgia Public Health Laboratory. Specimens may be shipped using a shipper other than UPS, but the birthing facility or healthcare provider will be responsible for the expense of using a different courier.

The Georgia Public Health Laboratory provides pre-addressed UPS labels specifically for birthing facilities to use to send newborn screening specimens to the Laboratory. The Department of Public Health will pay for one shipment per day per birthing facility for transport of specimens to the Georgia Public Health Laboratory. The Laboratory assumes responsibility for testing only; whoever submits specimens must assume liability for proper identification, collection and prompt delivery of specimens to the State Laboratory.

## 5.4 METABOLIC AND ENDOCRINE SCREENING CONSIDERATIONS AND NBS DRIED BLOOD SPOT COLLECTION SCHEDULES FOR SPECIAL POPULATIONS

There are additional screening considerations and schedules for:

- **NICU or Special Care Nurseries**
- **Transferred Infants**
- **Transfusions/Blood Products/ECMO**
- **Low Birth Weight Infants**
- **Parenteral Nutrition**
- **NPO/IV Fluids Only**
- **Older Infants/Children**

Multiple screening schedules may apply to an infant, and all relevant schedules described below should be followed.

**Infants in NICU or Special Care Nurseries**

a) **Upon admission**: Collect the first NBS DBS specimen, regardless of age and weight, and before any other treatments are begun (except respiratory).
b) **Between 48-72 hours of life**: Collect a second NBS DBS specimen from infants initially screened at < 24 hours of age at first screen.
c) **At 28 days of life or discharge, whichever comes first**: Collect a third NBS DBS specimen from infants <34 weeks gestational age or <2000 grams at birth.

**Transferred Infants**

Birthing facilities transferring an infant to another facility should document in the medical record whether the first newborn screen has been collected. The receiving facility should also note in the medical record whether newborn screening has been done. If it has not been done prior to transfer, the receiving facility should perform a newborn screen upon admission and follow any newborn screening schedules as appropriate to the status and treatment of the transferred infant.

**Transfusions/Blood Products/ECMO**

It is critical to collect a dried blood spot specimen for newborn screening for metabolic and endocrine disorders prior to the first transfusion/ECMO/blood product administration if possible. Even small transfusions can result in inaccurate screening test results. Therefore. a repeat dried blood spot specimen should be collected 120 days after the last receipt of blood product from infants who have received them during the newborn period. By this time, the specimen will no longer contain donor cells that could result in false-negative test results. Please note: This transfusion protocol is only applicable when the DBS schedule is interrupted. If all recommended specimens have been collected according to the appropriate guidelines and no further testing is necessary, please disregard this protocol. Additionally, when submitting specimens, ECMO should be specified as a "transfusion" on the NBS DBS card by facilities when they submit specimens.

**Low Birth Weight Infants**

Low birth weight infants (<2500 grams at birth) who were tested before 24 hours of life should have a screen at 48-72 hours. In infants <34 weeks gestational age or <2000 grams at birth, an additional third screen at 28 days of life or discharge, whichever comes first, is recommended.

If a low-birth-weight infant shows clinical signs consistent with any disorder prior to the scheduled collection of additional screening specimens, confirmatory testing should be done immediately. The state-designated Newborn Screening Follow-Up Programs can be consulted and have on-call specialists available. Refer to Section 9.4: Follow-Up Program Contact Information for information on contacting the Newborn Screening Follow-Up Programs.

Screening at 24-48 hours may result in inaccurate results in some newborns, such as elevated 17-hydroxyprogesterone (17-OHP) levels in premature infants and reduced thyroxine (T4) in some cases, which can cause false positives for certain conditions like congenital adrenal hyperplasia and hypothyroidism. These transient imbalances in hormone levels can affect the accuracy of metabolic and endocrine screenings, making it important to follow the NBS guidelines for re-screening and follow-up as appropriate.

**Parenteral Nutrition**

Parenteral nutrition (PN) may cause marked elevations in amino acid and acylcarnitine profiles, leading to potential false-positive results. Please collect the specimen before initiating PN whenever possible. If the specimen cannot be obtained prior to starting PN, a follow-up specimen should be collected 48-72 hours after it is discontinued to allow for the return to baseline. Please check the "Yes" box for TPN on the NBS DBS card to account for the potential influence on the screening results.

**NPO/ IV Fluids Only**

When an infant is NPO or only receiving IV fluids, newborn screening should continue according to NICU admission newborn screening criteria. While newborn screening can be performed without oral or enteral feeding, it is important to recognize that feeding activates certain metabolic pathways essential for the accurate detection of specific conditions. Without feeding, there is a potential for missed opportunities to identify conditions that rely on metabolic processes triggered by feeding such as phenylketonuria (PKU), maple syrup urine disease (MSUD), and galactosemia. Despite this potential reduction in accuracy for feeding-dependent conditions, other conditions which do not rely on feeding for diagnosis, such as hypothyroidism, cystic fibrosis, sickle cell disease, etc., which are part of the core screening panel, can still be assessed. Adhering to the NBS guidelines ensures the early detection of life-threatening conditions and prevents missed diagnoses, enabling timely intervention and optimal outcomes.

**Older Infants/Children**

Screening of infants older than 3 months old may yield in unreliable results, as reference ranges for markers (other than the hemoglobinopathies) are validated only for the newborn period. For infants up to 12 months of age who were not screened as newborns or lack available screening results, a new specimen should be collected and interpreted alongside clinical and physical findings.

# SECTION 6: PREVENTING SUBMISSION OF NEWBORN SCREENING CARDS THAT ARE UNSATISFACTORY FOR TESTING

## 6.1 REQUIREMENTS FOR NEWBORN SCREENING CARD ACCEPTABILITY FOR TESTING

**Demographic Data Inspection**

The Georgia Public Health Laboratory reviews the NBS DBS card to ensure patient information, date and time of birth, date and time of collection, submitter, and clinician information are complete. NBS DBS cards that lack this information cannot be reported until the missing information is resolved, or the specimen is re-collected.

**Quality Inspection of Newborn Screening Cards**

Prior to testing, dried blood spot specimens are inspected by the Georgia Public Health Laboratory to ensure that each circle has the amount of blood required for the performance of testing. Georgia Public Health Laboratory inspects all NBS DBS cards to verify that the entire circle is filled with blood and the blood has soaked into the filter paper.

**Example of a Satisfactory Specimen:**
Circles are filled completely to the outer edge and evenly saturated. The reverse side looks the same. All demographic information is provided.

## 6.2 CATEGORIES OF UNSATISFACTORY RESULTS

An NBS DBS specimen with a suboptimal quantity or quality of blood or missing demographic or clinical data is deemed unsatisfactory. Samples deemed unacceptable for testing are reported as "UNSATISFACTORY – PLEASE RESUBMIT." Unsatisfactory specimens result in the inconvenience and cost of re-collection of a specimen and delays in results, placing the infant at risk for a delayed diagnosis. It is the responsibility of the birthing facility and listed provider to ensure specimens are collected correctly, and the NBS DBS demographic information is correct and complete.

DPH
GEORGIA DEPARTMENT OF PUBLIC HEALTH

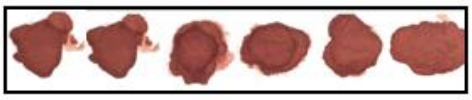
**Georgia Newborn Screening Program**
Newborn Dried Blood Spot (DBS) Collection
*Satisfactory and Unsatisfactory Specimens*

It is important to collect and submit satisfactory newborn dried blood spot (DBS) specimens. Submitting unsatisfactory DBS specimens can result in delays in screening, placing the newborn at risk for delayed diagnosis.

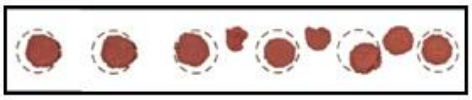
### Satisfactory Specimens

**Satisfactory specimen** — Circles are filled completely to the outer edge and evenly saturated. The reverse side looks the same.

### Unsatisfactory Specimens

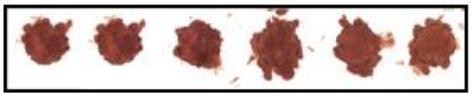


**Layered specimen** — Blood was applied multiple times to the same circle or the circle was filled on both sides of the filter paper.



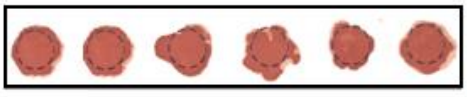
**Insufficient quantity of blood** — Circles are not completely filled. The reverse side is often poorly saturated as shown.

**Poor saturation** — The reverse side of circles are not completely filled as shown in the examples.



**Heel pressed against filter paper** — Specimens often have poor saturation on the reverse side as shown.


**Blood is chafed/abraded/torn** — This can happen when blood is applied using a capillary tube or other device.



**Serum rings** — Possible causes: anemic infant, excessively squeezing area surrounding puncture site, allowing filter paper to come in contact with alcohol, applying blood to filter paper with a capillary tube.

The Georgia Public Health Laboratory Newborn Screening Unit can be contacted with questions at (404) 327-7950. Additional information is available at: www.dph.ga.gov/NBS.

**Table 6.1 Reasons for Specimens to be Determined to be "Unsatisfactory-Please Resubmit"**

| CODE | REASONS FOR SPECIMENS TO BE DETERMINED TO BE "UNSATISFACTORY – PLEASE RESUBMIT" |
|---|---|
| 1 | **Oversaturated:** Excessive application of blood; applying blood to both sides of the filter paper. |
| 2 | **Delayed:** Received >10 days after the date of collection. |
| 3 | **Contaminated:** Excessive squeezing of the puncture site produces serous fluid; filter paper in contact with alcohol/antiseptic solution, hand lotion or powder, food, or water. |
| 4 | **Uneven Saturation:** The circle is not filled completely with blood and/or blood soaked through the filter paper from front to back. |
| 5 | **Capillary (Scratched/Abraded):** Uneven application of blood from a capillary tube. Capillary tubes have heparin which may lead to diluted or contaminated specimens. |
| 6 | **Expired Form:** Out of date or obsolete form. Always check the expiration date printed on the NBS DBS card. |
| 7 | **Crumpled:** Grossly oversaturated, excessive blood application that results in clumps or retraction of the filter paper (appears as though filter paper was put in water and then dried) |
| 8 | **Roughed Up:** Excessive handling of the specimen card or drying the specimen with heat. |
| 9 | **No Blood / Grossly QNS:** No blood on the card; scant amount of blood applied to the card. |
| 10 | **Insufficient Information:** Data not entered on the form. |
| 11 | **Blood Reattached to Form:** Filter paper with blood is stapled or reattached to the form, unable to verify that the blood specimen belongs to a specific child. |
| 12 | **ID Mismatch:** Mismatch of information on the NBS DBS card. |
| 13 | **Specimen Damage in Transit:** Screen unsuitable for testing. |
| 14 | **Invalid/Illegible Demographics:** Data on the form is not valid (e.g., the date of collection is prior to the date of birth; the submitter's handwriting is not legible). |
| 15 | **Lab Accident:** Lab accident. |
| 16 | **Incorrect Name and/or Blood:** Incorrect name and/or blood. |
| 17 | **Missing Infant Name:** No infant name listed. |

| CODE | UNSATISFACTORY REASON CONTINUED… |
|---|---|
| 18 | **QNS (Quantity Not Sufficient):** The quantity of blood is not sufficient for testing. |
| 19 | **Other:** Other |
| 20 | **Clots in Blood:** Clots visible on blood spots. |
| 21 | **Improperly Dried:** Blood on the flap of the card; heat used on the specimen. |
| 22 | **Pale Blood:** Blood is pale, indicating a low hematocrit, and appears watery, thin, and pink in color. |

## 6.3 CORRECTING AN UNSATISFACTORY NEWBORN SCREENING CARD

It is the responsibility of the birthing facility and the listed provider to contact the parents/guardians of an infant from whom the initial specimen was unsatisfactory to coordinate a repeat NBS DBS specimen collection.

Submitters who collected what is determined to be an unsatisfactory specimen will receive written notification from the Georgia Public Health Laboratory advising them of the reason that the initial specimen was unsatisfactory and the need to recollect and submit a specimen using a new NBS DBS card.

Submitters who have failed to include information on the NBS DBS card that is required for testing, will receive written notification and a Request for a Corrected Report form (Appendix O: Newborn Screen Correction Form). Submitters are required to complete, print, sign, and fax the form to the laboratory at **(404) 327-7919** for testing of the submitted specimen to be completed and the results to be finalized and reported.

# SECTION 7: CRITICAL CONGENITAL HEART DISEASE (CCHD) SCREENING

## 7.1 CCHD OVERVIEW

Congenital heart defects (CHDs) are problems with the heart's structure that are present at birth. Congenital heart defects are the most common birth defects and occur in almost 1% of births. There are many types of heart defects, with different degrees of severity based on size, location, and other associated defects. Critical Congenital Heart Disease (CCHD) screening with pulse oximetry is used to detect 12 CCHD conditions and six non-CCHD, secondary conditions.

Note: CCHD screening with pulse oximetry is only one tool for identifying newborns with CCHD. Due to the test's limitations and the characteristics of certain CCHD types, the sensitivity of pulse oximetry screening for

CCHD ranges from 50% to 76%. As a result, it is important to understand that CCHD cannot be ruled out based solely on "passing" pulse oximetry screening. Additionally, even when CCHD is excluded, pulse oximetry may still detect other hypoxemic conditions.

| Core Conditions (CCHD) | Secondary conditions (non-CCHD) |
|---|---|
| • Coarctation of the aorta<br>• Double outlet right ventricle<br>• Ebstein's anomaly<br>• Hypoplastic left heart syndrome<br>• Interrupted aortic arch<br>• Pulmonary atresia<br>• Single ventricle (not otherwise specified)<br>• Tetralogy of Fallot<br>• Total anomalous pulmonary venous return<br>• D-Transposition of the great arteries<br>• Tricuspid atresia<br>• Truncus arteriosus<br>• Other critical cyanotic lesions not otherwise specified | • Hemoglobinopathy<br>• Hypothermia<br>• Infection, including sepsis<br>• Lung disease (congenital or acquired)<br>• Non-critical congenital heart defect<br>• Persistent pulmonary hypertension<br>• Other hypoxemic conditions not otherwise specified |

CCHD is life-threatening and requires intervention in infancy. CCHD is not always detected prenatally or upon exam in the nursery. As a result, some infants with CCHD are discharged from the nursery to home, where they quickly decompensate. The Georgia NBS Program requires every newborn to receive a pulse oximetry screen for CCHD after twenty-four (24) hours of life or before discharge, whichever comes first.

Pulse oximetry, or "pulse ox," is a simple, noninvasive, and painless test that measures the percent oxygen saturation of hemoglobin in the blood.

## 7.2 CCHD SCREENING POLICIES AND PROCEDURES

All infants born in Georgia should be screened for CCHD. However, infants who have already received an echocardiogram for any reason may be excluded from screening.

**Personnel:** CCHD screening should be conducted by individuals who have pulse-oximetry testing within their scope of practice, who are trained in the use of pulse oximetry and the CCHD algorithm, and who regularly use pulse oximetry for other purposes.

**Timing of Screening:**
- Screening should occur as close to 24 hours of age or as close to discharge as possible.
- If the infant is admitted into a NICU or SCBU, the screening test should occur prior to discharge or once the infant is weaned from supplemental oxygen.

**Screening Environment:**
Pulse oximetry screening should take place in a quiet space, away from noises and harsh light.

**Equipment:**
A birthing facility-grade pulse oximeter designed for use in infants.

**Screening Algorithm:**
The following algorithm adapted from the American Academy of Pediatrics (AAP) endorsed screening algorithm must be used for CCHD screening. Oster ME, Pinto NM, Pramanik AK, et al; American Academy of Pediatrics, Section on Cardiology and Cardiac Surgery, Section on Hospital Medicine, Committee on Fetus and Newborn. Newborn Screening for Critical Congenital Heart Disease: A New Algorithm and Other Updated Recommendations: Clinical Report. Pediatrics. 2025;155(1): e2024069667.

**CCHD Screening Procedure:**

1. Perform pulse oximetry screening in a quiet space, away from noises and harsh light (e.g., bilirubin lamps and infrared light).

2. Assure that the skin is clean and dry before placing the probe on the infant. Skin color and jaundice do not affect the pulse oximeter reading.

3. Swaddle the infant to reduce infant movement and crying.

4. The screening should occur in the right hand and on either foot. If using only one pulse oximeter, test one site right after the other.

RH Application Foot Application Site

5. Place the probe on the palm or sole of the hand or foot, wrapping the light emitter around the lateral aspect of the hand or foot.

6. The photo emitter and light emitter must be directly opposite each other in order to obtain an accurate reading

7. Secure the probe to the infant's hand or foot using the adhesive or foam tape recommended by the vendor. Do not hold the probe with your own hand.

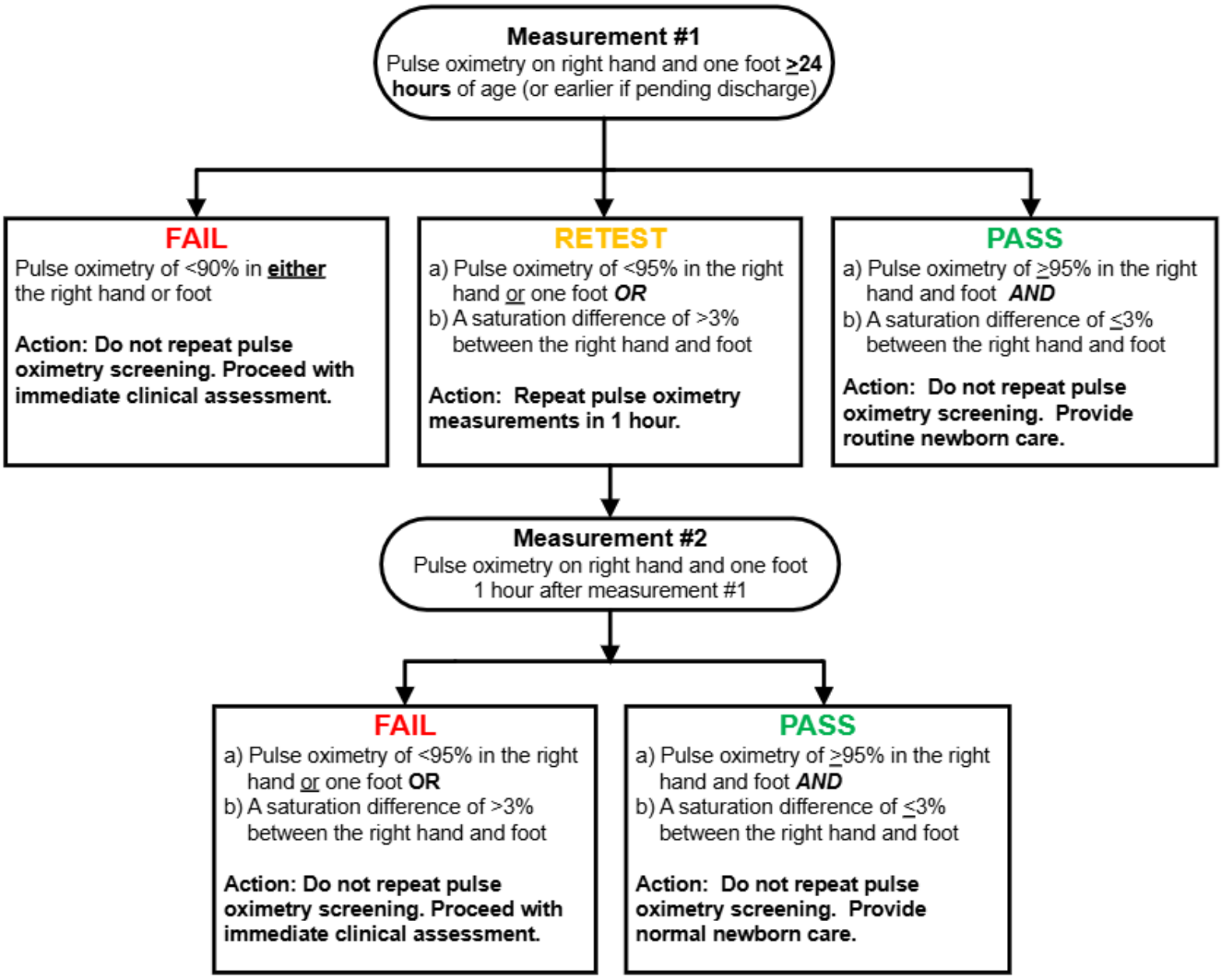
8. Allow the pulse ox to remain on the infant's hand or foot for at least 30 seconds before attempting to obtain a reading. Ensure that the pulse wave (arterial pulse) is consistent, indicating that perfusion to the site being monitored is without motion artifacts.

9. Measure and record baseline oxygen saturation.

10. Use the CCHD screening algorithm adapted from AAP to determine the outcome.
    a. Refer to algorithm.
        i. "Pass result"
        ii. "Fail result" = Action needed

11. Provide appropriate follow-up as needed once results from pulse oximetry screening are completed.

**Algorithm for Critical Congenital Heart Disease (CCHD) Screening with Pulse Oximetry:**




Adapted from Oster ME, Pinto NM, Pramanik AK, et al; American Academy of Pediatrics, Section on Cardiology and Cardiac Surgery, Section on Hospital Medicine, Committee on Fetus and Newborn. Newborn Screening for Critical Congenital Heart Disease: A New Algorithm and Other Updated Recommendations: Clinical Report. Pediatrics. 2025;155(1): e2024069667

*Screening results and any subsequent activity should be recorded in the infant's medical record.*

# 7.3 ABNORMAL CCHD RESULTS

The AAP-endorsed guidelines for the referral of infants with abnormal CCHD screening results should be followed. Infants who fail a screen should not be discharged until a follow-up assessment is completed. Although infants may appear well at the time of the failed screen, those with CCHD may rapidly decompensate as the ductus arteriosus closes, so follow-up on the failed screen should happen before an infant is discharged, rather than as a scheduled follow-up.

**AAP Guidance after a Failed Screen**
The first step is to examine the infant to ensure hemodynamic stability and then begin the process of evaluating for hypoxemia. Depending on the infant's status, this could involve evaluating for sepsis or pneumonia. Any signs or symptoms of congenital heart defect should prompt rapid evaluation, including potential urgent transfer to a center with advanced care capabilities.

If the infant is asymptomatic and otherwise well with no obvious cause for hypoxemia, a cardiologist or neonatologist should be consulted, and an echocardiogram should be performed. Infants should not be discharged home until the underlying reason or hypoxemia has been identified or the hypoxemia has resolved.

Each birthing facility should have a system in place with access to the following:
- Cardiac specialist or neonatologist consultation.
- An echocardiogram can be performed.

1. All birthing facilities and birthing centers shall be equipped to conduct a CCHD screening test on newborn babies in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual.
2. When a live birth occurs in any birthing facility, birthing center, or facility that is equipped to conduct a CCHD screening test, the test shall be conducted prior to the infant's discharge in accordance with the Georgia Newborn Screening Policy and Procedure Manual. Infants who have already received an echocardiogram for any reason may be excluded from CCHD screening.

# 7.4 CCHD REPORTING REQUIREMENTS

All birthing facilities must document each infant's pulse oximetry-CCHD screening results in the patient's medical record. Results must also be provided to parents or legal guardians and reported to DPH. There are two methods of reporting to DPH, as indicated below.

1. **NBS DBS Card** – Write CCHD results on the NBS DBS card and mail them to Georgia Public Health Laboratory. Use this method if CCHD has been completed at the time of NBS DBS collection. See Section 4.2 Guidance for Completing the Newborn Screening Card.
    - Do **not** hold the NBS DBS card pending CCHD results. Send NBS DBS card to Georgia Public Health Laboratory as outlined in Section 2: Responsibilities in the Newborn Screening Process.

**OR**

2. **Delayed Screening Report** (Appendix J: NBS Delayed Screening Report Form) - Method to be used only if CCHD screening was completed after the NBS DBS card was submitted.

- Fax a copy of the delayed screening report form to the Georgia Newborn Screening Program at (404) 657-2773 or email to DPH-NBS@dph.ga.gov. The form can be accessed at www.dph.ga.gov/NBS.
- Place the original form in the medical record.
- Do **not** hold the NBS DBS card pending hearing and/or CCHD screening results.

## 7.5 CCHD IN SPECIAL POPULATIONS

### NICU/SCBU

A CCHD screening test shall be performed prior to NICU/SCBU discharge or at least 24 hours after the baby has been weaned to room air with no supplemental oxygen, or any respiratory support should have an FiO2 of 21%. If weaning to room air prior to discharge is not possible, then echocardiography is warranted and screening with pulse oximetry is unnecessary.

### Prenatal CCHD Diagnosis

Pulse oximetry is not indicated for newborns diagnosed with congenital heart disease prenatally, as their condition has already been identified and is being actively managed. These infants will receive an ECHO. Additionally, infants who have already received an ECHO for any reason may be excluded from CCHD screening.

### Home Births or Infants Discharged Prior to CCHD Screening

CCHD screening can be performed in the primary care setting. The delivery facility should notify the infant's pediatric provider about the missed screening so that screening can be coordinated as soon as possible (e.g., first outpatient visit). Pediatric providers that perform CCHD screenings should have a referral plan for infants who need a repeat screening or an ECHO.

# SECTION 8: NEWBORN HEARING SCREENING

## 8.1 NEWBORN HEARING SCREENING OVERVIEW

All infants born in Georgia must have their hearing screened unless parents refuse due to religious objection. See Appendix D: Parent/Guardian Refusal of Newborn Screening and Appendix E: Declaration of Religious Objection to Newborn Screening Form.

A team of professionals, including audiologists, physicians, audiology technicians, and nursing personnel, is needed to establish and maintain the newborn hearing screening program. An audiologist should be involved in training staff and establishing protocols. Birthing facilities and agencies should designate a physician to oversee the medical aspects of the program.

Timely follow-up testing following a failed hearing screening is critical. There are 18 Early Hearing Detection and Intervention (EHDI) coordinators located around Georgia who help ensure infants who fail their newborn

hearing screening receive timely follow-up. Accurate screening and efficient reporting by the birthing facility are critical in determining the success of these follow-up efforts.

## 8.2 NEWBORN HEARING SCREENING POLICIES AND PROCEDURES

**Personnel:** Hearing screening should only be conducted by individuals who have completed the hearing screening training curriculum directed by an audiologist licensed in Georgia with initial and annual competency documented. See Appendix G: Training and Educational Resources.

**Timing of Screening:**

- Infants must be >32 weeks gestational age.
- Infants should be in stable condition, preferably off oxygen and antibiotics for 24 hours.
- At a minimum, infants must be ≥6 hours of age prior to their hearing screening. Infants should have their hearing screened as close to discharge as practical, while also allowing sufficient time for a single repeat screen to be performed.
- If an infant fails their initial hearing screening, **one repeat screening** (final screening) may be completed at least 4 hours after the first screening

**Screening Environment:**

Newborn hearing screening may be performed in the nursery, parent's birthing facility room, designated quiet room, or NICU. It is best to select an area that is quiet and free of electrical interference. Infants must be asleep and/or very calm and quiet for hearing screening. In many cases, it is best to leave an infant in the caregiver's arms during the test.

**Equipment:**

There are two technologies available for screening of hearing in newborns:

1. **Automated Auditory Brainstem Response (aABR)*** – aABR measurements reflect the status of the peripheral auditory system, the eighth nerve, and the brainstem auditory pathway. The screening level may not exceed 35dB HL.
   ***Infants with a NICU stay >5 days are required to be screened using aABR, as OAEs can miss Auditory Neuropathy Spectrum Disorder (ANSD)*

2. **Automated Otoacoustic Emissions (aOAE)** – OAEs reflect the status of the peripheral auditory system, specifically measuring cochlear (outer hair cell) function.

**Equipment Maintenance Requirements:**

- Equipment must be calibrated according to the manufacturer's recommendation (annually) and monitored with monthly checks to ensure proper operation.
- Calibration certificates must be kept on record annually.
- Logs must be maintained to show monthly equipment checks and any equipment issues with dates and explanations.
- Birthing facilities should have alternate plans for newborn hearing screening in the event of equipment malfunction.

**Hearing Screening Procedure:**

1. Ensure the infant is medically stable, >32 weeks gestation, and ≥6 hours old (ideally >12 hours old).

2. Assess the infant's status and only attempt the screening if it is asleep and/or very calm. Consider hearing screening immediately after feeding to increase the likelihood of the infant being calm for testing.

3. Have a caregiver hold the infant and/or swaddle the infant if able.

4. Set the infant up for hearing screening per the manufacturer's instructions.

5. Begin the hearing screening.

6. Assess for validity of hearing screening:
    a) Is the infant quiet and/or asleep?
    b) Are electrodes (if applicable) on well with low impedance?
    c) Are earphones and/or inserts on the ears?
    d) Is the room quiet?

    -If **yes** to all the above, proceed with testing, as the results should be valid.
    -If **no** to any of the above, pause the screening, correct the issue, and then resume screening.

7. Equipment will provide a result of "Pass" or "Fail/Refer"

If the infant fails the hearing screening in one or both ears, one additional screening can be completed prior to discharge. You must wait 4 hours in between screenings, and both ears will need to be tested.

## 8.3 NEWBORN HEARING SCREENING RESULTS

**Pass Result for both ears *(initial and/or final screening):***

1. Report results to DPH (see Section 8.4 Newborn Hearing Screening Reporting Methods and Requirements) and document results in the infant's medical record.
2. Inform parents of results verbally and in writing in their preferred language.
3. Inform the Primary Care Provider (PCP) on file of results (e.g., in the discharge summary).

**Fail/Refer Result for One or Both Ears *(initial screening):***

1. Inform the caregiver/s of the results and indicate whether you will be repeating the screening prior to discharge. If you will not be completing a second screening, skip to the *final screening* instructions below.
2. It is recommended that the hearing screen be repeated prior to discharge with at least four hours between screenings, if possible.
    - Only one re-screen is permissible prior to birthing facility discharge (a total of two hearing screenings per infant).
    - Rescreening of both ears is required, even if only one ear failed the initial screening.
3. You do not need to report the initial screening results, only the *final screening results*.

**Fail/Refer Result for One or Both Ears *(final screening):***

1. Report results to DPH (see Section 8.4 Newborn Hearing Screening Reporting Methods and Requirements) and document results in the infant's medical record.

2. Inform parents of results verbally and in writing in their preferred language with follow-up recommendations. Utilize Newborn Hearing Screening Results and Recommendation Form
3. Educate caregiver/s on the importance of completing follow-up testing (i.e., unidentified hearing loss can cause speech, language, and reading issues; follow-up testing can be very difficult once the infant is >3 months old, as they may not sleep for the test) via access to DPH's "Have You Heard?" resource.
4. Provide caregiver/s with follow-up locations. Best practice: Schedule an appointment prior to discharge.
5. Inform the Primary Care Provider (PCP) on file of results (e.g., in the discharge summary).

**Hearing-Targeted Congenital Cytomegalovirus (cCMV) Testing:**

As of October 10, 2024, if an infant does not pass the initial or final inpatient newborn hearing screening, in cases where a second screening is performed, the hospital or birthing center shall conduct cCMV testing before discharge or 21 days of age, whichever occurs earlier.

cCMV testing must be completed via urine or saliva Polymerase Chain Reaction (PCR). Saliva Loop-Mediated Isothermal Amplification (LAMP) is also acceptable. For all patients who fail their final hearing screening, the cCMV test status (e.g. pending results, not completed) must be shared with the primary care physician on record (e.g. on the discharge summary) and provided to the family. The final test result must be included in the patient's medical record. All positive cases of cCMV must be reported to DPH within 7 days (best practice is within 72 hours of result).

DPH's designated follow-up program will provide the healthcare provider on record with education, next steps, and assistance with referral coordination on all positive cases of cCMV reported to DPH prior to 21 days of life.

See the Congenital Cytomegalovirus (cCMV) Policy and Procedure Manual and https://dph.georgia.gov/EHDI/ccmv for more information.

## 8.4 NEWBORN HEARING SCREENING REPORTING METHODS AND REQUIREMENTS

NBS DBS Card is the default reporting method unless the birthing facility formally requests a different reporting method. Some birthing facilities may find electronic birth certificates or secure data file transfer advantageous. See Appendix K: Instructions for Selecting Hearing Screening Reporting Method for more information.

**Hearing Screening Reporting Methods:**
All birthing facilities must document all newborn hearing screening results and/or status (e.g., pass, fail, missed, transferred, etc.) in the patient's medical record or in a manual log in the hospital unit, report results to DPH, and provide results to the parents or legal guardians.

There are three methods for reporting hearing screening results to DPH. Each birthing facility must notify DPH of their preferred method of reporting (DPH-NBS@dph.ga.gov). Otherwise, NBS DBS card is the presumed method. See Appendix K: Instructions for Selecting Hearing Screening Reporting Method for more information.

1. **Newborn Dried Blood Spot Card (+ Delayed Screening Form):**
   - Write hearing screening results on the NBS DBS card and mail it to Georgia Public Health Laboratory
   - Do **not** hold the NBS DBS card to wait for hearing screening results.

**OR**

2. **Electronic Birth Worksheet (+ Delayed Screening Form):**
   - Submit hearing screening results via Electronic Birth Worksheet (Newborn Screening Section)
   - Ensure the birthing facility data clerk has access to and is trained on entering newborn hearing screening results into the Electronic Birth Worksheet.
   - Ensure the birthing facility has informed DPH of the reporting method selection, as data will not be received unless DPH is made aware to accept the data via this method. For more information, see Appendix K: Instructions for Selecting Hearing Screening Reporting Method.

**OR**

3. **Secure Data File Transfer**
   - Send a CSV file with all required information.
   - Ensure the birthing facility has informed DPH of the reporting method selection, as data will not be received unless DPH is made aware to accept the data via this method. For more information, see Appendix K: Instructions for Selecting Hearing Screening Reporting Method.

**+Delayed Screening Report Form** (Appendix J: NBS Delayed Screening Report Form) – This method should be used in conjunction with the NBS DBS Card and Electronic Birth Worksheet when the final hearing screening is completed after the NBS DBS card or Electronic Birth Worksheet is submitted.

- Fax a copy of the delayed screening report form to the Georgia Newborn Screening Program at (404) 657-2773 or email it to DPH-NBS@dph.ga.gov. The form can also be accessed at www.dph.ga.gov/NBS.

***Each birthing facility must notify DPH of their preferred method of reporting (DPH-NBS@dph.ga.gov), otherwise NBS DBS card is the presumed method.***

## 8.5 NEWBORN HEARING SCREENING IN SPECIAL POPULATIONS

**Infants >5 days in the NICU:** Infants must be tested using aABR technology.

**Infants with Congenital Aural Atresia:** Infants with congenital aural atresia in one or both ears or with visible pinna/ear canal deformity such as anotia, stenosis, or severe malformation should not be screened in either ear but should be referred for diagnostic audiologic evaluation immediately. (This can be completed inpatient if an audiologist is on staff. Otherwise, assist family if scheduling as an outpatient).

# SECTION 9: FOLLOW-UP PROGRAM PROCEDURES

## 9.1 METABOLIC CONDITIONS FOLLOW-UP

**Emory University Department of Human Genetics Follow-Up Program:**
The Emory Follow-Up program is a contracted service that consists of a team dedicated to reporting, providing support, and gathering data through the follow-up process for all children with an abnormal newborn screen of the following disorders:

- Organic Acid Disorders
- Fatty Acid Oxidation Disorders
- Amino Acid Disorders
- Lysosomal Storage Disorders
- Endocrine Disorders
- Other Disorders

The follow-up team at Emory is responsible for locating the infant with the abnormal result and contacting the health care provider listed on the newborn screening card to report the abnormality, delivering education and resources about the condition, and providing recommendations on how to proceed.

Abnormal newborn screening results are triaged into three categories:

- **Borderline:** These results and recommendations are reported via fax to the provider listed on the NBS DBS card. A letter is also mailed to the family asking them to contact their healthcare provider about the abnormal newborn screen result.
- **Routine abnormal:** The provider listed on the NBS DBS card is called to report the result and recommendations. These calls are then followed by a fax of the information. Letters are not routinely sent to families.
- **Critical abnormal:** The provider listed on the NBS DBS card is called immediately to report the result and recommendations. These calls are then followed by a fax of the information and a subsequent phone call when action has been delayed. Letters are not routinely sent to families currently.

The faxes will contain the screen results, basic information about the disorder and how to assess the child, and the follow-up recommendation.

**Emory Follow-Up Contact Information:**
Phone Number: (404) 778-8560
Physician on call (including genetics, endocrinology, immunology, pulmonology): (404) 778-8566
Website: www.med.emory.edu/departments/human-genetics/patient-care/newborn-screening.html

## 9.2 HEMOGLOBIN CONDITIONS FOLLOW-UP

**Augusta University, Children's Healthcare of Atlanta, and The Sickle Cell Foundation:**

Sickle Cell Disease (SCD) is the most prevalent genetic disorder identified by NBS in Georgia and includes both homozygous (Hb SS) and compound heterozygous forms of SCD (e.g., sickle Hb C disease, sickle β° thalassemia, and sickle $\beta^+$ thalassemia). The screening methodologies used also detect a variety of other clinically significant non-sickle hemoglobinopathies, such as homozygous Hb C, hemoglobin C/ $\beta^+$ and β° thalassemia, homozygous E, hemoglobin E/ $\beta^+$ and β° -thalassemia disease and others.

Infants with NBS results indicative of SCD or other clinically significant hemoglobinopathies should have confirmatory testing performed as soon as possible in early infancy so that family education and comprehensive care (including prophylactic penicillin for those with SCD) can be initiated during the first 2-3 months of age before signs and symptoms usually develop. For infants with SCD, timely completion of these actions is crucial in reducing the morbidity and premature death associated with SCD.

In Georgia, responsibility for ensuring timely follow-up is divided between Children's Healthcare of Atlanta (CHOA) for greater Metro-Atlanta counties and the Division of Pediatric Hematology/Oncology at Augusta University (AU) for all other counties located across Georgia (Athens, Albany, Dublin, Valdosta, and Waycross), and public health departments and agencies throughout the state to ensure that all babies identified with abnormal results receive timely diagnosis and treatment. The programs also utilize outreach and some telemedicine clinics to extend the reach of specialty care in more rural areas. AU operates clinics in Athens, Albany, Dublin, Valdosta, and Waycross, and CHOA has monthly SCD outreach clinics in Columbus. The follow-up teams also provide education and counseling to families and serve as a resource for physicians, partners, and families. Cases are referred to the county health departments as needed and the Office of Child Health district programs for child health intervention services.

Newborn screening also identifies healthy heterozygous carriers of sickle cell trait and other hemoglobin variants (e.g., Hb C, D, E) as well as some with thalassemia. The Sickle Cell Foundation of Georgia (SCFGa) and AU Sickle Cell Program provide treatment, counseling, and education to families of infants affected by SCD.

**Augusta University (AU) Hemoglobin Follow-up Program Contact Information:**

- NBS Program Coordinator: (706) 721-6251; On-call MD: (706) 721-5600
- Website: www.augusta.edu/centers/blood-disorders

**Children's Healthcare of Atlanta (CHOA) Hemoglobin Follow-up Program Contact Information:**

- NBS Follow-up Coordinator: (404) 785-1087 or CHOA Hematologist On-call MD: (404) 785-7778
- Website: www.choa.org/medical-services/cancer-and-blood-disorders/blood-disorders

**The Sickle Cell Foundation of Georgia, Inc (SCFGa):**

- SCFGa NBS Coordinator: (404) 755-1641 or 1-800-326-5287 (toll free)
- Website: www.sicklecellga.org

**Hemoglobin Follow-up Program's Responsibilities**

The hemoglobin follow-up programs are contracted services. The follow-up teams at CHOA and AU ensure that abnormal hemoglobin results are reported to the health care provider listed on the NBS DBS card or the current primary care provider. Support is provided to PCPs in educating the family about the results of the newborn screening test and coordination of referral to hematology specialty care for diagnostic testing and appropriate treatment. When necessary, the follow-up teams provide education and counseling directly to

families. Confirmed cases are referred to the Children 1st Program for determination of eligibility for DPH child health intervention services, and results of confirmatory testing are reported through SENDSS.

**NBS Follow-up Program Coordinators fax the following information to healthcare providers:**

1. A letter that explains the screening mandate, confirmation process, and contact information.
2. Copy of the Georgia Public Health Laboratory NBS report
3. Copy of The American College of Medical Genetics, Newborn Screening ACT Sheets and Confirmatory Algorithms
4. Confirmatory testing information depending on the follow-up program:
    1. AU: Copies of a lab slip for the Titus H.J. Huisman Hemoglobinopathy Laboratory at the Medical College of Georgia at Augusta University.
    2. CHOA: A referral is made to the hematology clinic for confirmatory testing at the first visit.

Signs of sickle cell disease can develop shortly after birth, which is why it is important to collect the confirmatory test (hemoglobin electrophoresis and high-performance liquid chromatography) as soon as possible, without delay. Below are resources for the collection of the test:

- The Hemoglobin Reference Laboratory located at Augusta University in Augusta, Georgia, is an international testing and reference center for sickle cell disease, thalassemia, and other hemoglobin disorders. The AU laboratory is one of a few in the country that studies abnormal hemoglobin and is a resource for researchers and providers throughout the country and beyond, it is the preferred testing site for AU confirmatory testing. Testing at AU is free for NBS confirmation of hemoglobinopathy and associated family studies. There may be a fee incurred for other testing; the lab should be contacted directly for additional information.
- The hematopathology laboratory of CHOA or Grady Birthing facility performs capillary hemoglobin electrophoresis five days per week with high-performance liquid chromatography (HPLC) confirmation of all abnormal hemoglobin variants.

**Special Circumstances – Transfusions:**

Receipt of a blood transfusion prior to specimen collection confounds the interpretation because the transfused hemoglobin of the blood donor remains in circulation for 120 days. Therefore, it is essential that both the initial NBS and subsequent confirmatory test specimens be collected prior to any blood transfusion. In situations where this is not possible, the prior transfusion history should be clearly indicated by the submitter of the specimen.

**Abnormal HgB Results for Transfused Infants**

Dried blood spot screening results that indicate the presence of sickle hemoglobin and normal hemoglobin in an infant transfused prior to blood collection should be referred as soon as possible to a reference lab for genetic (DNA) testing to exclude sickle cell disease. For confirmatory testing information contact Augusta University (706) 721-6251 and Children's Healthcare of Atlanta (404) 785-1087.

**Follow-up Recommendations:**

Post-transfusion confirmatory testing (HPLC, IEF, or DNA testing) should be completed in consultation with the newborn screening hematology consultant.

**Healthcare Provider's Responsibilities:**

The provider listed on the NBS DBS card is responsible for contacting the family to arrange diagnostic testing and follow-up. If the provider is not following the patient, the NBS follow-up team attempts to identify the current primary care provider (PCP). If no PCP is identified, the NBS follow-up team contacts the family directly to provide the results of the abnormal newborn screen.

**PCPs are asked to do the following:**

- Contact the family to schedule an appointment as soon as possible and share the NBS results and educational literature with them during the initial visit.
  - Notify the NBS Follow-up Coordinator if the family is seeing another healthcare provider.
  - If no provider can be located, provide notification about the abnormal results to the family by phone or by certified mail if unable to reach them by phone.
- Refer all NBS cases to a pediatric hematologist or SCD (Sickle Cell Disease) outreach clinic.
  - If confirmatory testing is performed before the first hematology visit, please fax the results to the NBS Follow-up Coordinator.
- Educate caregivers on the basics of SCD, including its genetic component, the immediate need for penicillin prophylaxis, and the benefits of protein-conjugated pneumococcal immunizations.

The NBS Follow-up Coordinators should make every attempt to contact the patient's PCP office to facilitate penicillin prophylaxis initiation within one month of birth (if warranted) and ensure SCD diagnosis confirmation. The NBS Follow-up Coordinator should notify the NBS Program to engage CHOA or Augusta University for evaluation of the need for penicillin prophylaxis and confirmatory diagnosis.

If the patient doesn't have a PCP or the parents refuse PCP recommendations, the NBS Follow-up Coordinator will contact the families with information about the abnormal test and assist with identifying a PCP and other interventions as needed for diagnosis confirmation.

## 9.3 NEWBORN HEARING SCREENING FOLLOW-UP

DPH has 18 Early Hearing Detection and Intervention (EHDI) district coordinators located around Georgia who can assist families in locating timely follow-up hearing testing.

To locate the EHDI coordinator for your health district, visit the Women, Children, and Nursing Service Locator and filter by the "Early Hearing Detection and Intervention" program.

## 9.4 FOLLOW-UP PROGRAM CONTACT INFORMATION

**Emory Follow-Up Contact Information**

The Emory Follow-Up program provides follow-up for infants with an abnormal newborn screen of the following disorders:

- Organic Acid Disorders
- Fatty Acid Oxidation Disorders
- Amino Acid Disorders
- Lysosomal Storage Disorders
- Endocrine Disorders
- Other Disorders

Phone Number: (404) 778-8560
Physician on call (including genetics, endocrinology, immunology, pulmonology): (404) 778-8566
Website: www.med.emory.edu/departments/human-genetics/patient-care/newborn-screening.html

**Augusta University (AU) Hemoglobin Follow-up Program**
The AU follow-up program provides follow-up for infants with NBS results indicative of SCD or other clinically significant hemoglobinopathies in designated locations outside of the greater Metro-Atlanta area.

- NBS Program Coordinator: (706) 721-6251; On-call MD: (706) 721-5600
- Website: www.augusta.edu/centers/blood-disorders

**Children's Healthcare of Atlanta (CHOA) Hemoglobin Follow-up Program**
The CHOA follow-up program provides follow-up for infants with NBS results indicative of SCD or other clinically significant hemoglobinopathies within the Greater Metro-Atlanta area and areas in the northwest part of the state.

- NBS Follow-up Coordinator: (404) 785-1087 or CHOA Hematologist On-call MD: (404) 785-7778
- Website: www.choa.org/medical-services/cancer-and-blood-disorders/blood-disorders

**The Sickle Cell Foundation of Georgia, Inc (SCFGa): Hemoglobin Traits/Carriers Follow-up**

The Sickle Cell Foundation of Georgia, Inc. (SCFGa) is responsible for following up on abnormal hemoglobin results that suggest a carrier or "trait" status (sickle C, D, E, and alpha thalassemia). The SCFGa staff provides testing, counseling, and education for the Georgia Newborn Screening Program. Additionally, SCFGa serves as a specimen collection site for confirmatory testing of clinically significant hemoglobin disorders and family studies.

- SCFGa NBS Coordinator: (404) 755-1641 or 1-800-326-5287 (toll-free)
- Website: www.sicklecellga.org

**Early Hearing Detection and Intervention (EHDI) District Coordinators:**
There are 18 EHDI coordinators located throughout Georgia, 1 per health district. The district EHDI coordinator will assist infants who failed their hearing screening get follow-up testing within 3 months of age.

To locate the EHDI coordinator for your health district, visit https://sendss.state.ga.us/ords/sendss/!mch.coord_search and filter by "Early Hearing Detection and Intervention" program.

# SECTION 10: APPENDICES AND REFERENCES

## 10.1 APPENDICES

## APPENDIX A: GLOSSARY OF TERMS

**Newborn Screening Definitions:**

**Abnormal test result**: A test result that is outside the screening limits set forth in the current edition of the Georgia Newborn Screening Program Policy and Procedure Manual.

**Adequate specimen**: A NBS DBS specimen that is properly collected in accordance with the current edition of the Georgia Newborn Screening Program Policy and Procedure Manual.

**Approved laboratory**: A laboratory licensed in Georgia, which has been specifically approved by the Georgia Department of Public Health to conduct laboratory analysis of NBS DBS specimens for the disorders specified in the Georgia Newborn Screening Policy and Procedure Manual.

**Automated auditory brainstem response (aABR)**: A specific test method that measures the brainstem's response to acoustic stimulation of the ear, using equipment that automatically provides a pass/refer outcome.

**Automated Otoacoustic Emissions Testing (aOAE)**: A specific test method that elicits a physiologic response from the outer hair cells in the cochlea, using equipment that automatically provides a pass/refer outcome.

**Birthing center/facility**: Any facility that is licensed by the Georgia Department of Community Health as a birthing center.

**Dried Blood Spot Specimen (DBS)**: This is a blood sample collected on filter paper and air dried before transport to the laboratory for screening.

**Confirmatory test/diagnostic test**: A test to prove or disprove the presence of a specific disease/condition suspected due to NBS results.

**Critical Congenital Heart Disease (CCHD)**: A group of serious heart defects that are present from birth, including coarctation of the aorta (CoA), double-outlet right ventricle, D-transposition of the great arteries, Ebstein's anomaly, hypoplastic left heart syndrome, interrupted aortic arch, pulmonary atresia, single ventricle, total anomalous pulmonary venous connection, tetralogy of Fallot, tricuspid atresia, and truncus arteriosus.

**Gestational age (GA)**: The number of completed weeks in a pregnancy (measured from the first day of the last menstrual cycle until birth).

**Low birth weight (LBW)**:  A birth weight of less than 2500 grams.

**Newborn Screening Specimen Card (NBS DBS Card)**: The current version of DPH Form 3491 is used to collect information and blood specimens from a newborn infant.

**Newborn Hearing Screening Test**: The completion of an objective, physiological test or battery of tests administered to determine the infant's hearing status and the need for further diagnostic testing by an audiologist or physician in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual's approved instrumentation, protocols and pass/refer criteria.

**Newborn Screening and Genetics Advisory Committee (NBSAC)**: A multi-disciplinary group of professional and consumer representatives with knowledge and expertise in newborn screening programs appointed by the Commissioner of Public Health.

**Parenteral nutrition (PN)**: Administration of nutrients intravenously.

**Preterm/premature**: Infant born before 37 completed weeks (259 days) of gestation.

**Recollection**:  Collection of another specimen from the same newborn due to an unsatisfactory initial specimen or due to NICU/SBCU admission retesting recommendations.

**Submitter/Submitting Facility**: Any person or entity submitting an NBS DBS card for analysis, typically the birthing facility, birthing facility, midwife, or birthing center.

**Unsatisfactory Specimen (Unsat)**: An NBS DBS specimen that is rejected by the laboratory because the quality of the specimen does not allow for accurate testing or because critical information is missing from the NBS DBS card, which inhibits the laboratory's ability to accurately identify the infant or interpret the test results.

### Abbreviations and Acronyms:

**DPH:**  Georgia Department of Public Health

**cCMV:** Congenital Cytomegalovirus

**CF**: Cystic Fibrosis

**DBS**:  Dried Blood Spot

**GEORGIA PUBLIC HEALTH LABORATORY:** Georgia Public Health Laboratory

**LBW:**  Low Birth Weight

**NBHS**: Newborn Hearing Screening

**NBS**: Newborn Screening

**NICU**: Neonatal Intensive Care Unit

**POC**: Point-of-Care

**SCBU**: Special Care Baby Unit

**SCD**: Sickle Cell Disease

# APPENDIX B: GEORGIA RULES AND REGULATIONS PERTAINING TO NEWBORN SCREENING

**Public Health Regulations**

The Georgia Department of Public Health is authorized by law to enact administrative regulations to protect public health. Thirty-three separate regulations chapters, each devoted to a particular subject, are available.

Each of Georgia's 159 County Boards of Health is also authorized to enact regulations to protect the public health in their jurisdiction, provided those county regulations do not contradict those of the Department. After reviewing the Department's regulations, you may check with your County Board of Health to see if it has elected to enact supplemental regulations on a particular subject.

**Web Link to Georgia Public Health Code 511-5-5 Testing for Inherited Disorders in the Newborn**

# APPENDIX C: NEWBORN SCREENING PANEL AND DISORDER-SPECIFIC INFORMATION

| | |
|---|---|
| **Organic Acid Disorders** | • Beta Ketothiolase (BKT)<br>• Cobalamin A and B Deficiency (Cbl A,B )<br>• Glutaric Acidemia type I (GA1)<br>• 3-OH 3-CH Glutaric Aciduria (HMG)<br>• Isovaleric Acidemia (IVA)<br>• 3 Methylcrotonyl-Co A Carboxylase Deficiency (3MCC)<br>• Multiple Carboxylase Deficiency (MCD)<br>• Methylmalonic Acidemia (MMA)<br>• Propionic Acidemia |
| **Fatty Acid Oxidation Disorders** | • Carnitine Uptake Defect<br>• Long Chain 3 hydroxyl acyl-CoA dehydrogenase Deficiency (LCHADD)<br>• Medium Chain acyl-CoA dehydrogenase Deficiency<br>• Trifunctional Protein Deficiency (TFP)<br>• Very Long-chain acyl-CoA dehydrogenase Deficiency (VLCADD) |

| | |
|---|---|
| **Amino Acid Disorders** | • Argininosuccinic Acidemia<br>• Citrullinemia<br>• Homocystinuria<br>• Maple Syrup Urine Disease (MSUD)<br>• Phenylketonuria (PKU)<br>• Tyrosinemia |
| **Lysosomal Storage Disorders** | • Mucopolysaccharidosis I (MPSI)<br>• Pompe Disease |
| **Endocrine Disorders** | • Congenital Adrenal Hyperplasia (CAH)<br>• Congenital Hypothyroidism (CH) |
| **Hemoglobinopathy Disorders** | • Sickle Cell Anemia<br>• Sickle Beta Thalassemia<br>• Sickle C Disease<br>• Other Hemoglobin Variants |
| **Other Metabolic Disorders** | • Biotinidase Deficiency<br>• Cystic Fibrosis (CF)<br>• Galactosemia<br>• Severe Combined Immunodeficiency (SCID)<br>• Spinal Muscular Atrophy (SMA)<br>• X-linked Adrenoleukodystrophy (X-ALD)<br>• Krabbe Disease |
| **Critical Congenital Heart Disease (CCHD)** | • Critical Congenital Heart Disease (CCHD) |
| **Congenital Hearing Loss** | • Congenital Hearing Loss |

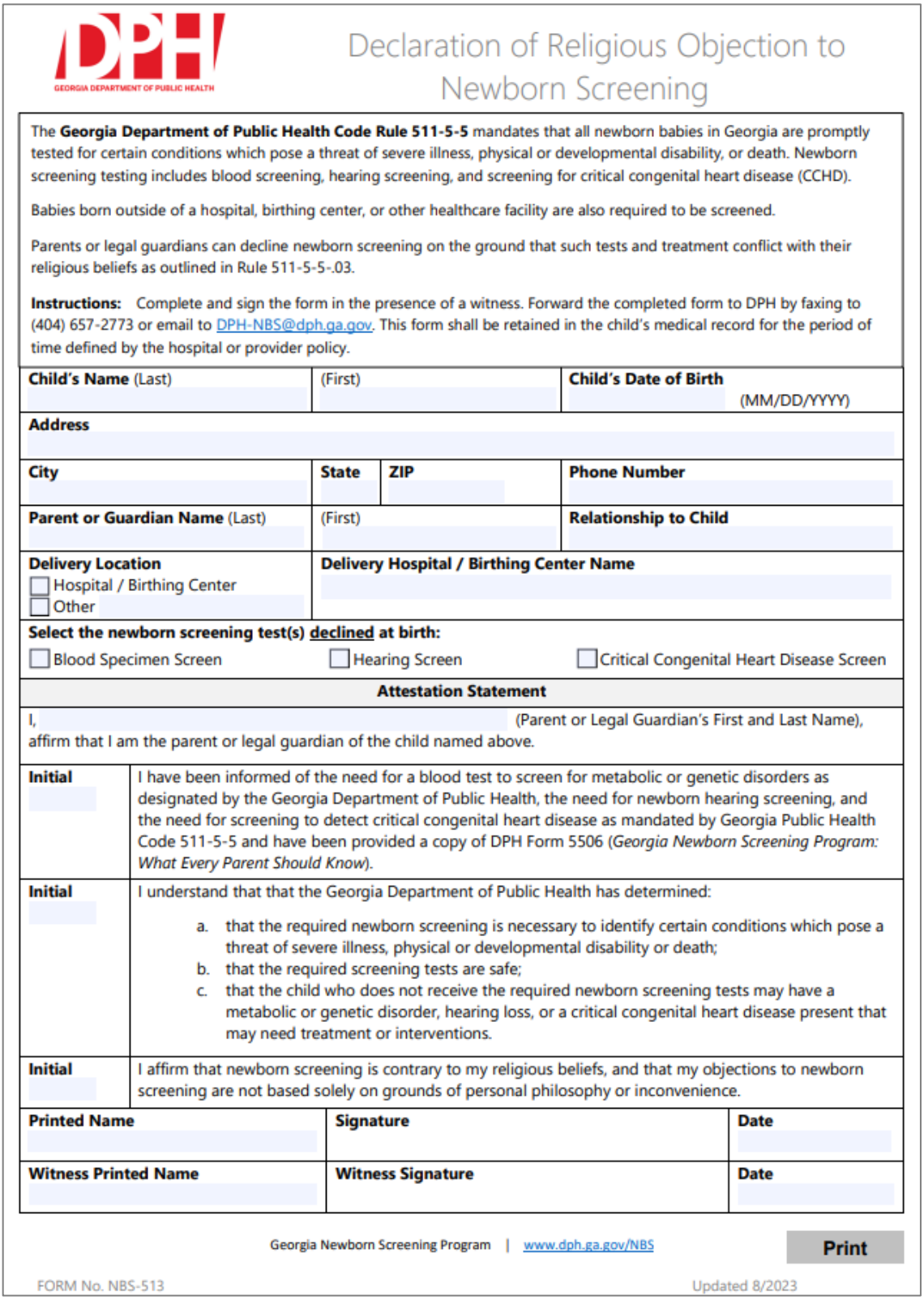
# APPENDIX D: PARENT/GUARDIAN REFUSAL OF NEWBORN SCREENING

Every infant born alive in Georgia shall receive newborn screening, unless the infant's parents or legal guardians object in writing on the grounds that such tests and treatment conflict with their religious beliefs.

The following process must be completed when a parent or legal guardian refuses to consent to newborn screening:

a) Notify appropriate birthing facility staff and infant care provider.
b) Provide parent with a copy of the NBS brochure, *What Every Parent Should Know* (DPH form #5506)
c) Document parent's confirmation that brochure was read, and questions were answered.
d) Offer parent NBS video to view.
e) Document parent confirmation of understanding the purpose of performing NBS.
f) Request the parent complete and sign institution's refusal form or DPH's Declaration of Religious Objection to NBS form (Appendix E: Declaration of Religious Objection to Newborn Screening Form) .
g) The refusal form must be signed by a witness.
h) Place copy of signed refusal form in infant's medical record
i) Fax the completed Refusal Form to DPH (404) 657-2773 or email to DPH-NBS@dph.ga.gov
j) Document parent refusal in the appropriate box on the NBS DBS card and Ship/Mail the NBS DBS card to Georgia Public Health Laboratory.
k) If parent agrees to newborn hearing and CCHD screening but not blood screening, document hearing and CCHD results on the NBS DBS card (or whichever reporting method facility has selected), document parental refusal of blood screening and ship/mail NBS DBS card to the Georgia Public Health Laboratory.

# APPENDIX E: DECLARATION OF RELIGIOUS OBJECTION TO NEWBORN SCREENING FORM



GEORGIA DEPARTMENT OF PUBLIC HEALTH

## Declaration of Religious Objection to Newborn Screening

The **Georgia Department of Public Health Code Rule 511-5-5** mandates that all newborn babies in Georgia are promptly tested for certain conditions which pose a threat of severe illness, physical or developmental disability, or death. Newborn screening testing includes blood screening, hearing screening, and screening for critical congenital heart disease (CCHD).

Babies born outside of a hospital, birthing center, or other healthcare facility are also required to be screened.

Parents or legal guardians can decline newborn screening on the ground that such tests and treatment conflict with their religious beliefs as outlined in Rule 511-5-5-.03.

**Instructions:** Complete and sign the form in the presence of a witness. Forward the completed form to DPH by faxing to (404) 657-2773 or email to DPH-NBS@dph.ga.gov. This form shall be retained in the child's medical record for the period of time defined by the hospital or provider policy.

| | | | | |
|---|---|---|---|---|
| **Child's Name** (Last) | (First) | | **Child's Date of Birth** (MM/DD/YYYY) | |
| **Address** | | | | |
| **City** | **State** | **ZIP** | **Phone Number** | |
| **Parent or Guardian Name** (Last) | (First) | | **Relationship to Child** | |
| **Delivery Location** ☐ Hospital / Birthing Center ☐ Other | **Delivery Hospital / Birthing Center Name** | | | |

**Select the newborn screening test(s) declined at birth:**

☐ Blood Specimen Screen ☐ Hearing Screen ☐ Critical Congenital Heart Disease Screen

**Attestation Statement**

I, (Parent or Legal Guardian's First and Last Name), affirm that I am the parent or legal guardian of the child named above.

| | |
|---|---|
| **Initial** | I have been informed of the need for a blood test to screen for metabolic or genetic disorders as designated by the Georgia Department of Public Health, the need for newborn hearing screening, and the need for screening to detect critical congenital heart disease as mandated by Georgia Public Health Code 511-5-5 and have been provided a copy of DPH Form 5506 (*Georgia Newborn Screening Program: What Every Parent Should Know*). |
| **Initial** | I understand that that the Georgia Department of Public Health has determined:<br>a. that the required newborn screening is necessary to identify certain conditions which pose a threat of severe illness, physical or developmental disability or death;<br>b. that the required screening tests are safe;<br>c. that the child who does not receive the required newborn screening tests may have a metabolic or genetic disorder, hearing loss, or a critical congenital heart disease present that may need treatment or interventions. |
| **Initial** | I affirm that newborn screening is contrary to my religious beliefs, and that my objections to newborn screening are not based solely on grounds of personal philosophy or inconvenience. |

| | | |
|---|---|---|
| **Printed Name** | **Signature** | **Date** |
| **Witness Printed Name** | **Witness Signature** | **Date** |

Georgia Newborn Screening Program | www.dph.ga.gov/NBS

Print

FORM No. NBS-513 Updated 8/2023

Link to the form: https://dph.georgia.gov/document/document/declaration-religious-objection-nbs-form/download

# APPENDIX F: GEORGIA NEWBORN SCREENING PROGRAM POLICY FOR RETENTION AND USE OF RESIDUAL DRIED BLOOD SPOT (DBS) SPECIMENS

DPH must comply with federal HIPPA requirements to protect the privacy of infants and their families and assure that all specimens are protected from inappropriate use or access.

**(1) How the newborn screening specimens will be stored:**

Upon receipt by the Georgia Public Health Laboratory, DBS cards are either stored refrigerated (2-8°C) or at ambient temperature (18-25°C) until testing is completed. After testing is finished, the DBS cards are stored in a walk-in refrigerator in low gas-permeable, zip-closure bags with desiccant and humidity indicator cards and CDC quality assurance materials (base and elevated DBS cards) as recommended by the Clinical and Laboratory Standards Institute (CLSI) until disposed of.

**(2) Length of time that specimens will be stored**

All DBS cards are retained for 16 weeks after testing is completed to allow for re-analysis if questions arise concerning the test results. Specimens that are determined to be presumptive positive for any of the diseases included in the newborn screening panel are stored for at least one year.

Any parent/guardian who desires to have his/her infant's newborn screening specimen (presumptive positive or confirmed case) destroyed twelve weeks after completion of testing may request such action in writing. Any parent/guardian who desires assurance that his/her infant's specimen has been destroyed after completion of testing may request confirmation of such action in writing.

**(3) Who will have access to the specimens**

Georgia Public Health Laboratory is a secure facility. Access to newborn screening specimens is restricted to Georgia Public Health Laboratory staff involved with specimen receipt, testing, data entry, and laboratory management only.

**(4) Use of DBS Specimens**

Residual DBS specimens and associated demographic information are used to support essential NBS program functions such as NBS program evaluation, quality assurance, result verification, test refinement, and quality improvement initiatives. Retained DBS cards and associated demographic information can be used for the following purposes:

- Laboratory quality control, quality assurance, and improvement
- Verification of equipment calibration
- Evaluation of equipment, reagents, and methods of newborn screening tests for conditions approved for screening by the program.
- Validation of equipment and screening methods
- Internal method development and method validation studies, including the setting of appropriate cutoffs or normal ranges.
- Quality assurance audits and gap analysis.

- For a project of public health importance deemed to be research or non-research for the purpose of public policy or health care operations that has been reviewed and approved by the Georgia Department of Public Health as described below.

De-identified NBS DBS samples may be sent to another laboratory when the reason for sending the sample is:

- Participation in a specimen exchange program designed to improve the quality of testing in newborn screening laboratories; or
- Collaboration with another laboratory in developing or validating a newborn screening method. This use requires a statement from the laboratory requesting the specimens that specifies how the specimens will be used, and written approval from the GPHL Director.

**(5) Release of Specimens to Another Entity**

DBS samples may be transferred to other entities as delineated below:

- An entity that has a contract with the *Public Health Department* to perform additional (i.e., second tier) testing in response to an out-of-range screening result.
- A health care provider at the request of the patient, legal guardian, or legal representative after completing and signing a written request form approved by the Public Health Department. See Appendix M: Authorization for Release of Protected Health Information.
- A named person in a legally executed subpoena following review and approval by the attorney general or his/her designee.
- A person to whom release is mandated by order of a court of competent jurisdiction.
- A researcher with written, informed consent from the patient, legal guardian, or legal representative, if the research project has been reviewed and approved by DPH.

**(6) Research or Third-Party Requests**

As part of its public health responsibility to improve newborn screening and public health, the Georgia Department of Public Health will consider study requests to use DBS samples for projects for which informed consent from the legal guardian, or legal representative has been obtained.

Affirmative responses by the Georgia Department of Public Health to a study request using DBSs will depend on, but are not limited to:

- The availability of staff and staff time within the Georgia Public Health Laboratory; and
- Review by the Georgia Department of Public Health's IRB to determine that the study:
  - Compliance with state and federal confidentiality and human subjects research protection requirements.
  - Public health or medical benefit
  - Is appropriate for the purpose and intended outcome of the study.

Prior to submitting a formal project proposal to the Georgia Department of Public Health, an investigator should first contact the Director of the Georgia Public Health Laboratory so the Laboratory Director may better understand the proposed project and advise whether the Laboratory will have sufficient resources to meet the request before the investigator initiates the formal project proposal and IRB process with the Georgia Department of Public Health.

**(7) Disposal**

DBS cards will be autoclaved and then handled as medical waste.

# APPENDIX G: TRAINING AND EDUCATIONAL RESOURCES

**Newborn Dried Blood Spot (DBS) Specimen Collection:**

- Georgia Department of Public Health's Newborn Screening Specimen Collection training video
- Newborn Screening: Sample Collection and Handling procedure instructions courtesy of Revvity

**Newborn Screening and Genetics:**

- The Centers for Disease Control and Prevention serve as the national focus for developing and applying disease prevention and control, environmental health, health promotion, and health education activities designed to improve the health of the United States's population.
- American College of Medical Genetics and Genomics Newborn Screening ACT Sheets: provides immediate steps for physicians to take upon receiving a positive screen for an infant in his or her practice.
- American Academy of Pediatrics (Georgia Chapter) works to improve the health and welfare of all infants, children, and adolescents in the State of Georgia.
- Clinical and Laboratory Standards Institute (CLSI) provides resources on specimen collection and newborn screening.
- Save Babies Through Screening Foundation, Inc. is a parent resource on newborn screening, provides information for parents, disease description information regarding screening in other states, a resource library, family stories, and much more.
- Sickle Cell Disease Association of America
- Sickle Cell Disease Clinical Guidelines
- Sickle Cell Information Center provides sickle patient and provider education.
- Sickle Cell Foundation of Georgia provides education to Georgia communities to improve the quality of life for people affected by Sickle Cell Disease.
- Cystic Fibrosis Foundation provides CF education and resources.
- National Organization for Rare Disorders

**Hearing Screening:**

- Newborn Hearing Screening - Automated Auditory Brainstem Response (AABR) serves as a Georgia-specific training resource created by Georgia-licensed audiologists.
- National Center for Hearing Assessment and Management serves as the National Technical Resource Center for all state-based Early Hearing Detection and Intervention (EHDI) programs in the United States.

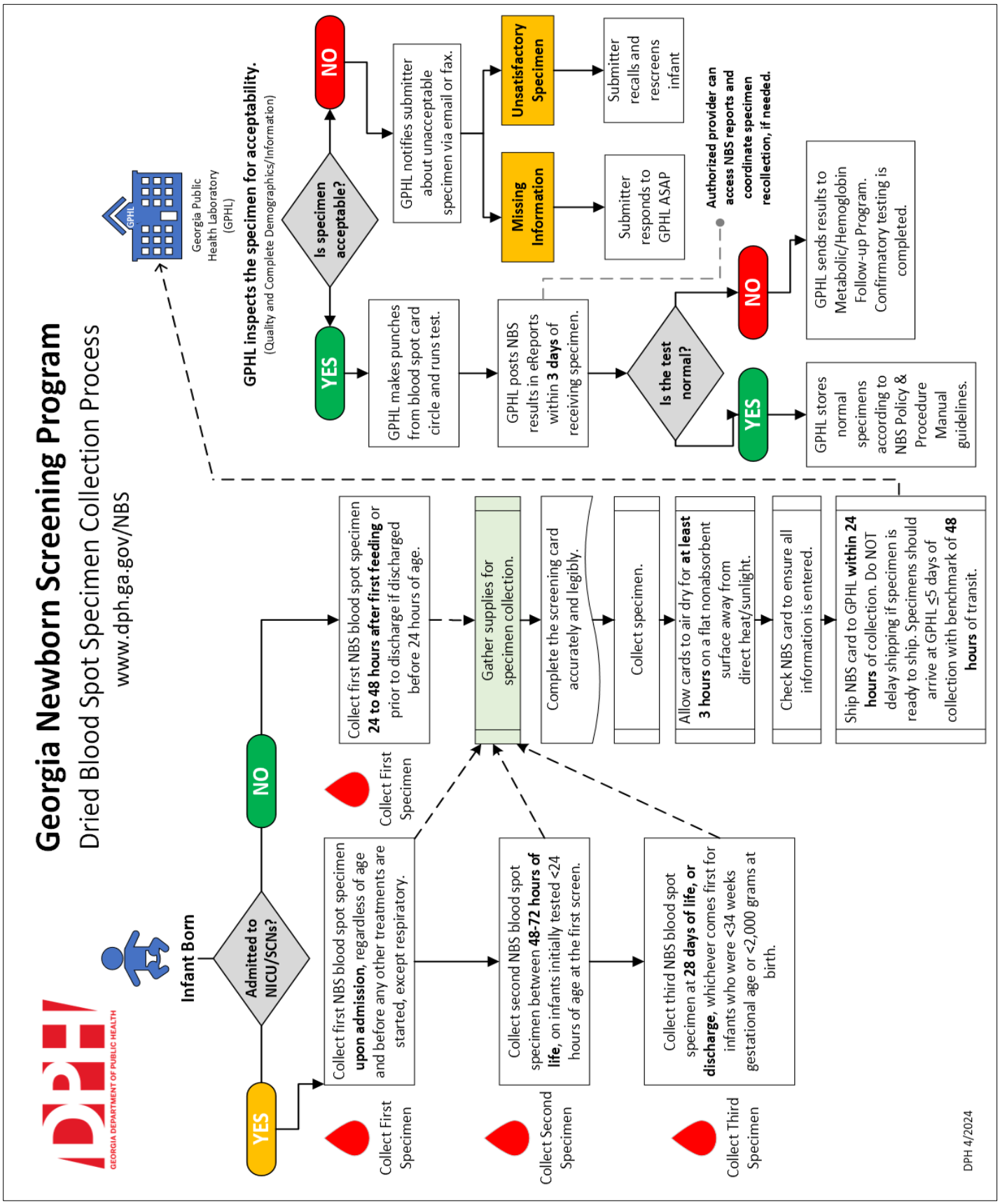
**cCMV Testing**:

- DPH cCMV Policy and Procedure Manual
- cCMV Implementation Toolkit for Medical Providers

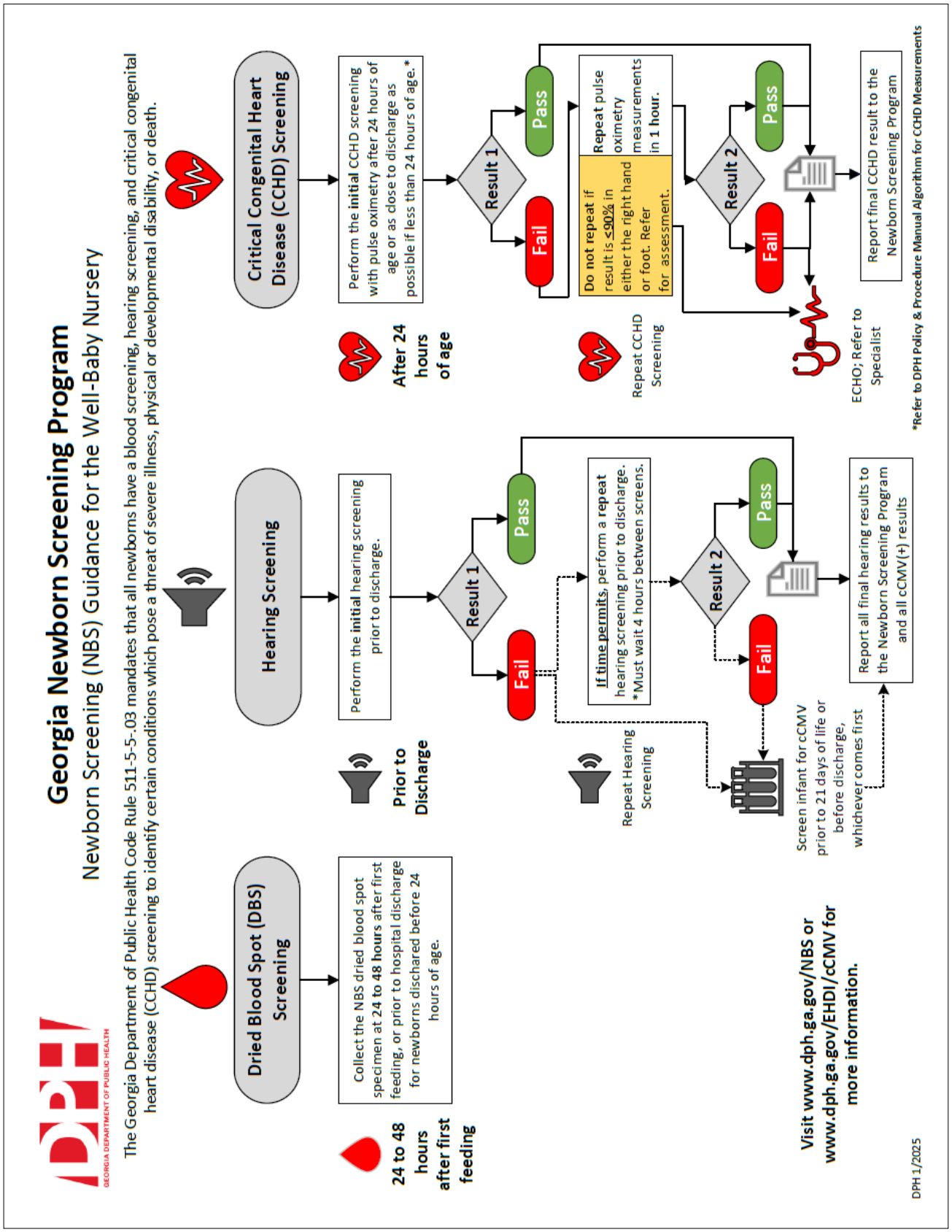
**CCHD Screening:**

- Newborn Screening for Critical Congenital Heart Disease (CCHD) resources courtesy of the American Academy of Pediatrics
- Critical Congenital Heart Disease: Updated Newborn Screening Guidelines for Pediatricians training video courtesy of the American Academy of Pediatrics

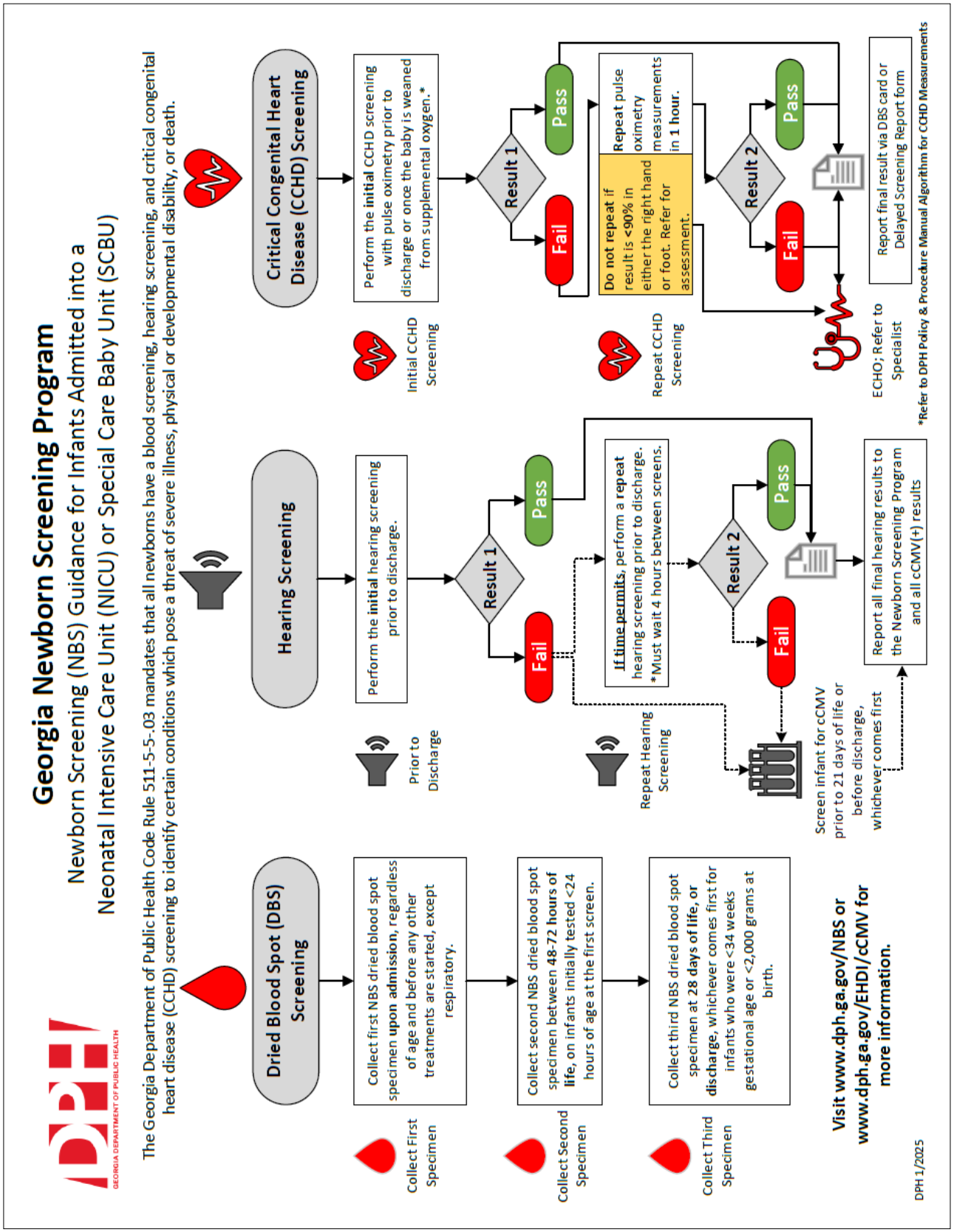
# Appendix G-1: Dried Blood Spot Specimen Collection Process Algorithm



# Appendix G-2: Newborn Screening Guidance for the Well-Baby Nursery Algorithm



# Appendix G-3: Newborn Screening Guidance for NICU or Special Care Baby Unit Algorithm



# APPENDIX H: E-REPORTS WEB PORTAL REGISTRATION FORM

Print

## Newborn Screening eReports Web Portal

*Licensed Provider Registration Form*

Instructions: Complete form and fax to **(404) 321-2265** or email to dph-nbs@dph.ga.gov. Contact the Georgia Department of Public Health Newborn Screening Program with questions at (404) 327-7950.

**Only licensed physicians, physician assistants, and registered professional nurses are permitted to register. License numbers will be verified with the State of Georgia.**

| | | | |
|---|---|---|---|
| **Name:** (Last) | (First) | | **Professional License Number:** |
| **Address:** | | | **Professional License Type:** ☐ Physician ☐ Physician Assistant ☐ Registered Professional Nurse |
| **City:** | **State:** | **ZIP:** | |
| **Fax Number:** | | | **Phone Number:** |
| **Email:** | | | *Email address will be used to notify user about account approval status, login credentials and to reset password.* |
| **Name of Facility / Practice:** | | | **Facility Type:** ☐ Hospital ☐ Primary Care ☐ Other (specify): |

**Newborn Screening eReports Privacy Statement**

This system allows persons authorized by the Georgia Department of Public Health (DPH) to access protected health information about individuals for reporting and treatment purposes. This information is entitled to significant privacy protections under federal and state law. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) permits a covered entity to use and disclose protected health information without written authorization, if the use or disclosure is for treatment, payment, or health care operations. However, HIPAA requires covered entities to have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information. The disclosure of this information to unauthorized persons or for unauthorized purposes is prohibited without the written authorization of the person who is the subject of the information, unless specifically permitted by federal or state law. Unauthorized disclosure of this information may result in significant criminal or civil penalties. Failure to properly log out of eReports can result in an unauthorized disclosure. All actions on this website can be monitored and audited. Any unauthorized use or disclosure brought to the attention of DPH or discovered via routine monitoring of this website will be investigated promptly. Approved users are required to secure their eReports password to prevent unauthorized access to the system using their password.

As an authorized user of eReports you agree to access the database only for reporting and treatment purposes related to your patient, and you acknowledge that you have received permission from the infant patient's legal guardian to view this information. As an authorized user of eReports, you agree to reasonably safeguard protected health information from any use or disclosure that is in violation of state or federal law.

**By signing the form, you are agreeing to the eReports privacy statement above.**

| | |
|---|---|
| **Provider Signature:** | |
| **Date:** | |

Fax completed form to **(404) 321-2265** or email to dph-nbs@dph.ga.gov

Georgia Newborn Screening Program | www.dph.ga.gov/NBS-Providers

FORM No. NBS-512 Updated 10/2024

Link to the form: https://dph.georgia.gov/document/document/registration-form/download

# APPENDIX I: AUTHORIZATION FOR RELEASE OF NEWBORN SCREENING REPORT FORM

GEORGIA DEPARTMENT OF PUBLIC HEALTH

## Newborn Screening Report Form

*Authorization for Release of Newborn Screening Report*

**Instructions:** Complete the form and fax to the Georgia Newborn Screening Program at (404) 657-2773 or email to dph-nbs@dph.ga.gov. Proof of identity must be provided (e.g., driver's license).

| | | | |
|---|---|---|---|
| **Child's Name:** (Last) | (First) | **Child's Date of Birth:** | **Gender:** ☐ Male ☐ Female ☐ Other |
| **Address:** | | | |
| **City:** | **State:** | **Zip:** | **Birth Facility Name:** |
| **Mother's Name at Delivery:** (Last) | (Maiden) | (First) | **Mother's Date of Birth:** |

**AUTHORIZATION FOR RELEASE OF NEWBORN SCREENING REPORT**

| | |
|---|---|
| 1. I hereby voluntarily authorize the Georgia Department of Public Health (DPH) to disclose the requested medical information to: | Name of Person/Facility:<br>Phone:<br>Fax: |
| 2. The purpose for this disclosure is for: | ☐ Continued patient care<br>☐ Personal Record<br>☐ Insurance<br>☐ Sport Requirement<br>☐ Other: |
| 3. The information to be disclosed includes: | ☐ Newborn Screening Report<br>☐ Follow-up Notes<br>☐ Other (specify): |
| 4. This authorization shall become effective immediately and shall remain in effect until the specified authorization end date or for one year from the date of signature if no date is entered: | Authorization End Date:<br>(MM/DD/YYYY) |

| | |
|---|---|
| **Initial:** | I understand that I may revoke this authorization in writing at any time prior to the release of information from DPH, and that revocation will not affect any action taken in reliance on this authorization before the written revocation was received. |
| **Initial:** | I understand that my eligibility for benefits, treatment, or payment is not conditioned upon the provision of this authorization. |
| **Initial:** | I understand that information disclosed by this authorization may be subject to redisclosure by the recipient and no longer protected by the Health Insurance Portability and Accountability Act (HIPAA). |

| | |
|---|---|
| **Patient's Printed Name:** | **Patient's Signature:** |
| **Date Signed:** (MM/DD/YYYY) | |
| **Authorized Guardian or Representative Printed Name:** | **Authorized Guardian or Representative Signature:** |
| **Date Signed:** (MM/DD/YYYY) | **Relationship to Child:** |

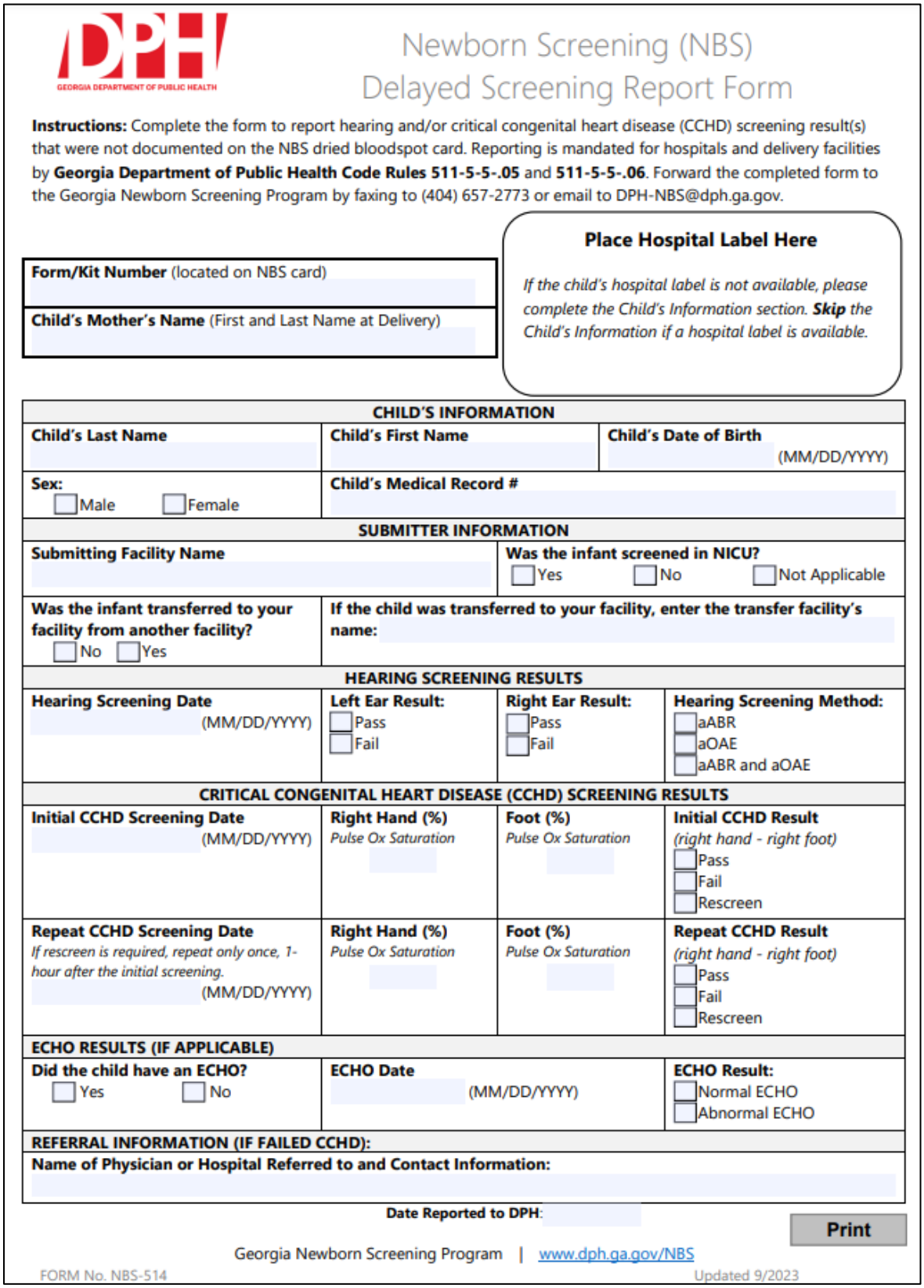
Georgia Newborn Screening Program | www.dph.ga.gov/NBS

Print Form

FORM No. NBS-511 Revised 8/2023

Link to the form: https://dph.georgia.gov/media/77981/download

# APPENDIX J: NBS DELAYED SCREENING REPORT FORM



DPH
GEORGIA DEPARTMENT OF PUBLIC HEALTH

## Newborn Screening (NBS) Delayed Screening Report Form

**Instructions:** Complete the form to report hearing and/or critical congenital heart disease (CCHD) screening result(s) that were not documented on the NBS dried bloodspot card. Reporting is mandated for hospitals and delivery facilities by **Georgia Department of Public Health Code Rules 511-5-5-.05** and **511-5-5-.06**. Forward the completed form to the Georgia Newborn Screening Program by faxing to (404) 657-2773 or email to DPH-NBS@dph.ga.gov.

**Form/Kit Number** (located on NBS card)

**Child's Mother's Name** (First and Last Name at Delivery)

**Place Hospital Label Here**

*If the child's hospital label is not available, please complete the Child's Information section.* ***Skip*** *the Child's Information if a hospital label is available.*

**CHILD'S INFORMATION**

| Child's Last Name | Child's First Name | Child's Date of Birth (MM/DD/YYYY) |
|---|---|---|
| Sex: ☐ Male ☐ Female | Child's Medical Record # | |

**SUBMITTER INFORMATION**

| Submitting Facility Name | Was the infant screened in NICU? ☐ Yes ☐ No ☐ Not Applicable |
|---|---|
| Was the infant transferred to your facility from another facility? ☐ No ☐ Yes | If the child was transferred to your facility, enter the transfer facility's name: |

**HEARING SCREENING RESULTS**

| Hearing Screening Date (MM/DD/YYYY) | Left Ear Result: ☐ Pass ☐ Fail | Right Ear Result: ☐ Pass ☐ Fail | Hearing Screening Method: ☐ aABR ☐ aOAE ☐ aABR and aOAE |
|---|---|---|---|

**CRITICAL CONGENITAL HEART DISEASE (CCHD) SCREENING RESULTS**

| Initial CCHD Screening Date (MM/DD/YYYY) | Right Hand (%) *Pulse Ox Saturation* | Foot (%) *Pulse Ox Saturation* | Initial CCHD Result *(right hand - right foot)* ☐ Pass ☐ Fail ☐ Rescreen |
|---|---|---|---|
| **Repeat CCHD Screening Date** *If rescreen is required, repeat only once, 1-hour after the initial screening.* (MM/DD/YYYY) | Right Hand (%) *Pulse Ox Saturation* | Foot (%) *Pulse Ox Saturation* | Repeat CCHD Result *(right hand - right foot)* ☐ Pass ☐ Fail ☐ Rescreen |

**ECHO RESULTS (IF APPLICABLE)**

| Did the child have an ECHO? ☐ Yes ☐ No | ECHO Date (MM/DD/YYYY) | ECHO Result: ☐ Normal ECHO ☐ Abnormal ECHO |
|---|---|---|

**REFERRAL INFORMATION (IF FAILED CCHD):**

**Name of Physician or Hospital Referred to and Contact Information:**

**Date Reported to DPH:**

Print

Georgia Newborn Screening Program | www.dph.ga.gov/NBS

FORM No. NBS-514 Updated 9/2023

Link to the form: https://dph.georgia.gov/media/78476/download

# APPENDIX K: INSTRUCTIONS FOR SELECTING HEARING SCREENING REPORTING METHOD

*The Newborn Screening Dried Blood Spot Card is the default reporting method unless birthing facility formally requests a different reporting method. Some birthing facilities may find electronic birth certificate or secure data file transfer to be advantageous. See information below to determine what is best for your facility:

| | **NBS Dried Blood Spot (NBS DBS) Card*<br>+<br>Delayed Screening Form** | **Electronic Birth Certificate<br>+<br>Delayed Screening Form** | **Secure Data File Transfer** |
|---|---|---|---|
| **Advantages** | • Utilizes a reliable transit method, requiring minimal extra steps | • Utilizes a reliable transit method, requiring minimal extra steps<br>• Requires fewer delayed screening forms, as the Electronic Birth Worksheet is submitted later (day 3-5) than the NBS DBS card | • Less data entry with fewer errors<br>• No need for delayed screening forms |
| **Disadvantages** | • Any infant who has their final hearing screening *after* the NBS DBS card has been mailed to the lab will require a *delayed screening form* to be filled out and faxed to DPH; time-intensive; high risk of underreporting | • Risk of inaccurate information if data clerk is not properly trained<br>• Delayed screening form will still be required for babies who are screened *after* the Electronic Birth Worksheet has been submitted | • Requires birthing facility and DPH IT involvement to set up a transfer<br>• Requires the birthing facility to submit a cleaned report on a weekly basis |

If your facility would like to request hearing screening reporting method be changed from an NBS DBS Card to an Electronic Birth Certificate or Secure Data File Transfer, follow the instructions below:

Instructions for Selecting Electronic Birth Worksheet as Primary Reporting Method (*Complete each step before moving on to the next):*

1. The birthing facility must train the Data Clerk/s who submit the Electronic Birth Worksheets.
    - Review the current birth worksheet section "Newborn Screening" to ensure understanding of each hearing-related question
    - Ensure they know where to locate the hearing screening results in the Electronic Medical Record

- Ensure they have access to the Newborn Hearing Screening Log in both the well-baby and NICU unit/s as a back-up to locate hearing screening results

2. Email DPH at DPH-NBS@dph.ga.gov and request a change from the NBS DBS Card to the *Electronic Birth Worksheet reporting method*.
3. Wait for a response indicating the effective start date (typically the first of the following month).
4. Birthing facilities should educate their staff on the change in reporting method and leave the NBS DBS card hearing screening results blank.

Instructions for Selecting Secure Data File Transfer as Reporting Method:

1. Email DPH-NBS@dph.ga.gov and request a change from the NBS DBS Card to the *Secure Data File Transfer reporting method*.
2. DPH will respond with the next steps (i.e., set up a meeting to share CSV file template and discuss the next steps)

Birthing facilities must document all newborn hearing screening results and/or status (i.e., pass, fail, missed, transferred, etc.) in the patient's medical record, report results to DPH (methods listed above) and provide results to the parents or legal guardians.

# APPENDIX L: FORM TO ORDER NEWBORN SCREEN COLLECTION FORMS (GEORGIA PUBLIC HEALTH LABORATORY) SPECIMEN COLLECTION OUTFIT ORDER FORM

FRM-CA 20 (version 1.0)

**GEORGIA PUBLIC HEALTH LABORATORY**
**SPECIMEN COLLECTION OUTFIT ORDER FORM**
**Decatur Lab Customer Service Phone: 404-327-7928 Fax:404-327-6862**

**INSTRUCTIONS**: Please fill out this form completely and print legibly.

- For the quantity, write the total number of items needed. For example, if you need 100 gold top tubes, enter the quantity as 100 next to the item number 0590.
- Fax the completed order form to **404-327-6862**. Not sure about what to order? We can help with that, just give us a call Decatur Lab Customer Service (404) 327-7928.
- Orders are processed daily in the order they are received. Please allow up to 5 days to receive your order. A pick-up option is available, contact us for scheduling.
- For supplies related to outbreaks, contact your local epidemiologist or call the Decatur Lab Customer Service (404) 327-7928.
- **Please remember, the supplies provided by the Georgia Public Health Laboratory (GPHL) should only be used for specimens submitted to the GPHL.**

| SUBMITTER INFORMATION(Required) | | | | |
|---|---|---|---|---|
| Company Name | Contact Name<br>Phone Number | Email Address | | |
| Street Address (**NO PO Boxes**) | Suite/Floor/Unit | City | State | Zip |

| Collection Tubes | | | Shipping Supplies | | |
|---|---|---|---|---|---|
| **ITEM** | **QUANTITY** | **DESCRIPTION** | **ITEM** | **QUANTITY** | **DESCRIPTION** |
| 0590 | EA | Gold Serum Separator Tubes (SST) | 0800 | EA | Biohazard Bag w/ Tyvek envelope |
| 0700 | EA | Conical Tube (50mL) for TB | 0803 | EA | Absorbent Sheet |
| 0705 | EA | Pearl Top Tube (HIV Viral Load) | 0805 | EA | Clear Biohazard Bag |
| 0710 | EA | Cryogenic (Pour Off) Tube (HIV Viral Load) | 0801 | EA | Fiberboard Can with Lid |
| 0502 | EA | HCV Viral Load (Includes Gold Top SST & Pour Off Tube) | UPS01 | EA | UPS Shipping Envelopes |
| QFT-1 | EA | QFT Tubes | CATB-B | EA | Category B Shipper Only- Limit 5 |
| 0575 | EA | Viral Transport Media Kit (VTM) w Swab | CATB-C | EA | Category B Shipper with Cooler- Limit 2 |
| 0505 | EA | Viral Transport Media Kit (VTM) w NP Swab | | | |
| 0595 | EA | Aptima Multitest Kit (STM) | | | |

| Parasitology and Bacteriology Supplies | | | NEWBORN SCREENING | | |
|---|---|---|---|---|---|
| **ITEM** | **QUANTITY** | **DESCRIPTION** | **ITEM** | **QUANTITY** | **DESCRIPTION** |
| 0555 | EA | Stool Culture (Para-Pak C&S Orange Top) | 3491 | EA | Newborn Screen Collection Forms (PKU) |
| 0545 | EA | Para-Pak® CLEAN *PREFERRED for Norovirus PCR | 3603 | EA | Mailing Envelopes for Newborn Screen |
| 0605 | EA | Capillary Blood Tube EDTA Purple Top | | | |

| GEORGIA PUBLIC HEALTH USE ONLY | FILLED BY |
|---|---|
| | NO. of BOXES SHIPPED |
| DATE RECEIVED | DATE SHIPPED |

The GPHL Submission Forms are also available on the Department of Public Health Website: http://dph.georgia.gov/lab/. Revised 07/14/2023

Link to the form: https://dph.georgia.gov/document/publication/specimen-collection-outfit-order-form-decatur/download

# APPENDIX M: AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

Georgia Department of Public Health

**AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION**

| NAME OF INDIVIDUAL/PATIENT | |
|---|---|
| | |
| **DATE OF BIRTH** | |
| | |
| **ADDRESS** | **CITY/STATE/ ZIP** |
| | |

1. I hereby voluntarily authorize _____ to disclose the medical information indicated below to _____.
2. The purpose for this disclosure is for _____.
3. The information to be disclosed is:

   ___ Entire Medical Record
   ___ Only medical information from the period _____ to _____.
   ___ Other (specify) _____

   If you would like any of the following sensitive information disclosed, please indicate with a check mark below:
   ___ Alcohol/ Drug Abuse Treatment
   ___ HIV/ AIDS- related Treatment
   ___ Mental Health (other than psychotherapy notes*)

4. This authorization shall become effective immediately and shall remain in effect until _____ (date) or for one year from the date of signature if no date is entered.

I understand that I may revoke this authorization in writing at any time prior to the release of information from DPH, and that revocation will not affect any action taken in reliance on this authorization before the written revocation was received.

I understand that my eligibility for benefits, treatment or payment is not conditioned upon my provision of this authorization.

I understand that information disclosed by this authorization may be subject to re-disclosure by the recipient and no longer protected by the Health Insurance Portability and Accountability Act.

_____ Print Patient's Name

_____ Patient's Signature

_____ Print Authorized Representative's Name (if applicable)

_____ Authorized Representative's Signature (if applicable)

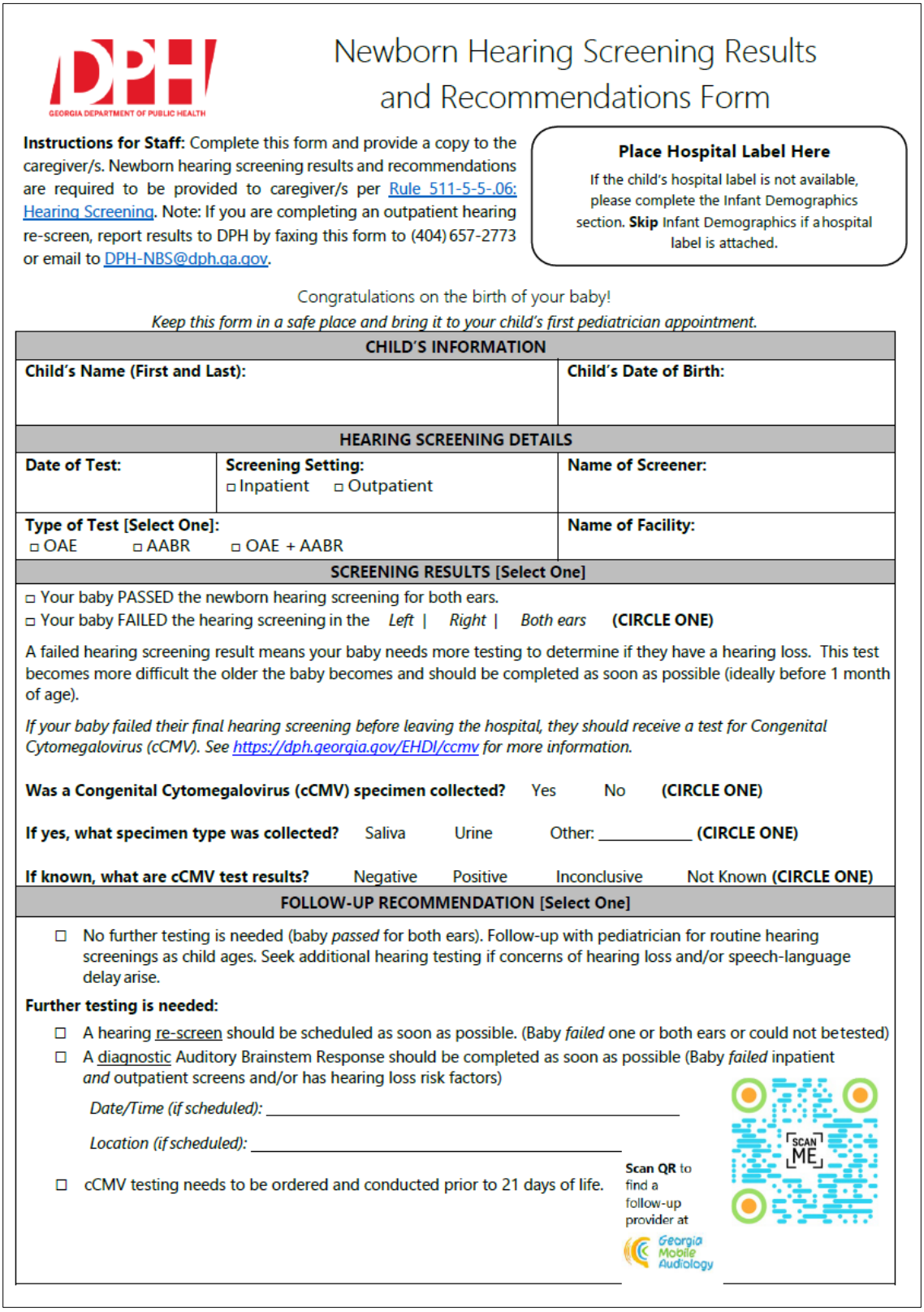
_____ Date

**Psychotherapy notes* means notes recorded by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. 45 C.F.R. 164.501.

DPH Form GC-09013C [Rev. 7/2/2013] Page 1 of 1

Link to the form:
https://dph.georgia.gov/sites/dph.georgia.gov/files/WicPM/forms/ReleaseOfInformationForm_Blank.pdf

# APPENDIX N: NEWBORN HEARING SCREENING RESULTS AND RECOMMENDATIONS FORM



GEORGIA DEPARTMENT OF PUBLIC HEALTH

## Newborn Hearing Screening Results and Recommendations Form

**Instructions for Staff:** Complete this form and provide a copy to the caregiver/s. Newborn hearing screening results and recommendations are required to be provided to caregiver/s per Rule 511-5-5-.06: Hearing Screening. Note: If you are completing an outpatient hearing re-screen, report results to DPH by faxing this form to (404) 657-2773 or email to DPH-NBS@dph.ga.gov.

**Place Hospital Label Here**

If the child's hospital label is not available, please complete the Infant Demographics section. **Skip** Infant Demographics if a hospital label is attached.

Congratulations on the birth of your baby!

*Keep this form in a safe place and bring it to your child's first pediatrician appointment.*

**CHILD'S INFORMATION**

| **Child's Name (First and Last):** | **Child's Date of Birth:** |
|---|---|
| | |

**HEARING SCREENING DETAILS**

| **Date of Test:** | **Screening Setting:** ▫ Inpatient ▫ Outpatient | **Name of Screener:** |
|---|---|---|
| **Type of Test [Select One]:** ▫ OAE ▫ AABR ▫ OAE + AABR | | **Name of Facility:** |

**SCREENING RESULTS [Select One]**

▫ Your baby PASSED the newborn hearing screening for both ears.

▫ Your baby FAILED the hearing screening in the *Left* | *Right* | *Both ears* **(CIRCLE ONE)**

A failed hearing screening result means your baby needs more testing to determine if they have a hearing loss. This test becomes more difficult the older the baby becomes and should be completed as soon as possible (ideally before 1 month of age).

*If your baby failed their final hearing screening before leaving the hospital, they should receive a test for Congenital Cytomegalovirus (cCMV). See https://dph.georgia.gov/EHDI/ccmv for more information.*

**Was a Congenital Cytomegalovirus (cCMV) specimen collected?** Yes No **(CIRCLE ONE)**

**If yes, what specimen type was collected?** Saliva Urine Other: _____ **(CIRCLE ONE)**

**If known, what are cCMV test results?** Negative Positive Inconclusive Not Known **(CIRCLE ONE)**

**FOLLOW-UP RECOMMENDATION [Select One]**

☐ No further testing is needed (baby *passed* for both ears). Follow-up with pediatrician for routine hearing screenings as child ages. Seek additional hearing testing if concerns of hearing loss and/or speech-language delay arise.

**Further testing is needed:**

☐ A hearing re-screen should be scheduled as soon as possible. (Baby *failed* one or both ears or could not be tested)

☐ A diagnostic Auditory Brainstem Response should be completed as soon as possible (Baby *failed* inpatient *and* outpatient screens and/or has hearing loss risk factors)

*Date/Time (if scheduled):* _____

*Location (if scheduled):* _____

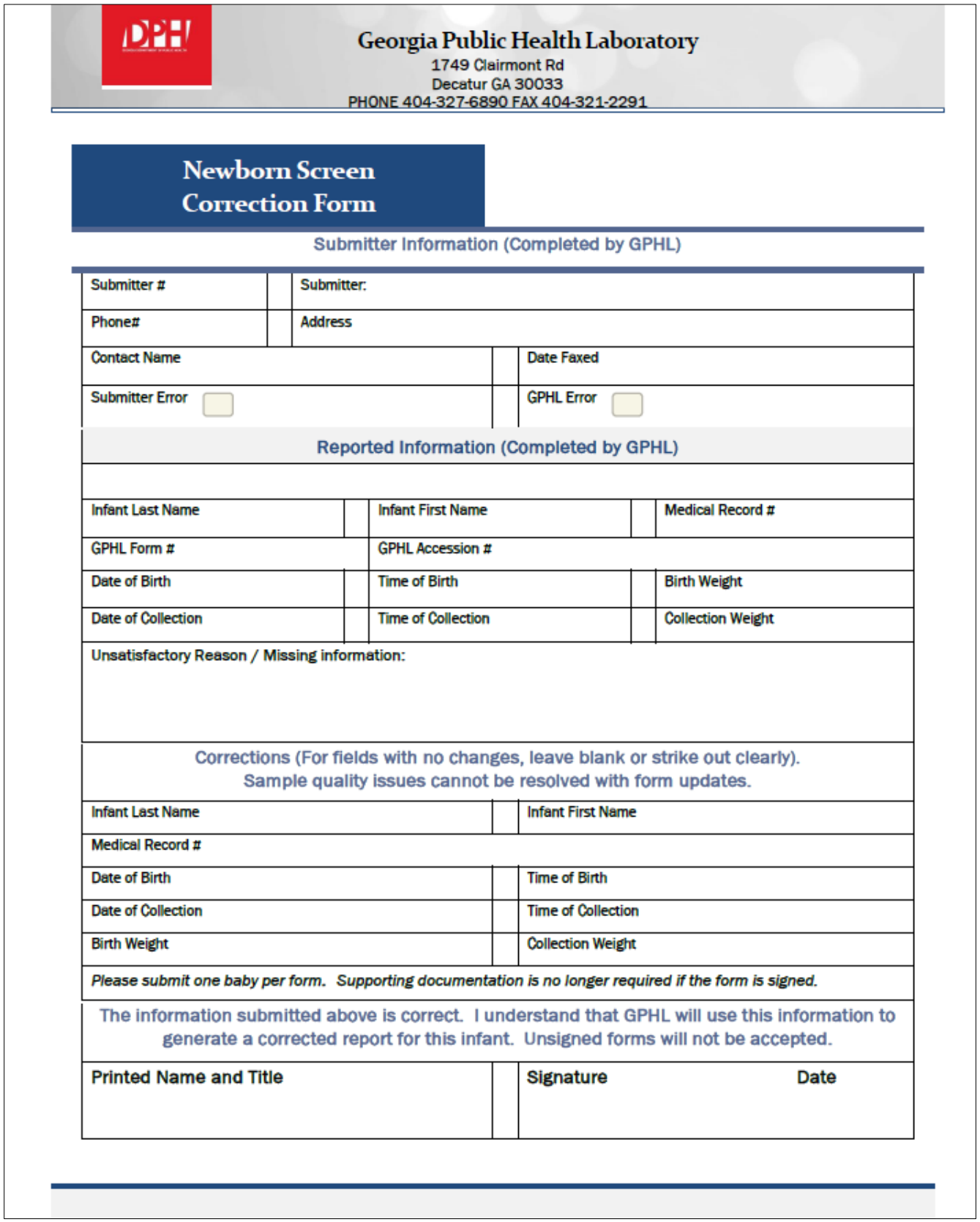
☐ cCMV testing needs to be ordered and conducted prior to 21 days of life.

**Scan QR** to find a follow-up provider at Georgia Mobile Audiology

SCAN ME

Link to the form:
https://dph.georgia.gov/document/document/newborn-hearing-screening-results/download

# APPENDIX O: NEWBORN SCREEN CORRECTION FORM



Georgia Public Health Laboratory
1749 Clairmont Rd
Decatur GA 30033
PHONE 404-327-6890 FAX 404-321-2291

## Newborn Screen Correction Form

**Submitter Information (Completed by GPHL)**

| | | | |
|---|---|---|---|
| Submitter # | | Submitter: | |
| Phone# | | Address | |
| Contact Name | | Date Faxed | |
| Submitter Error ☐ | | GPHL Error ☐ | |

**Reported Information (Completed by GPHL)**

| | | | | | |
|---|---|---|---|---|---|
| Infant Last Name | | Infant First Name | | Medical Record # | |
| GPHL Form # | | GPHL Accession # | | | |
| Date of Birth | | Time of Birth | | Birth Weight | |
| Date of Collection | | Time of Collection | | Collection Weight | |
| Unsatisfactory Reason / Missing information: | | | | | |

**Corrections (For fields with no changes, leave blank or strike out clearly).**
**Sample quality issues cannot be resolved with form updates.**

| | | | |
|---|---|---|---|
| Infant Last Name | | Infant First Name | |
| Medical Record # | | | |
| Date of Birth | | Time of Birth | |
| Date of Collection | | Time of Collection | |
| Birth Weight | | Collection Weight | |

*Please submit one baby per form. Supporting documentation is no longer required if the form is signed.*

The information submitted above is correct. I understand that GPHL will use this information to generate a corrected report for this infant. Unsigned forms will not be accepted.

| | | | |
|---|---|---|---|
| Printed Name and Title | | Signature | Date |

# APPENDIX P: NEWBORN SCREENING PANEL HISTORY

GEORGIA DEPARTMENT OF PUBLIC HEALTH

## Georgia Newborn Screening Program

Newborn Screening Panel Legislative and Regulatory History

| Category | | Core Condition | Abbreviation | Added to GA Panel |
|---|---|---|---|---|
| Organic Acid Conditions | | 3-Hydroxy-3-Methyglutaric Aciduria | HMG | 2007 |
| | | 3-Methylcrotonyl-CoA Carboxylase Deficiency | 3-MCC | 2007 |
| | | ß-Ketothiolase Deficiency | BKT | 2007 |
| | | Glutaric Acidemia Type I | GA-I | 2007 |
| | | Holocarboxylase Synthase Deficiency | MCD | 2007 |
| | | Isovaleric Acidemia | IVA | 2007 |
| | | Methylmalonic Acidemia (Cobalamin disorders) | Cbl A,B | 2007 |
| | | Methylmalonic Acidemia (methylmalonyl-CoA mutase) | MUT | 2007 |
| | | Propionic Acidemia | PROP | 2007 |
| Fatty Acid Oxidation Disorders | | Carnitine Uptake Defect/Carnitine Transport Defect | CUD | 2007 |
| | | Long-chain L-3 Hydroxyacyl-CoA Dehydrogenase Deficiency | LCHAD | 2007 |
| | | Medium-chain Acyl-CoA Dehydrogenase Deficiency | MCAD | 2003 |
| | | Trifunctional Protein Deficiency | TFP | 2007 |
| | | Very Long-chain Acyl-CoA Dehydrogenase Deficiency | VLCAD | 2007 |
| Amino Acid Disorders | | Argininosuccinic Aciduria | ASA | 2007 |
| | | Citrullinemia, Type I | CIT | 2007 |
| | | Classic Phenylketonuria | PKU | 1968 |
| | | Homocystinuria | HCY | 1978 |
| | | Maple Syrup Urine Disease | MSUD | 1978 |
| | | Tyrosinemia, Type I | TYR I | 1978 |
| Endocrine Disorders | | Congenital adrenal hyperplasia | CAH | 1990 |
| | | Primary Congenital Hypothyroidism | CH | 1978 |
| Hemoglobin Disorders | | S, βeta-Thalassemia | Hb S/ßTh | 1998 |
| | | S,C Disease | Hb S/C | 1998 |
| | | S,S Disease (Sickle Cell Anemia) | Hb SS | 1978 voluntary; 1998 universal |
| | | Other Hemoglobin Variants | Var Hb | 1998 |
| Other Disorders | Lysosomal Storage Disorders | Mucopolysaccharidosis Type I | MPS I | 2019 |
| | | Mucopolysaccharidosis Type II | MPS II | 2025[1] |
| | | Glycogen Storage Disease Type II (Pompe) | POMPE | 2019 |
| | | Krabbe Disease | KD | 2021 Pilot; 2025[1] |
| | Other | Biotinidase Deficiency | BIOT | 2003 |
| | | Classic Galactosemia | GALT | 1978 |
| | | Cystic Fibrosis | CF | 2007 |
| | | Guanidinoacetate Methyltransferase Deficiency | GAMT | 2025[1] |
| | | Severe Combined Immunodeficiencies | SCID | 2007 |
| | | Spinal Muscular Atrophy due to homozygous deletion of exon 7 in SMN1 | SMA | 2019 |
| | | X-linked Adrenoleukodystrophy | X-ALD | 2019 |
| | Point of Care | Critical Congenital Heart Disease | CCHD | 2014 |
| | | Hearing Loss<br>*-Congenital Cytomegalovirus* | HEAR<br>*-cCMV* | 2014<br>*-2024* |

[1]Projected screening start year is 2025.

DPH 11/2024

# 10.2 REFERENCES

CLSI. *Dried Blood Spot Specimen Collection for Newborn Screening*. 7th ed. CLSI standard NBS01. Clinical and Laboratory Standards Institute; 2021.

CLSI. *Newborn Screening for Preterm, Low Birth Weight, and Sick Newborns*. 2nd ed. CLSI guideline NBS03. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

Oster ME, Pinto NM, Pramanik AK, et al; American Academy of Pediatrics, Section on Cardiology and Cardiac Surgery, Section on Hospital Medicine, Committee on Fetus and Newborn. Newborn Screening for Critical Congenital Heart Disease: A New Algorithm and Other Updated Recommendations: Clinical Report. Pediatrics. 2025;155(1): e2024069667

JUSTIA Company. 2014 Georgia Code Title 31 – Health Chapter 1 - General Provisions; Access to Eye Care Article 1 – General Provisions § 31-1-3.2 - Hearing screenings for newborns
https://law.justia.com/codes/georgia/2014/title-31/chapter-1/article-1/section-31-1-3.2

JUSTIA Company. 2022 Georgia Code Title 31 – Health Chapter 1 – General Provisions § 31-1-3.2 - Hearing screenings for Newborns
Georgia Code Title 21 – Hearing Screenings for Newborns

# 10.3 POLICY REVISIONS RECORD

## Policy Revisions Record

### Georgia Newborn Screening Policy and Procedure Manual 2025

| REVISION DATE | SECTION & PAGE | REVISION DESCRIPTION | REVISION TYPE A=Added D=Deleted M=Modified | CITATION Revision required by Regulation, Legislation, etc. |
|---|---|---|---|---|
| 6/18/2024 | Page 4 | Corrected Appendix O title. Changed from "Newborn Hearing Screening Results and Recommendations Form" to "Newborn Screen Correction Form". | M | N/A |
| 6/18/2024 | Page 22; Table Code 21 | Corrected "Bood" typo. Updated to "Blood". | M | N/A |
| 6/18/2024 | Page 59 | Corrected Appendix O title. Changed from "Newborn Hearing Screening Results and Recommendations Form" to "Newborn Screen Correction Form". | M | N/A |
| 9/23/2024 | Page 18 | Clarified that the transfusion protocol is only applicable when the DBS schedule is interrupted. | M | N/A |
| 9/23/2024 | Page 21 | Changed >7 days after the date of collection to >10 days after the date of collection. The >10 days aligns with Georgia Code. | M | N/A |
| 9/23/2024 | Page 30 | Added overview of required cCMV testing for all infants who fail their final hearing screening prior to 21 days of age or before discharge, whichever one comes first. Added link to cCMV policy and procedure manual for further information. | A | In accordance with Georgia Code Section 31-5-1, amendments take effect on October 10, 2024. http://dph.georgia.gov/regulationsrule-making |
| 9/23/2024 | Page 58; Appendix N | Replaced "Newborn Hearing Screening Results and Recommendations Form" with updated version. | M | N/A |
| 9/23/2024 | Page 49; Appendix G-2 | Replaced "Newborn Screening Guidance for the Well-Baby Nursery Algorithm" with updated version. | M | N/A |

| REVISION DATE | SECTION & PAGE | REVISION DESCRIPTION | REVISION TYPE A=Added D=Deleted M=Modified | CITATION Revision required by Regulation, Legislation, etc. |
|---|---|---|---|---|
| 9/23/2024 | Page 50; Appendix G-3 | Replaced "Newborn Screening Guidance for Infants Admitted into a NICU or SCBU Algorithm" with updated version. | M | N/A |
| 11/13/2024 | Page 60; Appendix P | Added "Newborn Screening Panel Legislative and Regulatory History" document. | A | N/A |
| 12/3/2024 | Section 5.4, page 18 | Modified titling and moved introduction to be found under Low Birth Weight Infants section. | M | N/A |
| 12/3/2024 | Section 5.4, page 18 | Added clarification about the DBS schedule in the Transfusions/ Blood Products/ECMO section. | A | N/A |
| 12/3/2024 | Section 5.4, page 18 | Modified/clarified Parenteral Nutrition section. | M | N/A |
| 12/3/2024 | Section 5.4, Page 19 | Added section titled NPO/IV Fluids Only to clarify timing of screening for this population. | A | N/A |
| 12/3/2024 | Section 5.4, Page 19 | Modified Older Infants/Children section for clarity. | M | N/A |
| 12/3/2024 | Section 7.5, page 27 | Modified titling to include NICU/SCBU and Prenatal CCHD Diagnosis to address screening guidelines. | M/A | N/A |
| 12/3/2024 | Section 9.2, Page 34 | Modified wording in transfusion section for clarity; added Abnormal Hgb Results for Transfused Infants section per recommendation of Hemoglobin Committee. | M/A | N/A |
| 12/3/2024 | Section 4.2, page 13 | Modified verbiage describing "meconium ileus". | N | N/A |
| 12/17/2024 | Section 7.2, page 25 | Modified the Revised Algorithm for Critical Congenital Heart Disease (CCHD) Screening with Pulse Oximetry with the AAP's 12/16/2024 recommended algorithm. | M/A | N/A |
| 12/17/2024 | Section 7.1, page 23 | Modified/ added note regarding the use of CCHD as a screening tool. | M/A | Updated 2024 AAP CCHD Protocol |
| 12/17/2024 | Section 7.5, page 27 | Modified/added specific NICU/SBCU guidelines to align with new protocol. | M/A | Updated 2024 AAP CCHD Protocol |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