



# **Georgia Newborn Screening Program Policy and Procedure Manual**



**Maternal and Child Health Section**  
June 2015



## **PREFACE**

The Georgia Department of Public Health (DPH) is Georgia's lead agency in preventing disease, injury and disability; promoting health and well-being, and preparing for and responding to disasters from a health perspective.

Georgia's Maternal and Child Health (MCH) Section is housed within the Division of Health Promotion in the Georgia Department of Public Health. MCH is strategically structured into three units: Programs, Administration, and Strategy. MCH is the state's lead section that informs consumers and stakeholders on the health status and promotion of Georgia's women and children and administers prevention programs that protect the health of women and children.

The Newborn Screening (NBS) Program coordinates a multi-partner system for the early detection and intervention of congenital and heritable conditions. This policy and procedure manual will provide guidance on the implementation of newborn screening for genetic/metabolic, hearing, and critical congenital heart disease (CCHD) screening. This manual is also intended to be used as a resource guide for newborn screening in Georgia.

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## **SECTION 1**

### **The Georgia Newborn Screening Program**

## 1.1 Introduction

Newborn Screening (NBS) is a population-based screening program that prevents the morbidity and mortality outcomes of certain conditions and disorders on the NBS panel. NBS began in 1962 when Dr. Robert Guthrie developed the bacterial inhibition assay to identify phenylalanine in the newborn period, prior to the signs and symptoms associated with phenylketonuria (PKU). This methodology allowed for the simple collection of blood from newborn infants, mailing of large quantities of specimens to a central laboratory and ultimately, population-based screening of all newborns for PKU. Prior to Dr. Guthrie's discovery, children with mental retardation due to PKU suffered through seizures, behavioral disorders, and severe intellectual disability. Dr. Guthrie's discovery led to a nationwide reduction of individuals with severe intellectual disability. Since 1962, scientists have developed other tests to identify other conditions that cause severe morbidity or mortality. Other tests, such as isoelectric focusing (IEF), otoacoustic emissions (OAE), and pulse oximetry are also leading to a reduction in morbidity and mortality for affected children.

Georgia initiated universal newborn blood screening for PKU in 1968. Ten years later, the Georgia legislature expanded screening to include a group of six treatable metabolic/endocrine disorders, which cause intellectual disability if undetected in the newborn period. The 1978 legislative amendment also recognized that newborn screening had limited value unless it was coupled with rapid follow-up, expert diagnosis, adequate management and family counseling. This was the initiation of the NBS Program in place today.

The newborn hearing screening was the first point-of-care (in the birthing facility) newborn screening condition. Beginning in the 1990's, newborn hearing screening programs in the United States were limited to screening babies on the high-risk registrar, which excluded and missed a lot of infants with congenital hearing loss. Universal newborn hearing screening in the U.S. began in 1993 when a panel from the National Institutes of Health (NIH) reviewed evidence on early identification of hearing loss and made recommendations to universally screen. As a result of the passage of the Official Code of Georgia Annotated (OCGA) 31-1-3.2 in 1999, the Georgia Division of Public Health developed and implemented a statewide Universal Newborn Hearing Screening and Intervention initiative in 2001. Until 2014, these NBS programs operated in the same unit under different rule. The addition of hearing impairment to the NBS Rules and Regulations, Chapter 511-5-5, allows the Newborn Hearing Screening Program to operate under OCGA 31-12-6 and 31-12-7; thus requiring hearing screening on all newborns born in Georgia unless religious tenets do not allow.

### Georgia NBS Legislative History

- 1968 - Phenylketonuria (PKU)
- 1978 - Galactosemia, Tyrosinemia, Maple Syrup Urine Disease (MSUD), Homocystinuria, Congenital Hypothyroidism and selected voluntary screening for Sickle Cell Anemia were added
- 1990 - Congenital Adrenal Hyperplasia (CAH) was added
- 1998 – Universal screening for Sickle Cell Disease (SCD) was mandated for all newborns
- 1999- Legislation passed to initiate the Universal Newborn Hearing Screening and Intervention Program
- 2003 - DHR Board adopted Rules and Regulations to screen for Biotinidase Deficiency and Medium Chain acyl co-A Dehydrogenase Deficiency (MCADD)
- 2007 - Isovaleric Acidemia, Glutaric Acidemia type I, 3-OH 3-CH3 Glutaric Aciduria (HMG),

Multiple Carboxylase Deficiency, Methylmalonic Acidemia, 3-Methylcrotonyl-CoA Carboxylase Deficiency (3MCC), Propionic Acidemia, Beta-ketothiolase Deficiency, Very Long-chain Acyl-CoA Dehydrogenase Deficiency (VLCAD), Long-chain L-3-OH acyl CoA Dehydrogenase Deficiency (LCHAD), Trifunctional Protein Deficiency, Carnitine Uptake Defect, Citrullinemia, Argininosuccinic Acidemia, and Cystic Fibrosis were added through regulatory approval

- 2014 – Critical Congenital Heart Disease (CCHD), Hearing Impairment, and Severe Combined Immunodeficiency (SCID) were added through regulatory approval

## 1.2 Newborn Screening Program Overview

The NBS Program is committed to protecting and improving the health of all infants by assuring all newborns receive appropriate screening, follow-up, and medical services. The NBS Program screens for several genetic disorders, endocrine disorders, hemoglobinopathies, hearing impairment and critical congenital heart disease.

The Georgia NBS Program is a six part preventive health care system designed to identify and provide early treatment for 31 inherited disorders and conditions that otherwise would cause significant delays, morbidity or death.

The six components are:

1. **Education:** distribution of information to parents and health care providers
2. **Screening:** universal testing of all newborns
3. **Follow-up:** rapid retrieval and referral of the screen-positive newborn
4. **Medical Diagnosis:** confirmation of an abnormal screening test result by a private physician, audiologist, or tertiary treatment center
5. **Management:** rapid implementation and long-term planning of therapy
6. **Evaluation:** validation of testing procedures, the efficiency of follow-up and intervention, and benefit to the patient, family, and society. Includes consideration of adding other tests to the system as indicated by appropriate research and scientific evidence.

The goals of the Georgia Newborn Screening System are to ensure that:

1. Every infant born in Georgia will receive a newborn screen prior to hospital discharge
2. All infants whose screen results are outside of the normal limits for a newborn screening disorder will receive prompt and appropriate follow-up testing
3. All newborns diagnosed with a metabolic, endocrine, hemoglobin disorder, hearing impairment or CCHD are entered into an appropriate therapy/intervention

## 1.3 Rules and Regulations

### Rules and Regulations of the State of Georgia, Health Promotion and Disease Prevention Program, CHAPTER 511-5-5

#### TESTING FOR INHERITED DISORDERS IN THE NEWBORN

##### Table of Contents

- 511-5-5-.01 Purpose
- 511-5-5-.02 Definitions
- 511-5-5-.03 Testing Required of Newborn Babies
- 511-5-5-.04 Newborn Screening Specimen Cards and Laboratory Analysis
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- 511-5-5-.06 Hearing Screening
- 511-5-5-.07 Approved Laboratories
- 511-5-5-.08 Abnormal Test Results
- 511-5-5-.09 Reporting
- 511-5-5-.10 Revisions to Newborn Screening Panel

##### **511-5-5.01 Purpose**

The purpose of these rules is to provide administrative details and procedures to ensure that all newborn babies in Georgia are promptly tested for certain conditions that pose a threat of severe illness, physical or developmental disability, or death.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7

##### **511-5-5.02 Definitions**

- (a) "Abnormal test result" is a test result from blood testing or physiologic monitoring that is outside the screening limits set forth in the current edition of the Department's "Georgia Newborn Screening Program Policy and Procedure Manual";
- (b) "Adequate specimen" is a dried blood spot specimen that is properly collected in accordance with the current edition of the Department's "Georgia Newborn Screening Program Policy and Procedure Manual";
- (c) "Approved laboratory" is a laboratory licensed in Georgia, which has been specifically approved by the Department to conduct laboratory analysis of dried blood spot specimens for the disorders specified in the Georgia Newborn Screening Policy and Procedure Manual;
- (d) "Automated auditory brainstem response" or "aABR" is 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;
- (e) "Automated Otoacoustic Emissions Testing" or "aOAE" is 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;
- (f) "Birthing center" means any facility that is licensed by the Georgia Department of Community Health as a birthing center;
- (g) "Critical Congenital Heart Disease" or CCHD refers to 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;

- (h) "Department" means the Georgia Department of Public Health;
- (i) "Hospital" means any facility that is licensed by the Georgia Department of Community Health as a hospital;
- (j) "Newborn Screening Specimen Card" or "NBS Card" means the current version of DPH Form 3491 used to collect information and blood specimen from a newborn baby;
- (k) "Newborn Hearing Screening Test" means 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;
- (l) "Newborn Screening and Genetics Advisory Committee (NBSAC)" is a multi-disciplinary group of professional and consumer representatives with knowledge and expertise in newborn screening programs appointed by the Commissioner of Public Health;
- (m) "Submitter" means any person or entity submitting a Newborn Screening Specimen Card for analysis;
- (n) "Unsatisfactory Specimen" is a dried blood spot specimen that is rejected by the laboratory because the quality of the specimen does not allow accurate testing, or because critical information is missing from the NBS Card which inhibits the laboratory's ability to accurately identify the baby or interpret the test results;

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

### **511-5-5.03 Testing Required of Newborn Babies**

(1) It is the goal of the Department that every baby born alive in Georgia shall be tested for the following conditions, unless its parents or legal guardians object in writing on the grounds that such tests and treatment conflict with their religious beliefs:

- (a) critical congenital heart disease (CCHD),
- (b) hearing impairment,
- (c) argininosuccinic aciduria,
- (d) beta-ketothiolase deficiency,
- (e) Biotinidase deficiency,
- (f) carnitine uptake defect,
- (g) Citrullinemia,
- (h) congenital adrenal hyperplasia,
- (i) congenital hypothyroidism,
- (j) cystic fibrosis,

- (k) Galactosemia,
- (l) glutaric acidemia type I,
- (m) Homocystinuria,
- (n) isovaleric acidemia,
- (o) long-chain acyl-CoA dehydrogenase deficiency,
- (p) maple syrup urine disease,
- (q) medium-chain acyl Co-A dehydrogenase deficiency,
- (r) methyl malonic acidemia,
- (s) multiple carboxylase deficiency,
- (t) phenylketonuria,
- (u) propionic acidemia,
- (v) severe combined immunodeficiency (SCID),
- (w) sickle cell hemoglobinopathies,
- (x) trifunctional protein deficiency,
- (y) Tyrosinemia,
- (z) very long-chain acyl-CoA dehydrogenase deficiency,
- (aa) 3-methylcrotonyl-CoA carboxylase deficiency, and
- (bb) 3-OH 3-CH<sub>3</sub> glutaric aciduria.

(2) Unless otherwise noted in subparagraph (1) above, testing for conditions (1)(c) through (1)(bb) shall be conducted through laboratory analysis of the baby's blood on a Newborn Screening Specimen Card as provided in DPH Rule 511-5-5-.04.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

#### **511-5-5-.04 Newborn Screening Specimen Cards and Laboratory Analysis**

(1) It shall be the responsibility of the hospital, birthing center, physician's office or other healthcare facility in which the baby is born to ensure that an NBS Card is properly completed and submitted to the Department in accordance with these Rules, and that the parents are given a copy of DPH Form 5506 ("Georgia Newborn Screening Program: What Every Parent Should Know"). If the birth occurs outside a hospital, birthing center, or other healthcare facility, then it shall be the responsibility of the attending physician or midwife to do so.

(2) A Newborn Screening Dried Bloodspot Specimen (DBS) shall be completed 24 hours after birth, as follows:

(a) All information requested on the NBS Card shall be legibly and accurately collected;

(b) Specimens of the baby's blood shall be collected and placed on the DBS in accordance with the current edition of the Georgia Newborn Screening Program Policy and Procedure Manual and allowed to dry for at least three hours;

(c) The NBS Card shall be sent within 24 hours to the Georgia Public Health Laboratory, using a courier service that ensures next business day delivery and allows the tracking of the package. A copy of the completed NBS Card shall be maintained with the baby's clinical records.

(d) If an NBS Card does not reach the Georgia Public Health Laboratory within seven days after the blood sample was drawn, the submitter shall repeat this process and submit a new card for that baby.

(3) If the baby is admitted to a Neonatal Intensive Care Unit (NICU) or Special Care Nursery (SCN), the baby, shall have up to three specimens collected in accordance with the current edition of the Georgia Newborn Screening Program Policy and Procedure Manual.

(4) The Department shall charge a fee of \$50.00 per baby, for screening, patient retrieval and diagnosis to meet or defray Department cost. However, no parent shall be denied screening on the basis of inability to pay.

(5) If the Department or approved laboratory determines that the specimen is unsatisfactory, then the submitter shall obtain a second specimen and submit another card as soon as possible, but before the baby reaches three to four weeks of age. If the baby has been discharged, then the submitter shall be responsible for contacting the baby's physician or healthcare provider and/or parent or legal guardian to arrange for the second specimen.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

#### **511-5-5-.05 Critical Congenital Heart Disease Screening**

(1) All hospitals 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 hospital, birthing center or at a facility that is equipped to conduct a CCHD screening test, the test shall be conducted prior to the baby's discharge in accordance with the Georgia Newborn Screening Policy and Procedure Manual. Newborns who have already received an echocardiogram for any reason may be excluded from CCHD screening.

(3) If the baby is admitted into an NICU or SCN, the baby shall have a CCHD screening test prior to discharge or once the baby is weaned from supplemental oxygen. Newborns who have already received an echocardiogram for any reason may be excluded from CCHD screening.

(4) The person administering the test shall ensure that the CCHD screening test is conducted in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual.

(5) The results of the test shall be included in the baby's clinical record, reported to the Department and the parents or legal guardians shall be notified, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

#### **511-5-5.06 Hearing Screening**

(1) All hospitals and birthing centers shall be equipped to conduct a newborn hearing screening test in accordance with these Rules.

(2) When a live birth occurs in a hospital, birthing center, office or facility that is equipped to conduct a newborn hearing screening test according to these Rules, a newborn hearing screening test shall be conducted prior to the baby's discharge.

(3) A newborn hearing screening test shall be conducted in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual as follows:

(a) If the baby is in the well-baby nursery, then the test shall be conducted by aOAE and/or aABR;

(b) If the baby is in an SCN or NICU for greater than five days, then the test shall be conducted after 32 weeks gestational age and when the baby is medically stable, and must include an aABR;

(c) If the baby does not pass the initial newborn hearing screening test, then the submitter may perform a second newborn hearing screening test prior to hospital discharge in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual;

(d) In the event that a baby is transferred to another hospital or birthing center before the newborn hearing screening test has been completed, then it is the responsibility of the second facility to ensure that a newborn hearing screening test is completed.

(4) The results of the test shall be included in the baby's clinical record, reported to the Department, and the parents or legal guardians shall be notified and given follow-up recommendations, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

#### **511-5-5.07 Approved Laboratories**

(1) A private laboratory may seek approval from the Department to conduct newborn screening laboratory analysis by showing to the Department's satisfaction that it is licensed in Georgia, that it holds a valid Clinical Laboratory Improvement Amendments (CLIA) Certificate of Accreditation or Certificate of Registration from the Centers for Medicare & Medicaid Services (CMS) to perform high-complexity testing of newborns for the conditions listed in DPH Rule 511-5-5.03(c) through (bb), and that it can perform consistent and reliable testing in accordance with the rules of the Department.

(2) Approved laboratories performing analysis of a Georgia Newborn Screening Specimen Card shall conduct testing for all of the conditions listed in DPH Rule 511-5-5.03(c) through (bb), and shall report the results of the testing to the appropriate newborn screening follow-up provider and submitter on the day that testing is completed.

(3) Approved laboratories shall retain the NBS Cards according to the retention schedule in the current Georgia Newborn Screening Program Policy and Procedure Manual.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

#### **511-5-5.08 Abnormal Test Results**

(1) In the event of an abnormal test result from the NBS Card, the appropriate newborn screening follow-up provider shall notify the baby's physician or healthcare provider and/or parent or legal guardian in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

(2) In the event of an abnormal test result for CCHD, an appropriate assessment or referral shall be made immediately, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

(3) In the event of a newborn not passing the newborn hearing screening test, the person administering the newborn hearing screening test shall notify the Department of Public Health (DPH) in accordance with the Georgia Newborn Screening Policy and Procedure Manual

(4) If the parents or legal guardians cannot be reached or are non-responsive, the Department or the parents' county health department should be contacted for assistance.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

#### **511-5-5.09 Reporting**

Every licensed or permitted hospital, laboratory and/or physician 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 or Department in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

Authority: O.C.G.A. 31-12-2, 31-1-3.2

#### **511-5-5-.10 Revisions to Newborn Screening Panel**

The Commissioner of the Georgia Department of Public Health may from time to time change the roster of conditions for which testing is required. In determining which conditions are to be added or deleted from the newborn screening panel, the Commissioner may seek the advice and guidance of the Newborn Screening and Genetics Advisory Committee. Criteria to be considered in adding disorders shall include, but not be limited to any of the following:

(a) Whether the disorder has significant morbidity and mortality when not identified and not treated before symptoms appear;

(b) Whether early clinical identification of the disorder is unlikely;

(c) Whether the prevalence of the disorder in the population is frequent enough to justify screening an entire population;

(d) Whether appropriate and effective technology and trained personnel are available to perform the additional tests;

(e) Whether resources for follow-up and counseling are available;

(f) Whether resources and efficacious treatment are available; and

(g) Whether the disorder is recommended for screening by any national professional organization such as, but not limited to: the Secretary's Advisory Committee on Heritable Disorders of Newborns and Children, the American Academy of Pediatrics and the National March of Dimes.

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

## 1.4 Georgia's Newborn Screening Disorders

### Primary Target Conditions/Disorders

<b>Organic Acid Disorders</b>	<a href="#">Beta Ketothiolase (BKT)</a> <a href="#">Cobalamin A and B Deficiency (Cbl A,B )</a> <a href="#">Glutaric Acidemia type I (GA1)</a> <a href="#">3-OH 3-CH Glutaric Aciduria (HMG)</a> <a href="#">Isovaleric Acidemia (IVA)</a> <a href="#">3 Methylcrotonyl-Co A Carboxylase Deficiency (3MCC)</a> <a href="#">Multiple Carboxylase Deficiency (MCD)</a> <a href="#">Methylmalonic Acidemia (MMA)</a> <a href="#">Propionic Acidemia</a>
<b>Fatty Acid Oxidation Disorders</b>	<a href="#">Carnitine Uptake Defect</a> <a href="#">Long Chain 3 hydroxyl acyl-CoA dehydrogenase Deficiency (LCHADD)</a> <a href="#">Medium Chain acyl-CoA dehydrogenase Deficiency</a> <a href="#">Trifunctional Protein Deficiency (TFP)</a> <a href="#">Very Long-chain acyl-CoA dehydrogenase Deficiency (VLCADD)</a>
<b>Amino Acid Disorders</b>	<a href="#">Argininosuccinic Acidemia</a> <a href="#">Citrullinemia</a> <a href="#">Homocystinuria</a> <a href="#">Maple Syrup Urine Disease (MSUD)</a> <a href="#">Phenylketonuria (PKU)</a> <a href="#">Tyrosinemia</a>
<b>Hemoglobinopathy Disorders</b>	<a href="#">Sickle Cell Anemia</a> <a href="#">Sickle Beta Thalassemia</a> <a href="#">Sickle C Disease</a> <a href="#">Other Hemoglobin Variants</a>
<b>Other Disorders</b>	<a href="#">Biotinidase Deficiency</a> <a href="#">Congenital Adrenal Hyperplasia (CAH)</a> <a href="#">Congenital Hypothyroidism (CH)</a> <a href="#">Critical Congenital Heart Disease (CCHD)</a> <a href="#">Cystic Fibrosis (CF)</a> <a href="#">Galactosemia</a> <a href="#">Hearing Impairment</a> <a href="#">Severe Combined Immunodeficiency (SCID)</a>

## **SECTION 2**

### **Newborn Bloodspot Screening**

## 2.1 The Georgia Public Health Laboratory

The mission of the Georgia Public Health Laboratory (GPHL) is to improve the health status of Georgians by providing accurate, timely and confidential clinical and non-clinical laboratory testing in support of Georgia Department of Public Health programs, activities and initiatives as well as performing tests for Emergency Preparedness.

To accomplish the role of providing appropriate support for continually evolving public health programs, GPHL provides screening, diagnostic and reference laboratory services to citizens of the state through county health departments, public health clinics, physicians, other clinical laboratories, hospitals and state agencies.

GPHL is arranged in five broad areas of testing and support. They include:

- Chemistry (Newborn Screening Unit, Lead Screening, and Fluoride Testing)
- Emergency Preparedness (Biological/Chemical Threat and Molecular Biology Units)
- Facilities Support
- Microbiology (Bacteriology, Microbial Immunology, Mycobacteriology, Parasitology and Virology Units)
- Operations (Accessioning, Data Entry, Reports & Records, Budget, Personnel and Purchasing)

### Laboratory Tests

GPHL is responsible for specimen analysis, record keeping (as per CLIA '88 requirements), quality control of laboratory methods and notification of results to hospitals, practitioners, and follow-up programs.

### Limitations of Screening

The purpose of a screening test is to distinguish apparently healthy individuals from those individuals who may have a disease. However, screening programs are, by nature, imperfect and not confirmatory. In setting cutoffs, a balance must be struck between time, money, false positives, and, unfortunately, an acceptable number of missed cases.

Missed cases can be the result of biological variability, blood transfusion, errors at the specimen collection site, transit errors, and laboratory errors.

The Georgia Newborn Screening Program has educational and monitoring mechanisms in place to prevent and investigate any possible problems. However, it is still critical for health care providers to remain watchful for any signs or symptoms of these disorders in their patients. Any signs or symptoms of a disorder should be followed up immediately. The possibility of a disorder should not be ruled out solely based on the newborn screening test result. A newborn screening result should not be considered diagnostic and cannot replace the individualized evaluation and diagnosis of an infant by a well-trained, knowledgeable healthcare provider.

### Primary Conditions versus Secondary Conditions

In screening for the Primary Target Conditions/Disorders (see table on page 14) it is likely that secondary conditions/disorders will be detected. As an example, screening for the targeted hemoglobinopathy disorders (sickle cell disease, Hemoglobin C disease, and sickle beta-thalassemia) will identify a large number of other hemoglobin variants, as well as individuals with sickle cell trait.

Some of the analytes measured to screen for the target organic acid and fatty acid disorders are also abnormal for other metabolic conditions and will sometimes detect maternal conditions. Thus, it is critical that appropriate confirmatory and diagnostic testing be performed to distinguish between true positives and false positives, and to determine the true diagnosis.

## **Specimen Analysis**

All specimens are tested by a primary screening method. Abnormal results are then confirmed in duplicate and for some disorders a secondary test is done. Screening results are usually available two to three working days after the specimen is received by the newborn screening laboratory. Results for specimens labeled as a "requested repeat", are usually available in two to three working days.

## **Reporting**

A written report of newborn screening results is mailed to the hospital of birth and the clinician listed on the newborn screening specimen card, as long as this information is provided. Authorized providers can access newborn screening results on-line through the [State Electronic Notification Surveillance System \(SendSS\)](#) or DPH Newborn Screening Laboratory web portal (eReports): <https://services.georgia.gov/dph/eReports/>.

## **Dried Blood Spot Disposal Policy**

DPH recognizes the sensitive nature of the newborn screening dried blood spot specimens (DBS). DPH shall protect the privacy of newborns and their families by assuring that all specimens are protected from inappropriate use or access.

This policy delineates:

- (1) how the newborn screening specimens will be stored after receipt by the Georgia Public Health Laboratory (GPHL),
- (2) the length of time that the specimens will be stored,
- (3) who will have access to the specimens,
- (4) the appropriate uses of the specimens,
- (5) the disposal of the specimens and
- (6) any release of specimens to another entity.

### (1) Storage Conditions

Upon receipt by the GPHL, newborn screening DBS are stored refrigerated (2-8°C) or at ambient temperature (18-25°C) until testing is completed. After testing is finished, the DBS are stored in a walk-in refrigerator until disposed of.

### (2) Storage Time

All DBS are retained for twelve (12) weeks after testing is completed to allow for re-analysis if questions arise concerning the test results. Specimens that are presumptive positive for any of the diseases included in the newborn screening panel are stored in low gas-permeable, zip-closure bags with desiccant and humidity indicator cards along with CDC quality assurance materials (base and elevated DBS) as recommended by the Clinical and Laboratory Standards Institute (CLSI)<sup>1</sup>. These presumptive positive DBS, required for laboratory quality assurance purposes, may be stored at the GPHL for up to two years at 2-8°C.

### (3) Access

The GPLH is a secure facility. Access is through key-cards distributed to employees. All visitors must sign in and out with the armed security guard at the front desk, which is manned 24/7. Visitors must be accompanied at all times by a staff member. Access to newborn screening specimens is restricted to GPLH staff involved with specimen receipt, testing, data entry, and laboratory management only.

#### (4) Use of Specimens

Retained DBS and associated demographic information can be used for the following purposes:

1. Re-analysis to confirm the original test results.
2. Internal method development and method validation studies, including the setting of appropriate cutoffs or normal ranges.
3. Quality assurance audits and gap analysis.
4. De-identified DBS samples may be sent to another laboratory when the reason for sending the sample is:
  - a. Confirmation of an unusual newborn screening result;
  - b. Participation in a specimen-exchange program designed to improve the quality of testing in newborn screening laboratories; or
  - c. Providing assistance to another laboratory in developing or validating a newborn screening method (which requires a statement from the laboratory requesting the specimens that specifies how the specimens will be used, and written approval from the GPLH Director).

#### (5) Disposal

DBS will be autoclaved and then handled as medical waste, which involves off-site incineration.

#### (6) Release of Specimens

In addition to the applications described in the “*Use of Specimens*” section above, DBS may be transferred to other entities as delineated below:

1. An entity that has a contract with DPH to perform additional (i.e., second tier) testing in response to an out-of-range screening result.
2. 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 DPH.
3. A researcher with written, informed consent from the patient, legal guardian, or legal representative, as long as the research project has been reviewed and approved by DPH.
4. A named person in a legally executed subpoena following review and approval by the attorney general or his/her designee.
5. A person to who release is mandated by order of a court of competent jurisdiction.

Any parent who desires to have his/her child’s newborn screening specimen (presumptive positive or confirmed case) destroyed twelve weeks after completion of testing may request such action in writing. Any parent who desires assurance that his/her child’s specimen has been destroyed after completion of testing may request confirmation of such action in writing. Information on the retention and potential use of residual newborn screening specimens are available on the Department’s website.

## 2.2 Dried Bloodspot Specimen Collection Policies and Procedures

DBS specimen collection is the first step in newborn blood screening.

This policy delineates:

- (1) the appropriate time to collect a specimen,
- (2) the importance of filling out the NBS specimen card accurately and completely,
- (3) the procedure for blood collection and
- (4) the process for shipping NBS specimen cards

### (1) When to Collect

- A sample of the infant's blood is taken after 24 hours of age or prior to the infant's discharge from the hospital; whichever comes first
- If the infant has moved to this state from another state, it may be necessary to retest the infant since not all states screen for the same disorders
- Collect a specimen if the infant is less than 6 months old and the results of the screening test from another state cannot be obtained
- If it is discovered that a screening test has not been done, and signs and symptoms are **not** present, a specimen should be collected on infants younger than twelve months old or upon the provider's order

There are no special exceptions to collecting a specimen for breastfed babies. Breast milk and colostrum are considered an adequate protein challenge. There are no special exceptions to collecting a specimen for babies on antibiotics.

The NBS Card should be stored in a cool, dry place. Be sure to take note of the card expiration date. Cards are to be used on or before the expiration date. Destroy all outdated forms immediately and request a new supply from the Georgia Public Health Laboratory. Order no more cards than can be used in 6 months. To order specimen cards, please call (404) 327-7928.

### (2) Filling out the NBS Specimen Card

All information requested on this form is vital for the screening, follow-up, and diagnostic components of the newborn screening process. Information must be **accurate, legible and complete**.

The laboratory uses this information to determine whether results are normal or abnormal based on date of birth, date of collection, birth weight, time of birth, and time of collection. Omitting this information can cause **inaccurate interpretation of results, reporting delays** and unnecessary repeats. Providers listed on the specimen card are considered the ordering provider and are responsible for the follow-up of the results of the screen.

GPHL reports abnormal results to the Follow-up Programs, who then use the demographic information to locate the child and use the results to make appropriate follow-up decisions and recommendations. Omitting this information can result in delays in locating a child and possibly result in a **delayed diagnosis** or **unnecessary death**. Details on how to fill out the card can be found in Section 5.

### (3) Blood Collection Procedure

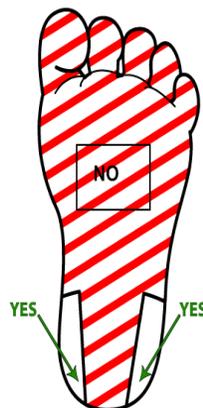
Gloves are worn for personal safety. Avoid contamination of blood collected on the circles with antiseptic solutions, powders, petroleum jelly, lotions or other materials, which may adversely affect the testing process.

#### Equipment List:

- Newborn Screening Specimen Card (NBS card) DPH Form 3491
- Disinfectant (Alcohol only)
- Heel Warmer (disposable commercial brand only)
- Lancet (1.0 mm incision depth; 2.5mm incision length)
- Sterile Gauze
- Band-Aid

#### Procedures:

1. When collecting blood, fold back the cover sheet to expose the filter paper. Do not touch or handle the filter paper before or after applying blood.
2. Swaddle infant or allow the parent to hold to reduce infant movement and crying.
3. Position the infant with feet lower than the level of the heart to help increase the blood flow.
4. Warm the heel, using a disposable commercial heel warmer, to increase blood flow to the area. Cover the puncture site for three to five minutes. A warm, moist towel, at a temperature of no more than 42 degrees centigrade or 107.6 degrees Fahrenheit may also be used.
5. Clean the puncture site with a sterile alcohol pad. Allow to air dry. Excess alcohol may cause hemolysis and denature some of the enzymes tested.



6. Use a sterile disposable automatic lancet, e.g., Tenderfoot™, BD Quick heel device, to make a standard incision 1.0mm deep by 2.5 mm long in the areas indicated on the diagram. Wipe away the first drop of blood with dry sterile gauze.

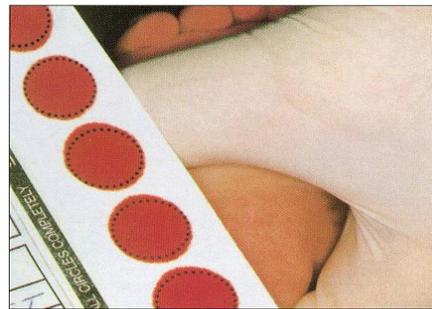


7. Allow a large drop of blood to form. To enhance blood flow during collection, apply very gentle intermittent pressure to the area surrounding the puncture site.

8. Lightly touch the filter paper card to the blood drop and fill each printed circle with **one single drop**, allowing the blood to soak through completely.

**Note: Excessive "milking" causes an admixture of tissue fluids with the blood specimen, resulting in an unsatisfactory specimen.**

9. Apply blood to **one side** of the filter paper only. Either side may be chosen for this procedure. Fill all circle areas. **Do not layer successive small drops of blood to the same circle.** Avoid touching or smearing the blood spots.



10. **Do not** use capillary tubes for blood collection. Capillary tubes contain heparin, which may lead to diluted or contaminated specimens.

11. If blood flow is diminished, repeat steps three through six with sterile equipment.

12. If you are having trouble collecting blood, alternative methods of collection can be used\*. An umbilical catheter and or venipuncture specimen may be used.

**\*Refer to the Clinical And Laboratory Standards Institute (CLSI) Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard-Fifth Edition. LA4-A for additional information.**

13. Allow NBS card to thoroughly air dry for at least three hours on a flat, nonabsorbent surface, away from direct heat and sunlight.

**Do not allow the protective flap to come into contact with blood spots until spots are thoroughly dry. Do not refrigerate.**

14. Ship NBS cards to the Georgia Public Health Laboratory within 24 hours of collection. Delayed submission to the laboratory may result in significant delay in 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.***

#### (4) NBS Specimen Card Shipment

Ship NBS cards to:

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

Specimens must be shipped within 24 hours of collection (via next day courier, UPS, or FedEx for tracking purposes). The GPLH provides pre-addressed United Parcel Service (UPS) labels to hospitals. GPLH will pay for one shipment, per day, per hospital, for transport of specimens, Monday through Friday to the laboratory.

The State Laboratory assumes responsibility for testing only; whoever submits specimens must assume liability for proper identification, collection and prompt delivery of specimens to the State Lab.

### 2.3 Sample Acceptability/Unsatisfactory Specimens

When testing a sample, GPLH makes four or five 1/8" punches from each "circle" that require precise quantities of blood. Therefore, it is necessary that blood fills up the entire circle and soaks through the filter paper, but does not alter the homogeneity of the filter paper surface.

Prior to testing, all specimens are inspected for acceptability. Those samples deemed unacceptable for testing are reported as "**UNSATISFACTORY - PLEASE RESUBMIT.**" Submitting an invalid specimen leads to the inconvenience of retesting and delays in screening; thus placing the newborn at risk for a delayed diagnosis. It is then the responsibility of the birth hospital and the listed clinician to retrieve the newborn for a repeat collection.

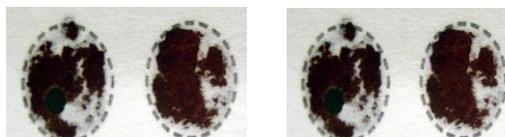
#### Categories of Unsatisfactory Specimens

1. **Acceptable Specimen**



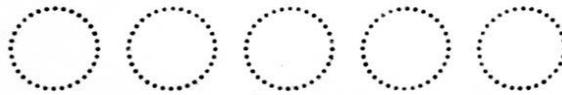
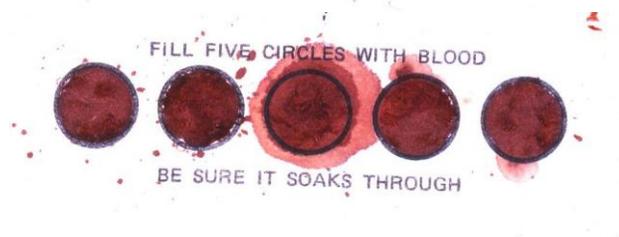
2. **QNS** - quantity of blood is not sufficient for testing

3. **Unevenly Saturated** - blood has not completely filled the circle and/or



soaked through the filter paper from front to back

4. **Oversaturated** – excessive application of blood; repeated layering of blood; applying blood to both sides of the filter paper.
5. **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.
6. **Crumpled** - excessive blood application that results in clumps, clots/retraction of the filter paper (appears as though filter paper was put in water and then dried).
7. **Capillary Application** - uneven application of blood from a capillary tube; tearing the filter paper with the capillary tube. Capillary tubes contain heparin which may lead to diluted or contaminated specimens.
8. **No Blood** – no blood on the filter paper.
9. **Roughed Up** – excessive handling of the specimen card or drying the specimen with heat.
10. **Obsolete form** – out of date or expired filter paper form. (Check expiration date printed NBS card).
11. **Delayed** – specimen received by the laboratory 7 days after the date of collection.
12. **Insufficient Information** – failure to fully complete form.
13. **Invalid Data** – data on the form cannot be true (e.g., date of collection prior to the date of birth).



14. **Illegible Data** - data entry staff cannot read submitters' handwriting
15. **Blood reattached to form** – filter paper with blood is stapled or reattached to the form. (Does the blood specimen belong to this baby?) *(If you are certain that you have reattached the blood spot to the correct baby, attach a letter of verification and send to the laboratory with the specimen.)*

## 2.4 Special Populations

### NICU/Special Care Nursery Admissions

A critically ill or premature infant may have persistent abnormalities in the newborn screening test results without actually having a disorder. Prematurity is associated with physiological elevation of 17-hydroxyprogesterone (17-OHP) and reduction of thyroxine (T4). Total parenteral nutrition (TPN) may cause a false positive result for several of the metabolic disorders. Additionally, a normal screen on an infant who has insufficient enteral intake does not rule out metabolic disease.

The Georgia NBS Program requires infants admitted to a Neonatal Intensive Care Unit (NICU) or Special Care Nursery (SCN) receive a blood screen according to the [Clinical and Laboratory Standards Institute \(CLSI\), Newborn Screening for Preterm, Low Birth Weight, and Sick Newborns; Approved Guideline \(I/LA31-A, Vol. 29 No. 24\)](#).

The following is the screening schedule outlined by this guideline and shall be used for infants in NICUs/SCNs.

- a) Upon admission, regardless of age and before any other treatments are begun (except respiratory).
- b) Between 48-72 hours of life, on infants initially tested < 24 hours of age at the first screen or <2000 grams at birth.
- c) At 28 days of life, or discharge, whichever comes first for all infants <2000 grams.

### Transferred Infants

In the event of a transfer to another facility, shortly after birth or before screening has been accomplished, the transferring facility must complete a newborn screen prior to the transfer and ensure that the next facility is aware of the need for screening. Hospitals transferring a sick neonate to an NICU should document in the medical record whether the first newborn screen has been collected. The receiving NICU should also note whether newborn screening has been done. If not, the neonate should have a newborn screen collected upon admission, a second screen collected again at 48-72 hours of age and a third screen at 28 days or at discharge, whichever comes first on all infants weighing <2000 grams at birth.

## Transfusions

If a newborn is to receive a transfusion, it is critical to collect a specimen prior to the transfusion. Even small transfusions may invalidate screening test results. A second sample for newborn screening should be collected 120 days after the last transfusion. Unscreened infants transfused before admission to the NICU should be screened regardless, but will need re-screening.

## Low Birth Weight Infants

Low birth weight (LBW) infants (<2500 grams) will also need retesting due to immature enzyme systems or thyroid functioning. If the infant is <2500 grams and was not admitted to an NICU, repeat blood screening at **4 weeks of age**. If the LBW infant shows clinical signs consistent with any disorder prior to repeating the NBS, confirmatory testing should be done immediately. You may contact a follow-up provider to reach a specialist on-call if assistance is needed.

## 2.5 Blood Screening Follow-up Programs

Follow-up of an abnormal result is an important component of the early detection and intervention of a disorder that may result in severe morbidity or mortality. GPHL reports abnormal results to the follow-up program at the same time or even before a report has been made available for the listed provider. The primary function of the follow-up component is to locate infants with positive screening results and to facilitate the entry of those infants into the diagnostic and management components of the NBS system within in a timely fashion.

### Newborn Screening Follow-up Providers

- (1) Emory University Department of Human Genetics
- (2) Sickle Cell Disease Follow-up
  - a) Georgia Regents University
  - b) Children's Healthcare of Atlanta
  - c) The Sickle Cell Foundation of Georgia

1. Emory University Department of Human Genetics - Follow Up Program: Metabolic, Endocrine, Cystic Fibrosis and Immunology Disorders

The Emory follow up program is a contracted service that consists of a team of licensed nurses dedicated to reporting, providing support, and gathering data through the follow-up process for all children with an abnormal newborn screen. Abnormal screens for the following groups of disorders are handled by Emory:

- Metabolic disorders
- Endocrine disorders
- Cystic Fibrosis (CF)
- Severe Combined Immunodeficiency (SCID)

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 NBS card to report the abnormality, deliver education and resources about the condition, and providing recommendations on how to proceed.

Abnormal newborn screening results are triaged into three categories: borderline (results that are slightly out-of-range), routine abnormal (results that are elevated and can be consistent with a disorder) and critical abnormal (results that are critically out-of-range).

- **Borderline:** These results and recommendations are reported via fax to the provider listed on the 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 card is called within 24 hours to report the result and recommendations. These calls are then followed with a fax of the information and a subsequent phone call when action has been delayed. Letters are not routinely sent to families at this time.
- **Critical abnormal:** The provider listed on the card is called immediately to report the result and recommendations. These calls are then followed with a fax of the information and a subsequent phone call when action has been delayed. Letters are not routinely sent to families at this time.

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

### Healthcare Provider's Responsibility

Providers may be asked to do one or more of the following:

2. Contact the family and bring them in for an assessment - Infants should be assessed as soon as possible. For some urgent results, the follow-up nurse may advise you that an immediate assessment is necessary or possibly a referral to the emergency department.
3. Repeat the newborn screen - Many infants will need a repeat screen instead of diagnostic testing. This request will be included in the verbal and/or faxed report from the follow-up team.
4. Collect diagnostic test samples including whole blood and/or urine - Some infants will require whole blood and/or urine testing. This will be included in the verbal and faxed report from the follow-up team. The details on which tests to order and recommended labs will also be included in the verbal and faxed report from the follow-up team.
5. Refer the child for a sweat test - All children with a positive screen for cystic fibrosis need a sweat test at a laboratory accredited by the Cystic Fibrosis Foundation. Contact details for accredited laboratories in Georgia are provided. Assistance for laboratories in other states can be provided, if more appropriate.

### Provider of Record

The provider listed on the NBS card is responsible for contacting the family. In some cases, the family has not made an appointment yet, so it is important to bring in the child as soon as possible for the recommended follow-up activities. If the child is seeing a different healthcare provider, the follow-up team should be notified immediately with the name and phone number of that provider.

## Diagnostic Test Results

Please fax diagnostic test results to the Emory follow-up program as soon as you receive them: 404-778-8564. Emory will help guide you in ensuring appropriate clinical follow-up takes place. For some disorders, an immediate consultation may be warranted, so do not hesitate to call Emory if you have questions or concerns.

### Important contact information:

**Emory Follow-Up Program phone number: 404-778-8560**

**Physician on call (including genetics, endocrinology, immunology, pulmonology): 404-785-7778**

**Metabolic Nutritionist's phone number: (404) 778-8566**

### (2) Hemoglobin Follow-up Program

The three types of sickle cell disease (Sickle Cell disease, Hemoglobin C disease, and sickle beta-thalassemia) make sickle cell disease the leading genetic disorder identified by newborn screening. However, the screening methodologies used may detect a variety of hemoglobinopathies other than sickle cell disease: e.g., homozygous C disease, hemoglobin C/ beta-thalassemia disease, homozygous E disease, hemoglobin E/beta-thalassemia disease and others. Following a positive hemoglobin screening result, it is recommended by the American Academy of Pediatrics (AAP) that positive screens be **confirmed within three (3) months of age**. Early diagnosis of sickle cell disease is crucial in reducing the morbidity and premature death associated with sickle cell disease.

The follow-up of abnormal screening results that suggest hemoglobin diseases are divided between Children's Healthcare of Atlanta (CHOA) for Metro-Atlanta counties and the Division of Pediatric Hematology/Oncology at Georgia Regents University (GRU) for all other counties and the bordering states. These follow-up programs work in partnership with healthcare providers, public health sickle cell outreach clinics located in ([Albany, Dublin, Valdosta, Waycross](#)) and hematologists throughout the state to ensure all babies identified with abnormal results receive timely diagnosis and treatment.

Newborn blood screening identifies healthy carriers of sickle cell trait or thalassemia. Counseling and education is provided for families of infants that are traits/carriers (single hemoglobin mutation) by the Sickle Cell Foundation of Georgia (SCFGa). Confirmatory and family testing for families of infants with hemoglobin disease is also provided. Parents may benefit from genetic testing, especially if test results reveal a risk of hemoglobinopathy for a subsequent pregnancy.

### Hemoglobin Follow-up Program's Responsibilities

The follow-up programs are contracted services. The follow-up teams at CHOA and GRU ensure timely diagnostic testing and appropriate care is instituted to confirm or rule out abnormal hemoglobin findings, report abnormal results to the health care provider listed on the NBS card and to the parents. The follow-up teams also provide education and counseling to families, serve as a resource for physicians and families, and to refer confirmed cases to the Children 1st Program for determination of eligibility for public health child health intervention services.

The following information is faxed to the healthcare provider:

- Letter that explains the screening mandate, confirmation process, and contact information
- Copy of the GPHL NBS report
- Copy of [Newborn Screening ACT Sheets and Confirmatory Algorithms](#)

- Other disease information as appropriate
- Copy of a lab slip for the GRU Hemoglobin Reference Laboratory

It is important for the confirmatory test (hemoglobin electrophoresis) to be done as soon as possible after birth and should not be delayed because signs of sickle cell disease can develop shortly after birth. The [Hemoglobin Reference Laboratory](#) that is located at Georgia Regents University in Augusta, Georgia is an international testing and reference center for sickle cell disease, thalassemia, and other hemoglobin disorders. However, samples are also encouraged to be submitted to CHOA for Metro-Atlanta clients needing rapid turnaround times in confirmatory results. The GRU laboratory is one of a few in the country that studies abnormal hemoglobin and is a resource for researchers and clinicians throughout the country and beyond. It is the preferred testing site for confirmatory testing. Testing at GRU is free for NBS confirmation of a hemoglobinopathy and associated family studies. There may be a fee incurred for other testing; the lab should be contacted directly for additional information.

### Special Circumstances - Transfusions

Efforts should be made to collect a specimen prior to any planned transfusion. Specimens are flagged when the electrophoresis pattern shows hemoglobin A (Adult) in a greater amount than hemoglobin F (Fetal). This may suggest a transfusion when the infant is less than 30 days of age at specimen collection, or when a transfusion has occurred < 120 days before collection. The follow-up coordinator will provide information on the appropriate time to collect a confirmatory sample after transfusions have occurred.

### Healthcare Provider's Responsibilities

The provider listed on the NBS card is responsible for contacting the family to arrange diagnostic testing.

Providers are also asked to do the following:

- Contact the family and schedule them for an appointment as soon as possible or notify the follow-up coordinator if the family is seeing another healthcare provider.
- Share the NBS results and hemoglobin educational literature with the family during the initial visit.
- Provide notification to the family about the abnormal hemoglobin via phone or in writing using the certified mail system, if a different healthcare provider cannot be located
- Collect the confirmation test using whole blood, complete the lab slip that was included in the fax from the NBS FPC and send samples to the Hemoglobin Reference Laboratory or refer the family to the SCFGa for confirmation testing and family studies. Referrals can also be made to a hematologist or outreach sickle cell clinic where the confirmation test can be collected. **Do not** use the NBS collection card to confirm abnormal hemoglobins
- Fax confirmation results to the follow-up coordinator if a private laboratory is used.
- Refer all confirmed cases to a hematologist or a sickle cell outreach clinic.

### Follow-up Providers Contact Information

#### Georgia Regents University (GRU) Hemoglobin Follow-up Program

The GRU follow-up program is a contracted service dedicated to reporting, providing support, and gathering data through the follow-up process for children with an abnormal hemoglobin screen in a designated area outside of Metro-Atlanta.

**Important contact information:**

**NBS Program Coordinator: (706) 721-6251**  
**On-call MD: (706) 721-3893**

Children's Healthcare of Atlanta (CHOA) Hemoglobin Follow-up Program

The CHOA follow-up program is a contracted service dedicated to reporting, providing support, and gathering data through the follow-up process for children with an abnormal hemoglobin screen in a designated area within Metro-Atlanta.

**Important contact information:**

**NBS Follow-up Coordinator: (404) 785-1087**

The Sickle Cell Foundation of Georgia: Hemoglobin Traits/Carriers Follow-up

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

**Important contact information:**

**SCF NBS Coordinator: (404) 755-1641 or 1-800-326-5287 (toll free)**

## **SECTION 3**

### **Newborn Hearing Screening**

### 3.1 Policies and Protocols

Birthing hospitals and healthcare facilities must conduct newborn hearing screening using at least one of the following automated physiological hearing screening methods that does not require interpretation by the screener.

This policy delineates the:

- (1) Equipment,
- (2) Equipment requirements,
- (3) Personnel,
- (4) Location and
- (5) Protocols for conducting newborn hearing screening.

#### (1) Equipment

There are two technologies available for automated physiologic screening of hearing in newborns.

1. Automated Auditory Brainstem Response (aABR) – Objective measurement obtained from surface electrodes that record neural activity generated in the cochlea, auditory nerve, and brainstem in response to low-intensity click stimuli delivered through earphones. 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.

**Note:** Screenings on babies admitted to the neonatal intensive care unit (NICU) for greater than five days must include aABR technology as stated in O.C.G.A. 31-2A-6, 31-12-5 through -7

**Limitation:** Infant must remain quiet, it is best if baby is asleep

2. Automated Otoacoustic Emissions (aOAE) – Objective measurement obtained from the ear canal using a sensitive microphone within a probe assembly that records cochlear responses to low intensity acoustic stimuli. OAEs are a physiologic test that reflects the status of the peripheral auditory system specifically measuring cochlear (outer hair cell) function. There are two types of OAE technologies: Transient Evoked Otoacoustic Emissions (TEOAE) click stimuli and Distortion Product Otoacoustic Emissions (DPOAE) tone pairs.

**Note:** aOAEs may miss a disorder called Auditory Neuropathy Spectrum Disorder (ANSD)

**Limitations:** Infant must be relatively inactive during the test, and aOAEs are very sensitive to middle-ear effusions, and cerumen or vernix in the ear canal

#### (2) Equipment Requirements

Despite both technologies being appropriate in detecting cochlear hearing loss, some infants who pass newborn hearing screening will later demonstrate permanent hearing loss. Although this loss may reflect delayed-onset hearing loss, both aABR and aOAE screening technologies will miss some hearing loss (e.g., mild or isolated frequency region losses).

Requirements:

1. Hearing screening equipment must be calibrated in accordance with manufacturer's recommendation and should be monitored with monthly equipment checks to ensure equipment is functioning properly
2. Calibration certificates must be kept on record (annually)
3. Log maintained to show monthly equipment checks and any equipment issues with dates and explanations
4. Birthing facilities should have alternate plans for newborn hearing screening in the event of equipment malfunction
5. Equipment should be cleaned with disinfectant wipes before and after every hearing screen
6. Disposable components of equipment must not be re-used

(3) Hearing Screening Personnel

A team of professionals, including audiologists, physicians, and nursing personnel, are needed to establish and maintain the newborn hearing screening program. It is important that all members of the team work together to ensure a successful program. An audiologist should be involved to train staff and establish protocols and hospitals and agencies should also designate a physician to oversee the medical aspects of the newborn hearing screening program.

Children Under 3 Months of Age

OCGA Section 43-44-7 (h) states that a person not licensed as an audiologist may perform non-diagnostic electro-physiologic screenings of the auditory system, using automated otoacoustic emissions or automated auditory brainstem response technology as part of a planned and organized screening effort for the initial identification of communication disorders in infants under the age of three months, provided that:

1. The person not licensed as an audiologist has completed a procedure-specific training program directed by an audiologist licensed under this chapter;
2. The screening equipment and protocol used are fully automated, and the protocol is not accessible for alteration or adjustment by the person not licensed as an audiologist;
3. The results of the screening are determined automatically by the programmed test equipment, without discretionary judgment by the person not licensed as an audiologist, and are only reported as "pass" or "refer";
4. An audiologist licensed under this chapter is responsible for the training of the person not licensed as an audiologist, the selection of the screening program protocol, the determination of administration guideline the periodic monitoring of the performance of the person not licensed as an audiologist, and the screening program results; and,
5. The participation of the person not licensed as an audiologist in such an automated screening program is limited to the recording of patient demographic information, the application of earphones, electrodes, and other necessary devices; the initiation of the test; the recording of the results; and the arrangement of the referral for those who do not pass the screening to an audiologist licensed under this chapter for follow-up evaluation.

### Children Over 3 Months of Age

For children over 3 months of age, refer the child to a licensed audiologist or physician for testing. A physician, by law, may delegate aOAE and aABR hearing screenings to staff under their supervision, while they are on the premises, for infants over 3 months of age as stated in O.C.G.A. 43-44-7 (g).

1. Screeners should be knowledgeable about screening technologies and competent in performing newborn hearing screening
2. Screeners should be comfortable working with newborns and their families
3. Screeners should be prepared to educate parents about newborn hearing screening including describing the hearing screen, type of technology, and delivering the results, and follow up recommendations
4. Screener scripts are recommended to assist screeners with education and follow-up for newborn hearing screening
5. Screeners should complete a hearing screening training curriculum directed by an audiologist licensed in Georgia with initial and annual competency documented

#### (4) Where to Screen

Newborn hearing screening may be performed in the nursery, mother's hospital room, designated quiet room, or NICU. It is best to select an area that is quiet and free of electrical interference.

\*Screeners should be knowledgeable about optimal screening conditions and troubleshooting techniques to minimize interference and obtain an efficient screen.

#### (5) Hearing Screening Protocol

##### *At a Glance:*

1. Make sure the baby is medically eligible and stable for a hearing screen
2. Hearing screen must be conducted after 32 weeks gestational age
3. It is advisable to screen after an infant has completed nursing or feeding, to increase the chance of the infant sleeping during the screening
  - Newborn hearing screening is more efficient and accurate when the newborn is quiet and content
  - Swaddling a baby is often helpful
4. Newborns receiving antibiotic therapy or phototherapy for hyperbilirubinemia should have a repeat hearing screen prior to discharge if the screening was completed prior to treatment.
  - Antibiotic therapy or phototherapy should **not** be a reason for a "missed" screen
5. If a baby "refers" on the initial hearing screening it is recommended that the hearing screen be repeated prior to discharge with at least four hours between screenings, if possible.
  - **Rescreening on both ears** is required, even if only one ear "referred" the initial screening

## Screening Protocols in Well-Baby Nursery

### **1. Screening Technologies:**

- It is appropriate to use either technology (aOAE or aABR) in the Well-Baby Nursery
- A combination of screening technologies, such as a two-step protocol using an aOAE for the initial screening and an aABR if the baby “refers” the aOAE screening is acceptable
  - *With this approach, infants who “refer” on an aOAE but “pass” an aABR are considered a “pass” screening result*
  - Infants who “refer” on an aABR screening should never be rescreened with aOAE technology and “passed” because these infants are considered to be at risk for auditory neuropathy spectrum disorder.

### **2. Time of Screening:**

Hearing screens may be performed as early as 6 hours after birth. Waiting at least 12 hours before newborn hearing screening allows more time for birth debris or vernix that may be in the newborns ear canal to clear. The additional time maximizes the opportunity to obtain an efficient newborn hearing screen especially for babies that are delivered by caesarean section.

Delaying a hearing screen 12 hours after birth may not be feasible if early discharge policies are in place. However, screening too early can result in high refer or false positive rates. Repeating the screening prior to discharge will help eliminate this problem. Hospital policy should be reviewed with regard to discharge when developing individual hospital newborn screening protocols. It is standard for vaginal deliveries to discharge between 24 to 48 hours and cesarean deliveries between 48 to 72 hours.

### **3. Newborn “passes” the hearing screen with no known risk factor(s):**

- Document the result of the screen on the NBS Card or Delayed Screening Report Form (See Section 4.4) and in the infant’s medical record
- Parents should be notified of results verbally and in writing in their native language
- Educate the parent(s) on the importance of the baby achieving hearing developmental milestones; provide the “*Georgia Newborn Screening Program: What Every Parent Should Know*” brochure DPH Form 5506
- PCP should be notified of the hearing screen results in writing
  - Infant should be followed by their medical home/PCP according to the American Academy of Pediatrics (AAP) Periodicity Schedule

### **4. Newborn “refers” the initial hearing screen:**

- Rescreen the baby prior to discharge remembering that a “refer” result on an aABR hearing screen must be followed up with an aABR hearing screen
- Both ears must be screened at every screening even if only one ear “refers”
- It is recommended that screens be separated by a minimum of 4 hours if possible
  - Successive back to back screenings is highly discouraged

### **5. Newborn “passes” second/final screen; follow protocol for a “passed” screen.**

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**6. Newborn “refers” the second/final hearing screen:**

- Document the result of the screen on the NBS Card or Delayed Screening Report Form (See Section 4.4) and in the infant’s medical record
- Parents should be notified of results verbally and in writing in their home language
- Parents should be educated on the importance of keeping the rescreen appointment or scheduling an out- patient rescreen appointment if not made prior to discharge
  - For follow-up procedures, see section 3.4 Follow-Up
- Rescreen appointment should be scheduled if possible prior to discharge
- The PCP should be informed of the “refer” result on the newborn hearing screen by the hospital in writing
  - Infant should be followed by the medical home/PCP according to the AAP Periodicity Schedule
- Complete the *Children 1<sup>st</sup> Screening and Referral Form* with risk factors indicated and forward to Public Health or document risk factors in the EBC if applicable

*Perform no more than two completed hearing screens prior to discharge.*

When statistical probability is used to make pass/refer decisions, as is the case for (aOAE) and (aABR) screening technologies, the likelihood of obtaining a pass outcome by chance alone is increased when screening is repeatedly performed .

## 3.2 Special Cases

Infants admitted to the NICU have higher rates of hearing loss than infants in the well-baby nursery. NICU infants more frequently than well-baby infants have Auditory Neuropathy Spectrum Disorder and require screening with aABR technology. The Joint Committee on Infant Hearing (JCIH) identified specific risk factors that are associated with infant and childhood hearing loss. The Georgia Early Hearing Detection and Intervention (EHDI) Program requires infants in the NICU and those with specific risk factors (well-baby and NICU) be screened accordingly, and results are reported to the Department.

### Screening Protocols in the Neonatal Intensive Care Unit:

#### 1. Screening Technologies:

- Must include aABR technology unless in the NICU for less than 5 days

#### 2. Time of Screening:

- prior to discharge
- after 32 weeks gestational age
- with infant in stable condition and off oxygen and antibiotics for 24 hours

#### 3. Newborn “passes” the hearing screen with risk factor(s):

- Document the result of the screen on the NBS Card or Delayed Screening Report Form (See Section 4.4) and in the infant’s medical record
- Parents should be notified of results verbally and in writing in their native language
- Educate the parent(s) on the importance of the baby achieving hearing developmental milestones and recommended follow-up for risk factor(s)
- PCP should be notified of the hearing screen results in writing
  - Infant should be followed by their medical home/PCP according to the AAP Periodicity Schedule
- Complete the *Children 1<sup>st</sup> Screening and Referral Form* with risk factors indicated and forward to Public Health or document risk factors in the EBC

#### 4. Newborn “refers” the initial hearing screen:

- Rescreen the baby prior to discharge, remembering that a “refer” result on an aABR screen must be followed up with an aABR screen
- Both ears must be screened at every screening even if only one ear “refers”
- It is recommended that screens be separated by a minimum of 4 hours if possible

#### 5. Newborn “passes” second/final screen; follow protocol for a “passed” screen.

#### 6. Newborn “refers” the second/final hearing screen:

- Document the result of the screen on the NBS Card or Delayed Screening Report Form (See Section 4.4) and in the infant’s medical record
- Parents should be notified of results verbally and in writing in their home language

- Parents should be educated on the importance of keeping the rescreen appointment or scheduling an out-patient rescreen appointment if not made prior to discharge
  - For follow-up procedures, see section 3.3 Follow-Up
- Rescreen appointment should be scheduled if possible prior to discharge
- The PCP should be informed of the “refer” result on the newborn hearing screen by the hospital in writing
  - Infant should be followed by the medical home/PCP according to the AAP Periodicity Schedule
- Complete the *Children 1<sup>st</sup> Screening and Referral Form* with risk factors indicated and forward to Public Health or document risk factors in the EBC if applicable

#### Risk Factor Protocol

Georgia has a protocol for infants, up to six months, who pass the newborn hearing screening but are identified with risk factors based on recommendations from the JCIH Position Statement 2007.

#### Readmissions to Hospital

It is recommended that a hearing screening (rescreening) be completed on all infants readmitted during the first month of life when there are conditions associated with potential hearing loss. For infants not passing a screening subsequent to readmission, who passed their initial screen, these babies should be referred to their PCP for follow-up. The EHDI District Coordinator may be used to assist the family in locating providers for follow-up evaluation.

#### Border State Babies

Infants whose parents are residents of Georgia but are born in another state are followed up according to the same procedures as infants that are residents of Georgia and born in Georgia. Neighboring states have differing protocols with regard to notification and follow-up procedures. Once a referral is received from another state indicating a newborn “referred” on hearing screening or was identified with hearing impairment, that information is forwarded to the EHDI District Coordinator for appropriate follow-up, documentation, and referrals to other Georgia public health programs. Referrals of infants that are born in Georgia but reside in another state are forwarded to the appropriate state’s EHDI Coordinator immediately for notification and follow-up.

### 3.3 Follow-up

#### Roles and Responsibilities

##### Role of EHDI District Coordinator as Follow-up Provider

- Act as a liaison between the hospital(s) within their health district with reference to the EHDI program
- Work with state EHDI program staff to address hospital performance falling below set benchmarks on screening and referral rates
- Receive and track referrals on newborns who have “referred” initial or follow-up screenings, whose parents refused screenings, or who have been discharged from the hospital without having a newborn hearing screening
- Coordinate with the PCP/Medical Home to facilitate referral of newborns that “refer” screening for rescreening and for diagnostic audiological evaluation if necessary, and linkage to appropriate intervention for those babies diagnosed with hearing loss
- Receive and refer as appropriate all referrals entered directly into SendSS
- Receive and track all out of state referrals for children who “refer” on an initial screening or rescreening or those identified with hearing loss, and enter the information into the SendSS database
- Document in SendSS the follow-up activities on all referrals from initial screen to enrollment of intervention
- Perform tasks as outlined in Georgia’s Loaner Hearing Aid Bank protocol
- Identify areas to provide education and awareness of the EHDI program in their local Public Health District and community

##### Role of the Primary Care Physician and Medical Home

The primary care physician’s role and support is vital to the success of the newborn screening program. The primary care physician is to be the center of the medical home as they are an active participant in the life of the family during a baby’s first year. The medical home is responsible for ensuring appropriate and timely referrals to providers that are capable of performing evaluations and knowledgeable in congenital hearing impairment. As the medical home provider, the primary care physician should:

- Obtain the written results of newborn hearing screening from the birthing facility on all newborns.
- By one month of age, ensure that all newborns have at minimum one hearing screening or a secondary screening if infant “referred” inpatient hearing screening.
- Refer for audiological diagnostic evaluation for infants “referring” secondary screening before three months of age.
- Provide referrals to early intervention, otolaryngologist, ophthalmologist and genetics after diagnosis of permanent hearing impairment.
- Manage otitis media with effusion.
- Closely monitor for signs of hearing loss for infants who pass newborn hearing screening and refer for audiological evaluation per JCIH recommendations, developmental/speech delay, or parental concern, as hearing loss may develop at any age.
- Closely monitor the development of children with hearing loss

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### Role of the Otolaryngologist

A child newly diagnosed with a permanent hearing loss is to be referred to an Otolaryngologist (ENT) for a medical evaluation. The ENT's role is to determine the potential etiology of the hearing loss, provide clearance for hearing aids, and make referrals to the appropriate specialists as needed. Additionally, the physician will also determine if the problem is medically or surgically treatable, and if so, provide the necessary medical or surgical treatment. To determine the cause of hearing loss or possible treatments, the ENT may refer the child for procedures such as imaging studies (X-rays, CT-scans, MRI scans).

### **Out-Patient Hearing Screening/Rescreen and Follow-up**

For infants that are “missed” or “refer” on an inpatient newborn hearing screening, an outpatient hearing screening/rescreen may be conducted at the birth facility, health department, audiologist/ENT office, or physician's office. Automated OAE or ABR hearing screens may be conducted by trained screeners in accordance with Georgia Law, (Official Code of Georgia, Section 43-44-7), on infants under 3 months of age. An infant who stayed in the NICU greater than five days that “referred” screening should be scheduled with a pediatric audiologist for a rescreen or diagnostic evaluation.

### Out-Patient Procedure

- Infants are to be screened **one time**
  - Outpatient hearing screening/rescreen should be completed prior to 1 month of age
- Both ears should be screened at outpatient hearing screening; **even if infant only “refers” on one ear**

### Technology

- An aOAE may be followed up with an aOAE or aABR
- An aABR **MUST** be followed up with an aABR
  - **Infants who “refer” on an (ABR) screening should never be rescreened with (OAE) technology and “passed” because these infants are considered to be at risk for auditory neuropathy spectrum disorder**

### Immediately Following Outpatient Screening/Rescreening

- Parents should be notified of results verbally and in writing in their home language
- PCP should be notified of the hearing screen results in writing
- Results, including screening technology, should be documented in the child's medical record
- Screening results must be reported to Public Health on the *Children 1<sup>st</sup> Screening and Referral Form* or electronically submitted through SendSS within 7 days of completed screen
  - Both “Pass” and “Refer” results are required to be reported to Public Health as stated in Georgia Rule **511-5-5-.09**
- **Infants that “refer” outpatient hearing screening should be referred to pediatric audiologist for diagnostic evaluation immediately**
  - Diagnostic evaluation should be completed prior to 3 months of age

## **Diagnostic Audiological Assessment on “Referred” Infants**

Diagnosis of hearing loss or audiological evaluation should not be delayed due to suspicion of middle ear dysfunction. Confirmation of an infant’s hearing status requires a battery of audiological tests procedures to assess the integrity of the auditory system in each ear, to estimate hearing sensitivity across the speech frequency range, to determine the type of hearing loss, to establish a baseline for further monitoring, and to provide information needed to initiate amplification-device fitting if appropriate.

Audiologists performing audiological evaluations must hold a valid and current Georgia Audiology license. Audiologists designated to provide assessment and management of infants and children with hearing loss must have the commensurate knowledge, skill, and instrumentation necessary for use with current pediatric hearing assessment methods and evaluation procedures from the Pediatric Working Group, <http://aja.pubs.asha.org/article.aspx?articleid=1773672>. The goal of the audiological evaluation is to determine the current hearing status of the infant.

### Audiological assessment of infants referring on newborn hearing screening:

Georgia’s EHDI Program offers training curriculum to assist Audiologists best practice information on diagnostic audiological procedures, specifically auditory brainstem response (ABR) threshold testing. The training curriculum entitled *Georgia’s Pediatric Audiology Training Curriculum* can be retrieved from the DPH website <http://dph.ga.gov>.

### 3.4 Intervention Services

Infants identified with hearing loss may receive a variety and combination of intervention services to include: 1) Pediatric Amplification, and 2) Language Intervention Services.

#### Guidelines for Pediatric Amplification

Audiologists providing amplification services must hold a valid and current Georgia Audiology license and must have knowledge, skill, and instrumentation necessary for providing amplification and management for children. Medical clearance must be obtained from an otolaryngologist prior to hearing aid fitting. Amplification decisions should be based on audiological information from ABR and behavioral testing. Electrophysiological results may need to stand alone for a period of time to determine appropriate fitting levels. However, as soon as the child is able to participate, behavioral threshold measures should be obtained and used to cross-check prior results (American Academy of Audiology, 2012). Other factors contributing to fitting include, but are not limited to performance in the home and/or educational environments, family preference, other existing conditions, and speech and language development.

#### **Amplification Options**

- Behind-the-ear (BTE) hearing aid
  - Most appropriate for children due to rapid growth of the outer ear
  - Hearing aid features (e.g. directional microphone, volume control, tamper resistant battery door) and processing schemes should be closely considered when choosing an appropriate hearing aid given child's age and hearing loss
  - Ear molds should be made of soft material for safety and retention
- Bone conduction aid
  - Appropriate for conductive hearing loss in cases that a BTE hearing aid cannot be fit
  - A bone anchored hearing aid may be considered, but is not approved for use in children less than five years old by the U.S. Food and Drug Administration (FDA)
- Cochlear Implant
  - Currently not FDA approved until 12 months of age for children with bilateral profound hearing loss
  - Eligibility and candidacy criteria should be carefully considered prior to implantation and should include a team of professionals working with the family and child
- Frequency Modulation (FM) system: *Coupled with personal hearing aid or cochlear implant, which is used to improve the signal to noise ratio*

#### **Verification and Monitoring**

Verification of hearing aid fitting should be performed to ensure the child has optimal settings of hearing aid. Probe microphone measurements and aided sound field responses are recommended to be conducted after hearing aid fitting to evaluate the hearing aid output values and the audibility of sounds. Follow up visits, at minimum, should include parent input on child performance with hearing aids (Cochlear implant, FM system), functional auditory skill assessments, verification of proper usage and fit of hearing aid and any necessary troubleshooting. The frequency and scheduling of follow-up visits depend on the patient's age and family needs, but should occur more frequently after initial fitting.

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Revised October 15, 2015

## Georgia Hearing Aid Loaner Bank – GA HALB

In September 2012, the Georgia Hearing Aid Loaner Bank (GA HALB) began servicing infants/children in need of amplification. The program provides temporary hearing aids for children with hearing loss, who are birth to 36 months of age while they are waiting to receive their personal amplification devices. The GA HALB lends hearing aids for up to six months, on a one time per child basis, for children newly diagnosed with a hearing loss.

For more information, please contact the NBS Program at 404-657-4143.

Another loaner hearing aid bank program:

- Georgia Lions Lighthouse Foundation <https://lionslighthouse.org/services/hearing-aids/>

## Language Intervention Services and Providers

Families of children, birth through five years, diagnosed with permanent hearing loss are linked to two state intervention programs: Babies Can't Wait (BCW) and Georgia Parent Infant Network for Education Services (Georgia PINES) through newborn screening. Each program has its own eligibility criteria and has different program goals. Parents may also choose private intervention to supplement state intervention services or as their only source of intervention. All children should have access to intervention services by six months of age.

Georgia PINES: The goal of Georgia PINES is to have the child demonstrate 12 months language advancement in one calendar year.

- Georgia PINES offers an initial early hearing orientation specialist (EHOS) visit within 7 days of initial referral from Public Health.
- The EHOS visit is to provide written and oral information on hearing loss, to give information on communication options and amplification devices, and to stress the importance and urgency of enrollment in intervention. Additionally, parents and families receive information on local, state, and national resources and services.
- Georgia PINES also offers Parent Advisors, who serve as a resource for newly diagnosed families and outline the curriculum that will be used to promote the child's acquisition of communication and listening skills. The parent advisor works in partnership with the family to set goals/outcomes for the child specific to hearing loss. Home visits focus on strategies to obtain the goals and assess progress.
- Georgia PINES provides family-centered services that include the provision of information and emotional support, a home hearing aid program, preparation for a cochlear implant, communication and auditory and/or visual (e.g. sign language) programs, as well as assisting parents with resources. Visits are conducted at minimum bi-monthly and last 60 minutes in duration.
- Parents have options for the SKI-HI or INSITE curriculum, and Signing Deaf Mentors are available as well.
- For more information on Georgia PINES services visit <http://www.gapines.info/>.

BCW: A goal of BCW is to provide coordinated, comprehensive and integrated services for children birth to three with special needs.

- BCW provides intervention for children with bilateral, mild to profound hearing loss, or any children with any type of documented developmental delay.
- BCW offers service coordination that assists the family and other professionals in developing a plan to enhance the child's development.
- The services are provided in the natural environment (home) and are provided by agencies and individuals from both the public and private sectors. Intervention services, training, resources and referrals in the community are made to help meet the developmental needs of the child.
- For more information visit <http://dph.georgia.gov/Babies-Cant-Wait>.

Private Intervention Resources: There are a variety of private resources available across the state, including audiologists, speech-language pathologists, and programs that specialize in the development of a particular mode of communication. A brief description with contact information for statewide programs serving children with hearing loss is provided to all families during the EHOS visit described above.

For more information about hearing impairment-related resources available in a particular community, you may wish to contact the Georgia Council for the Hearing Impaired (1-800-541-0710 [V/TTY] or 404-292-5312 [V/TTY] in metro Atlanta, [www.gachi.org](http://www.gachi.org)) and Parent to Parent of Georgia (1-800-229-2038 or 770-451-5484 in metro Atlanta, [www.parenttoparentofga.org](http://www.parenttoparentofga.org)).

### 3.5 Documentation and Reporting

#### Documentation

All hospitals must document newborn hearing screening results in the baby's medical record and on the NBS Specimen Card.

#### Data Elements:

- Date of hearing screen
- Technology: aABR or aOAE
- Hearing screen results
- Verify correct primary care physician (PCP)
- PCP notified of results on all hearing screens in writing
  - Hospital should have a process in place where PCP is receiving results on all hearing screens (e.g. progress notes, discharge summary, etc.)
- Verify two primary contacts and numbers for the family
- Results of screen given to the parents verbally
- Results of screen given to the parents in writing
- Parents provided the "Have You Heard?" educational brochure
- Results of the screening are delivered semi-scripted to the parents
- Follow-up appointment scheduled, if available, for an infant with a "refer" hearing screen result

#### Reporting

##### Reporting Screening Results

Georgia law 31-1-3.2, "Hearing screenings for newborns", mandates that all hospitals report to the Department of Public Health.

1. **In-patient screens** - must be reported on the NBS Specimen Card (details on how to fill out the card can be found in Section 5). In the event, the hearing screening cannot be performed at the time blood is collected for metabolic screening nor can be documented before the card is shipped to GPHL.
  - a. **Do not hold metabolic screen**, send NBS card to GPHL
  - b. Obtain the delayed screening report form (Section 5.5)
  - c. Place a hospital label on the form
  - d. Write in date, submitting facility name and CCHD results
  - e. Fax completed for to NBS Program at 404-657-2773
2. **Out-patient screens** – must be reported through the *Children 1<sup>st</sup> Screening and Referral Form* and sent to the health district that the child resides or through SendSS

##### Reporting Suspected or Confirmed Hearing Impairment

In July 2002, the Board of the Department of Human Resources approved a request to add childhood hearing impairment to the state's Notifiable Disease List. Birth defects are reportable under State Law, Official Code of Georgia Annotated (O.C.G.A.) 31-12-2 and 31-1-3.2.

Revised October 15, 2015

The following conditions related to hearing loss are required to be reported to Public Health within 7 days of testing:

1. Suspected Hearing Impairment
  - Newborns are not passing the initial or follow-up hearing screening
2. Confirmed Hearing Impairment through the age of five (5) years with the initial confirmation/diagnosis of hearing loss/impairment, which is suspected to be permanent, measured and described by a licensed audiologist
  - Hearing loss/impairment is defined as a threshold average of 15 dB or greater between 500Hz - 4000Hz, whether unilateral or bilateral

In addition to O.C.G.A. 31-12-2 and 31-1-3.2, with the addition of hearing impairment to the newborn screening panel under Georgia Rule 511-5-5, every licensed or permitted hospital, laboratory and physician confirming abnormal test results or clinical symptoms for the conditions listed in DPH Rule 511-5-5-.03 must report those findings back to the department.

For hearing impairment, the impact is that **all** follow-up screening results (“Pass” and “Refer”) and diagnostic evaluation findings in newborns that do not pass the newborn screen have to be reported back to Public Health. **Audiologists are required to report hearing results electronically through SendSS.**

## **SECTION 4**

### **Newborn Critical Congenital Heart Disease Screening**

## 4.1 Screening Policies

Critical Congenital Heart Disease (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 receive a pulse oximetry screen for CCHD after twenty-four (24) hours of life or before discharge, whichever comes first.

This policy delineates the guidelines for CCHD screening:

- (1) personnel for screening,
- (2) timing for screening,
- (3) environment for screening,
- (4) equipment,
- (5) prescreening assessment,
- (6) screening protocol, and
- (7) follow-up of positive screens.

### (1) Personnel

The following licensed staff should perform CCHD screening:

- RN and LPN
- Respiratory Therapists
- Medical Staff (physicians, residents, advanced practice nurses, PA's and midwives)

### (2) Required time for Screening

All infants greater than **24 hours of age** should be screened unless a previous echocardiogram was performed. If discharged before 24 hours old, perform a screen as close to 24 hours as possible.

### (3) Place/Environment to Perform Screening

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

### (4) Equipment

Screening must be performed with:

- FDA approved motion-tolerant pulse oximeter
- Infant disposable or reusable probes
- Newborn Screening data collection form (NBS Card)

### (5) Assess Newborn for adequacy of screening

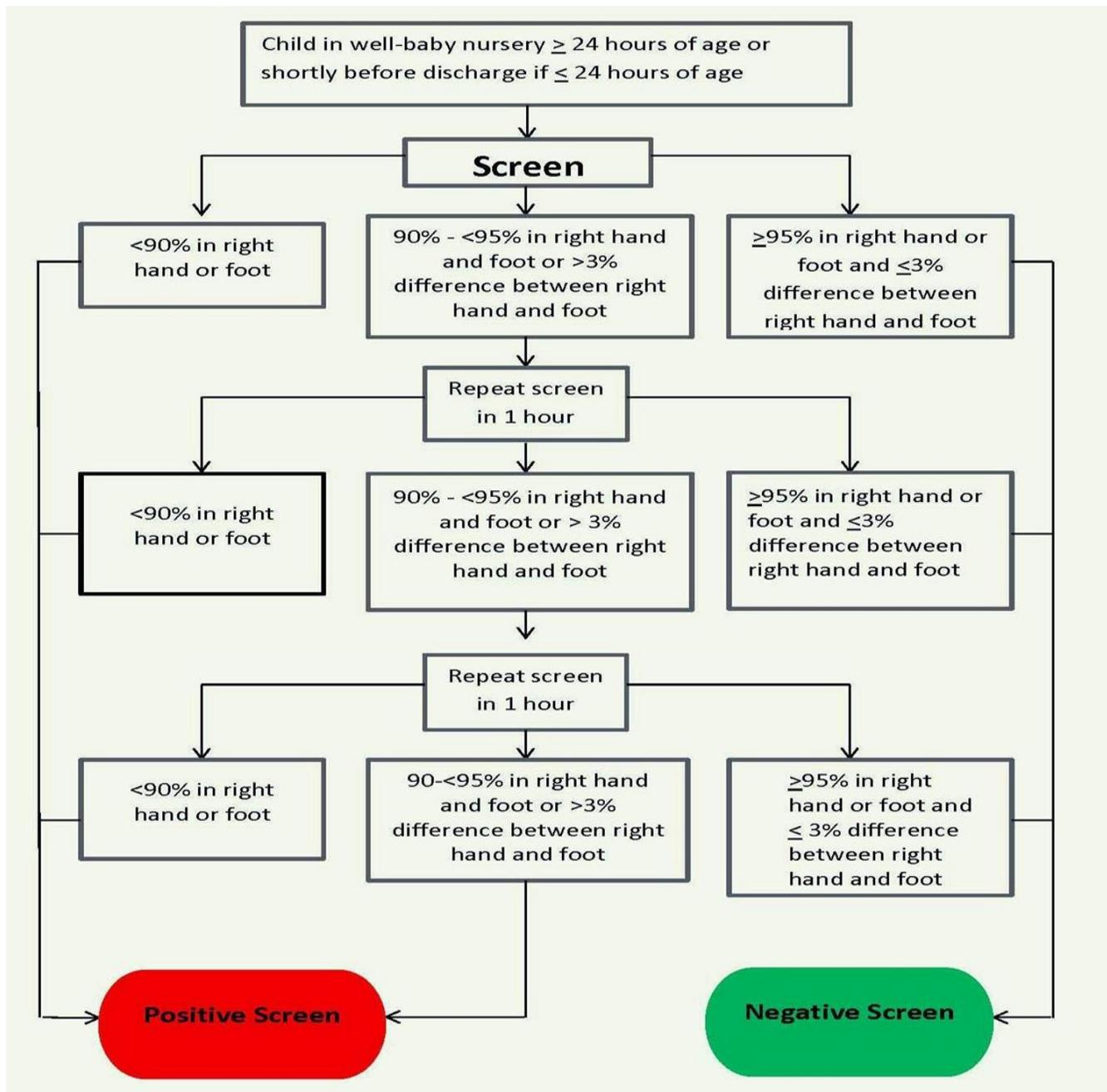
Prior to screening, newborns must be assessed to determine adequacy for screening. The following should be completed prior to screening:

- Evaluate for hypothermia
- Presence/Adequacy of pulse

- Phototherapy (bilirubin lights)
- Receiving oxygen therapy

#### (6) Screening Protocol

The following American Academy of Pediatrics (AAP) endorsed screening algorithm must be used for CCHD screening. (Kemper et al. 2011)



### (7) Referral/Follow-up for a positive screen

The AAP endorsed guidelines for referral of newborns with abnormal screening results should be followed. Newborns that screen positive (fail) should *not* be discharged until complete follow-up assessment is complete.

Each hospital should have a system to:

- Contact and consult a cardiac specialist
- Perform an echocardiogram

### **AAP Guidance after a Failed Screen**

The first step is to examine the infant to make sure the baby is hemodynamically stable, and then begin the process of evaluation for hypoxemia. Depending on the status of the baby, 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 baby is asymptomatic and otherwise well, with no obvious cause for hypoxemia, a cardiologist or neonatologist should be consulted, and an echocardiogram should be performed. Newborns should not be discharged home until the underlying reason for hypoxemia has been identified, or the hypoxemia has resolved. Remember, these babies will often appear normal and have no clinical findings other than the low oxygen saturation. Still, a careful and thorough evaluation is necessary.

### (8) Delayed Reporting

If CCHD screening cannot be performed at the time blood is collected for metabolic screening:

- Do not hold the NBS card. Send NBS card to the Georgia Department of Public Health Laboratory as outlined in Section 2.
- Complete the “Delayed Screening Report Form” (Section 5)
- Fax a copy of the delayed screening report form to “Newborn Screening Program” at 404-657-2773.
- Place the original form in the medical record.

## 4.2 Screening Procedures

1. Perform pulse oximetry screening in a quiet space, away from noises and harsh light.
2. Assure that the skin is clean and dry before placing the probe on the infant.
3. Swaddle Infant to reduce infant movement and crying
4. The screening should occur in the right hand and either foot. If using only one pulse oximeter, test one site right after the other.
5. Select application site on the outside, fleshy area of the infant's hand and foot.

Skin color and jaundice do not affect the pulse ox reading.



RH Application



Foot Application Site

6. Place the photo-detector portion of the probe on the fleshy portion of the outside of the infant's hand or foot
7. Place the light emitter portion of the probe on the top of the hand or foot. Place the photo-detector directly opposite of light emitter, on the bottom of the hand or foot.
8. The photo-detector and emitter must be directly opposite each other in order to obtain an accurate reading.
9. Secure the probe to the infant's hand or foot using the adhesive or foam tape recommended by the vendor



10. 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 pleth wave (arterial pulse) is stable, indicating perfusion to the site being monitored and without motion artifact.

11. Use AAP-endorsed CCHD screening algorithm and pulse oximetry grid to determine the outcome.  
*Negative screen: “Pass result”*  
*Positive screen: “Fail result” Action Needed*  
*Refer to algorithm and screening grid*
12. Provide appropriate follow-up as needed, once results from pulse oximetry screening completed.
13. Give NBS brochure to parent, Georgia Newborn Screening Program: *“What Every Parent Should Know”*
14. Document results on the NBS card and in infant’s medical record
15. Ship NBS cards to the Georgia Public Health Laboratory for processing.  
*\*Complete all required fields on the NBS Specimen Card*

### 4.3 Algorithm Tools

The American Academy of Pediatrics and American Heart Association endorsed CCHD screening algorithm requires detailed consideration of the pulse oximetry results to accurately interpret the screening outcome.

The tools below are useful in accurately interpreting the screening outcome.

- 1) Algorithm Phone Application
- 2) Visual Grid

- 1) Algorithm Phone Application  
<http://pulseoxtool.com/about.php>
- 2) Visual Grid

		Foot												
		100	99	98	97	96	95	94	93	92	91	90	<90	
Right Hand	100	Pass	Pass	Pass	Pass	Repeat	Fail							
	99	Pass	Pass	Pass	Pass	Repeat	Fail							
	98	Pass	Pass	Pass	Pass	Pass	Repeat	Fail						
	97	Pass	Pass	Pass	Pass	Pass	Pass	Repeat	Repeat	Repeat	Repeat	Repeat	Repeat	Fail
	96	Repeat	Pass	Repeat	Repeat	Repeat	Repeat	Fail						
	95	Repeat	Repeat	Pass	Repeat	Repeat	Repeat	Fail						
	94	Repeat	Repeat	Repeat	Pass	Pass	Pass	Repeat	Repeat	Repeat	Repeat	Repeat	Repeat	Fail
	93	Repeat	Repeat	Repeat	Repeat	Pass	Pass	Repeat	Repeat	Repeat	Repeat	Repeat	Repeat	Fail
	92	Repeat	Repeat	Repeat	Repeat	Repeat	Pass	Repeat	Repeat	Repeat	Repeat	Repeat	Repeat	Fail
	91	Repeat	Fail											
	90	Repeat	Fail											
	<90	Fail	Fail											

Key	
Pass	Green
Fail	Red
Repeat (1-2)	Yellow

### How to use the Pulse Oximetry Grid

1. The pulse oximetry values for the right hand are located in the column on the left side of the grid.
2. The rest of the grid contains the pulse oximeter values for either foot.
3. Obtain values for the right hand and either foot.
4. If the value falls in “green” section, no action is needed.
5. If the value falls in “yellow” or “red” section, **Action is needed**. Refer to the AAP – endorsed CCHD screening algorithm to determine the action required.

## 4.4 Documentation and Reporting

### Documentation

All hospitals must document newborn pulse oximetry-CCHD screening results into the baby's medical record and on the NBS Specimen Card. Details on how to fill out the card are in Section 5.

#### Data Elements:

- Hospital label or patient demographics and name of hospital
- Time of initial pulse oximetry screen
- Right Hand and Foot pulse oximetry results of initial screen
- Time of repeat pulse oximetry results, if applicable
- Right Hand and Foot pulse oximetry results of repeat screens, if applicable
- Outcome of the screen: pass or fail
- Referral hospital or physician, if the screen result is a fail, in the transferred field

### Reporting

CCHD screening results will be reported on the NBS Specimen Card. In the event the CCHD screening results cannot be performed at the time blood is collected for metabolic screening nor can be documented before the screen is shipped to the GPHL:

1. **Do not hold the metabolic screen**, send NBS card to GPHL
2. Obtain the delayed screening report form (Section 5.5 )
3. Place a patient hospital label on the form
4. Write in date, submitting facility name and CCHD results
5. Fax completed form to NBS Program at 404-657-2773

# **SECTION 5**

## **Additional Information**

## 5.1 Contact Information

### **Georgia Public Health Laboratory**

**Arthur F. Hagar, Ph.D., HCLD**

*Director of Chemistry & Hematology*

Georgia Department of Public Health

1749 Clairmont Road

Decatur, GA 30033-4050

404.327.6800 (office)

404.327.7919 (fax)

[Arthur.hagar@dph.ga.gov](mailto:Arthur.hagar@dph.ga.gov)

### **Georgia Newborn Screening Program**

**Tanya Spells, MS, MT(ASCP)**

*Newborn Screening Program Manager*

Georgia Department of Public Health

2 Peachtree Street NW, 11<sup>th</sup> floor

Atlanta, GA 30303

404.651.5492 (office)

404.657.2773 (fax)

[Tanya.Spells@dph.ga.gov](mailto:Tanya.Spells@dph.ga.gov)

### **Georgia Newborn Screening Program**

**Pamela Clark, RN, MSN**

*Child Health Screening Clinical Coordinator*

Georgia Department of Public Health

2 Peachtree Street NW, 11<sup>th</sup> floor

Atlanta, GA 30303

404.657.3135 (office)

404.657.2773 (fax)

[Pamela.Clark@dph.ga.gov](mailto:Pamela.Clark@dph.ga.gov)

### **Georgia Newborn Screening Program**

*EDHI Program Coordinator*

Georgia Department of Public Health

2 Peachtree Street NW, 11<sup>th</sup> floor

Atlanta, GA 30303

404.657.2850 (office)

404.657.2773 (fax)

## 5.2 Quality Assurance

Newborn screening is a time sensitive early detection system. The system's success is dependent upon quality among all partners. Hospitals and providers should establish quality assurance processes to assure quality in specimen collection, timely shipment and follow-up. The Georgia NBS Program offers a monthly hospital specimen report to support hospital staff in their quality assurance processes.

In this section you will learn more about:

- (1) Registration for the State Electronic Notifiable Disease Surveillance System (SendSS) - a web-based system that provides data and statistical measures of the submitters blood specimens and
- (2) Hospital Specimen Reports in SendSS.

### Registration for SendSS

SendSS is a population-based surveillance and tracking system designed to identify and monitor at-risk children throughout Georgia. The SendSS database is accessible to all hospitals, health district offices, audiologists, and primary care providers with a SendSS account.

Blood specimens from newborns are sent to the Newborn Screening Unit of the Georgia Public Health Laboratory (GPHL) for testing along with documentation of hearing screening and CCHD screening results. A hospital specimen report is available to view statistics of unsatisfactory specimens and transit times. To register, visit <https://sendss.state.ga.us/sendss/login.screen>

### Hospital Specimen Reports in SendSS

Babies can suffer permanent disability or death from delays in treatment caused by batching or delays in delivery of specimens to GPHL. "Batched" samples occur when samples are sent in bunches throughout the week instead of each day.

The NBS Program sets a performance benchmark for unsatisfactory specimens and transit times.

- 1) Unsatisfactory specimens – no more than 1% of specimens submitted to GPHL should be unsatisfactory
- 2) Transit times – all specimens should arrive at GPHL within 5 days of collection with a performance benchmark of 48 hours in transit
  - i) This benchmark takes into consideration babies born during the weekend. NBS Cards delivered after seven (7) days are considered delayed and cannot be tested. To avoid batching and transit delays, send all screens within 24 hours of collection to the GPHL and for those screens collected during the weekend, send on Monday.

Birth hospitals and facilities have the ability to review their screening rates and collection techniques in order to identify areas of strength and needs for improvement utilizing their monthly hospital specimen report feature found in SendSS

[https://sendss.state.ga.us/sendss/nbsmart\\_genetics\\_reports.hospital](https://sendss.state.ga.us/sendss/nbsmart_genetics_reports.hospital).

- Confirming Lab Report
- HGB Contract Report
- Hospital Specimen Report**
- Reports
- Queue Admin
- Hearing Summary Report
- Hearing Quarterly Report
- Births by Facility Report
- Children 1st Quarterly Report
- TANF Report

Child

Last Name:

First Name:

DOB From:

DOB To:

Sex:  M:  F:

County:

Medical Record #:

Kit Number:

Specimen Number:

Plurality:  Yes  No

SendSS NB Patient ID:

Sort By:

### 5.3 Filling Out the Newborn Screening Specimen Card

All information requested on this form is vital for the screening, follow-up, and diagnostic components of the newborn screening process. Information must be **accurate, legible and complete**. A data dictionary is included in each section that describes the information that is required to complete the NBS specimen card.

IVD 2017-06 102277 / 314132 LOT PerkinElmer 226 Ahlstrom	PEDIATRICIAN SUBMITTER	Submitting Healthcare Provider (Report and Invoice to): Street _____ City _____ County _____ State _____ ZIP Code _____ Submitter Code: _____	For GA State Lab Use Only	Georgia Public Health Laboratory - Newborn Screening 1749 Clairmont Road, Decatur, GA 30033 Telephone: (404) 327-7900 Fax: (404) 327-7919 Form 3491 (Rev. xxxxxx)
	PEDIATRICIAN AFTER DISCHARGE	Pediatrician's Mailing Address (Report Copy To): Street _____ City _____ County _____ State _____ ZIP Code _____ Submitter Code: _____ Pediatrician's Phone Number: (Area Code) _____ Number _____		
BABY	Reason for Test: <input type="checkbox"/> 1 <sup>st</sup> Test <input type="checkbox"/> Routine Retest <input type="checkbox"/> Retest - Prior Unsatisfactory <input type="checkbox"/> Retest - Prior Abnormal If Retest, Previous Lab Number: _____	State Lab Use Only Unsat Code: <input type="checkbox"/> NICU <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Adoption <input type="checkbox"/> No <input type="checkbox"/> Yes Collected By (Initials): _____		
MOTHER	Infant's Last Name _____ Infant's First Name _____ Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown Single Birth: <input type="checkbox"/> Multiple Birth: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D Transfusion: <input type="checkbox"/> Yes <input type="checkbox"/> No   Date of Last: _____ Infant's Race: <input type="checkbox"/> White <input type="checkbox"/> Black <input type="checkbox"/> Asian <input type="checkbox"/> American Indian/Alaskan Native <input type="checkbox"/> Multiracial <input type="checkbox"/> Unknown Hispanic: <input type="checkbox"/> Yes <input type="checkbox"/> No	Birth Weight (Grams): _____   Collection Weight (Grams): _____   Gestational Age (Weeks): _____ Birth Date: Month _____ Day _____ Year _____   Birth Time (Military): _____ Collection Date: Month _____ Day _____ Year _____   Collection Time (Military): _____ Protein Feed: <input type="checkbox"/> Breast <input type="checkbox"/> Formula <input type="checkbox"/> Both Parenteral Nutrition: <input type="checkbox"/> Yes <input type="checkbox"/> No   Formula Trade Name: _____		
	Mother's Last Name _____ Mother's First Name _____ Mother's Address: Street _____ City _____ County _____ State _____ Zip Code _____	Mother's Birth Date: Month _____ Day _____ Year _____   Mother's or Contact's Number: (Area Code) _____ Number _____ Emergency Contact Number: (Area Code) _____ Number _____		
	HEARING: Right Ear <input type="checkbox"/> Pass <input type="checkbox"/> Refer   Left Ear <input type="checkbox"/> Pass <input type="checkbox"/> Refer   Screen Method: <input type="checkbox"/> aABR <input type="checkbox"/> aOAE <input type="checkbox"/> aABR and aOAE Not Screened: <input type="checkbox"/> Delayed/WBN <input type="checkbox"/> Parental Refusal <input type="checkbox"/> Other: _____ <input type="checkbox"/> Delayed/NICU <input type="checkbox"/> Equipment Down <input type="checkbox"/> Transfer (Hospital: _____)	CCHD Results: Initial: Right Hand _____ Foot _____ Time _____ Repeat #1: Right Hand _____ Foot _____ Time _____ Repeat #2: Right Hand _____ Foot _____ Time _____ Final Outcome: <input type="checkbox"/> Pass <input type="checkbox"/> Fail   Transferred To: _____		
LAB DATA ENTRY COPY				

## A. Submitting healthcare provider/pediatrician after discharge section:

<b>Section</b>	<b>Data Field</b>	<b>Description</b>
Submitter	Submitting Healthcare Provider (Report & Invoice to)	Name of the facility where the specimen was collected
Submitter	Submitter Code	Unique identifier for the facility (three digits/letters)
Submitter	Submitting Facility's Street	Street of the Submitting Facility
Submitter	Submitting Facility's City	City of the Submitting Facility
Submitter	Submitting Facility's County	County of the Submitting Facility
Submitter	Submitting Facility's State	State of the Submitting Facility
Submitter	Submitting Facility's Zip Code	Zip Code of the Submitting Facility
Pediatrician	Pediatrician After Discharge	Name of Pediatrician given by parent or guardian whom will administer care after discharge
Pediatrician	Submitter Code	Unique identifier for the Pediatrician (six digits "123456") <b>if known add</b>
Pediatrician	Pediatrician's Phone Number	Named pediatrician's phone number
<b>Section</b>	<b>Data Field</b>	<b>Description</b>
Pediatrician	Pediatrician's Street	Street of the Pediatrician's Facility
Pediatrician	Pediatrician's City	City of the Pediatrician's Facility
Pediatrician	Pediatrician's County	County of the Pediatrician's Facility
Pediatrician	Pediatrician's State	State of the Pediatrician's Facility
Pediatrician	Pediatrician's Zip Code	Zip Code of the Pediatrician's Facility

## B. Baby's section:

Section	Data Field	Description
Baby	Reason for Test	Select 1 <sup>st</sup> Test if this is the initial screen for newborn.
Baby	Reason for Retest <b>Please Select one Response</b>	Select <b>Routine Retest</b> for infants in NICU.
Section	Data Field	Description
Baby	Reason for Retest <b>Please Select one Response</b>	Select <b>Retest Prior Abnormal</b> for out of range result.
Baby	If Retest, Previous Lab Number	Enter Laboratory form number This number is the ten digit number in red on the submitter copy. If retest was checked, and the <b>number is known (optional)</b> .
Baby	Chart Number/Medical Record Number	Place infant's chart number/medical record number here.
Baby	Hospital Lab Access Number	If your hospital uses lab access number to log the specimens, lab will place that number here
Baby	Birth Weight (grams)	Weight taken at birth
Baby	Collection Weight (grams)	Current weight at the time of collection if the newborn is older than 7 days.
Baby	Gestational Age	Gestation determined by a physician or based on the dates of pregnancy.
Baby	NICU	Check yes if the newborn has been admitted to a Level II or III special care nursery.
Baby	Infants Last Name	Last Name of Newborn
Baby	Birth Date	Enter Newborn's birthdate (MM/DD/YR) <b>(Critical Information)</b>
Baby	Birth Time (military)	Newborn's Time of Birth <b>(Critical Information)</b>
Baby	Adoption	If adopted check yes, if not select no

Baby	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.
Baby	Sex	Indicate if newborn is a male, female or unknown
<b>Section</b>	<b>Data Field</b>	<b>Description</b>
Baby	Collection Date	The date the specimen was collected ( <b>Critical information</b> )
Baby	Collection Time (military)	Time the specimen was collected (Critical Information).
Baby	Collected By	The nurse or lab tech that collected the specimen (initials only).
Baby	Birth Plurality	If a mother delivered a single baby check single birth. If a mother delivered more than one baby check multiple births and indicate what order this baby was delivered (A=1st, B=2 <sup>nd</sup> , C=3 <sup>rd</sup> , D=4 <sup>th</sup> etc.).
Baby	Transfusion	Did the newborn have a transfusion? Yes or No. If yes indicate the date of the last transfusion.
Baby	Infant's Race	Indicate the race of newborn. Ask mother.
Baby	Ethnicity	Indicate if the newborn is Hispanic (yes/no)

## C. Mother's section:

Section	Data Field	Description
Mother	Mother's Last Name	Last name of the birth mother <b>(Critical Information)</b>
Mother	Mother's Birth Date	Birth date of the birth mother
Mother	Mother's Contact Number	Mother's number where she can be reached after discharged. Either house phone or cell phone. <b>(Critical Information)</b>
Mother	Emergency Contact Number	Friend or relative of the mother that can be contacted if the mother cannot be reached. <b>(Critical Information)</b>
Mother	Mother's First Name	Birth mother's first name
Mother	Mother's Street	Residing street of the mother.
Mother	Mother's City	Residing city of the mother.
Mother	Mother's County	Residing county of the mother.
Mother	Mother's State	Residing state of the mother.
Mother	Mother's Zip Code	Residing Zip Code of the mother.

## D. Hearing screening section:

Section	Data Field	Description
Hearing	Final Screen Date	Write the date of the final screen. (If screened twice the <b>date of the second screen</b> )
Hearing	Right Ear	Check pass/refer of the final screen for the right ear
Hearing	Left Ear	Check pass/refer of the final screen for the left ear
Hearing	Screen Method	Check the screening instrument (aABR, aOAE, aABR and aOAE) used for the final screen.
Hearing	Not Screened	If the infant did not receive a final screen before the card was submitted indicate the reason: delayed/wbn (well baby nursery), delayed/NICU

Revised October 15, 2015

		(neonatal intensive care unit), transfer/hospital, parental refusal, equipment down and other
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## E. CCHD screening section:

Section	Data Field	Description
CCHD Results	Date	Write the date the CCHD screen was completed
CCHD Results	Initial	Enter the pulse ox results and the time the pulse ox test was completed for the right hand and either foot ( <b>Both right hand and either foot must be tested</b> ).
CCHD Results	Repeat #1	If the results are inclusive. Retest in one hour and enter 2 <sup>nd</sup> test results for the right hand and either foot.
CCHD Results	Repeat #2	If the results are inclusive. Retest in one hour and enter 3 <sup>rd</sup> test results for the right hand and either foot.
Final Outcome	Pass	Indicate if the infant pass with a check in the box.
Final Outcome	Fail	Indicate if the infant fails with a check in the box.
Final Outcome	Referred To	Indicate if the infant was referred to a cardiologist or hospital (write the full name of the cardiologist or hospital). No abbreviations

## 5.4 Obtaining an NBS Report

Screening reports can be obtained by a licensed healthcare provider directly from the NBS Program by registering for one of two web-based portals (eReports and SendSS) or faxing an Authorization Release Form.

In accordance with Clinical Laboratory Improvement Amendments (CLIA) and Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, individuals have the right to access their own or child's lab test reports. Parents and legal guardians can request NBS reports by mailing an Authorization Release Form and a copy of a legal photo identification card to the Department of Public Health.

This section includes instructions on:

- (1) Authorization to receive NBS reports
- (2) How to register for eReports Web Portal
  - a. eReports web portal registration form
  - b. eReports web portal procedure
- (3) How to register for SendSS
  - a. SendSS registration
  - b. SendSS procedure
- (4) How to obtain a NBS report from the NBS Program
- (5) Newborn Screening Authorization Release Form

### (1) Authorization to Access NBS Reports

The Department is committed to protecting the confidentiality of personal health information in accordance with the federal HIPAA and all state and federal privacy laws. Authorization to access official or unofficial NBS reports is provided to:

- Licensed primary care physicians caring for pediatric patients born in Georgia
- Nurses and medical assistants accessing reports on behalf of a pediatric primary care practice
- Parents and legal guardians of newborns and children
- Individuals seeking access to their NBS report

Authorized users of SendSS or eReports must agree to access the database only for reporting and treatment purposes related to their patient, and agree to reasonably safeguard protected health information from any use or disclosure that is in violation of state or federal privacy laws.

### (2) Registration for e-Reports Web Portal

The Georgia Public Health Laboratory's (GPHL) web portal, eReports, gives access to licensed physicians to obtain official newborn screening results for reporting and treatment purposes.

#### a. eReports Web Portal Registration Form

The registration form can be accessed on the web at [eReports Form](#)

#### b. eReports Web Portal Procedure

To obtain NBS blood specimen results from the GPLH web portal, it is necessary to have the 10 digit form number on the NBS card. If the 10 digit number is not available, an unofficial report can be obtained from SendSS, using the DOB of the child and the mother's first and last name.

1. Open your browser and enter the web portal address: <https://services.georgia.gov/dph/eReports/>
2. Type in your Username
3. Type in your Password
4. Click the "Login" box
5. Type in the Form Number
6. Click the "Search" box
7. Click the "View Report List" Link
8. Click on the report link (pdf extension)
9. Click "Open" to view the report, or "Save" to save the report
10. To search for another report, click "Specimen Search" in the green box on the left of the screen
11. Follow steps# 5-9 above

It is very important to log out from the portal when you are done. Failure to do so can result in other users not being able to access the portal. For assistance call: 404-327-7950

### (3) Registration for SendSS

The State Electronic Notifiable Disease Surveillance System (SendSS) provides access to unofficial reports to licensed primary care physicians and their authorized staff seeking results for newborns and children.

- a. SendSS Registration  
To register for SendSS go to <https://sendss.state.ga> and click registration and login procedure on the welcome page
- b. SendSS Procedure  
To obtain a NBS blood specimen result from the SendSS web portal, it is necessary to have the 10 digit form number on the NBS card or use the DOB of the child and the mother's first and last name

1. In the analysis column, click onto newborn screening
2. Enter the 10 digit number you are searching for (the form number is located on the NBS card)
3. Click on the search box

**SendSS**  
State Electronic Notifiable Disease Surveillance System

Uid: [ ] 4/20/2015  
Help Contact Us My Account Logout

Home Case Reporting Analysis Admin

## Public Health Lab Newborn Screening Results

### Newborn Screening Result Search

Official newborn screening reports are now available on line from the Georgia Department of Public Health Laboratory for specimens received after July 11, 2011. This system may be accessed by licensed physicians authorized by the Georgia Department of Public Health for reporting and treatment purposes. We recommend using the Laboratory portal to obtain the most complete information possible for your files. For information on using the web portal, call 404-327-7950.

Please enter the kit number you are searching for

⊕ **Expanded Search:** If kit number is unknown, please click the plus icon to open expanded search criteria

#### Information and Other Resources

- ▶ [Georgia Newborn Screening Program](#) -- (404) 657-4143
- ▶ Emory Newborn Screening Follow-up program can be reached at (404) 778-8560
- ▶ [Newborn Screening ACT Sheets and Confirmatory Algorithms](#)
- ▶ [SendSS Newborn Screening Training Manual](#)

4. The screen should populate with a link conaining the infant's name and mother's information, refer to the information that is circled in red in the slide below.
5. A link showing the infant's name or a lab number may appear, click on the link and the NBS report should appear.

**SendSS**  
State Electronic Notifiable Disease Surveillance System

Uid: [ ] 4/20/2015  
Help Contact Us My Account Logout

Home Case Reporting Analysis Admin

## Public Health Lab Newborn Screening Results

### Newborn Screening Result Search

Official newborn screening reports are now available on line from the Georgia Department of Public Health Laboratory for specimens received after July 11, 2011. This system may be accessed by licensed physicians authorized by the Georgia Department of Public Health for reporting and treatment purposes. We recommend using the Laboratory portal to obtain the most complete information possible for your files. For information on using the web portal, call 404-327-7950.

Please enter the kit number you are searching for:

Expanded Search: If kit number is unknown, please click the plus icon to open expanded search criteria

#### Search Results

Please check to confirm the information is required for treatment purposes.  
 Please check to confirm you have received a signed release from a legal guardian to view this information.

Name	DOB	Mother's Name	Phone #	Collected	S	R
<b>Information and Other Resources</b>						
<ul style="list-style-type: none"> <li>▶ <a href="#">Georgia Newborn Screening Program</a> -- (404) 657-4143</li> <li>▶ Emory Newborn Screening Follow-up program can be reached at (404) 778-8560</li> <li>▶ <a href="#">Newborn Screening ACT Sheets and Confirmatory Algorithms</a></li> <li>▶ <a href="#">SendSS Newborn Screening Training Manual</a></li> </ul>						

6. If the NBS report does not appear, you can also use the expanded search box to find the NBS. There are two other ways to search for the report:

- a. Enter the child's birthdate and the mother's first and last name. (If using the mother's name, the spelling must be the same as what was entered by the GPL)

**SendSS**  
State Electronic Notifiable Disease Surveillance System

Uid: [locked icon] 4/20/2015

Help Contact Us My Account Logout

Home Case Reporting Analysis Admin

## Public Health Lab Newborn Screening Results

### Newborn Screening Result Search

Official newborn screening reports are now available on line from the Georgia Department of Public Health Laboratory for specimens received after July 11, 2011. This system may be accessed by licensed physicians authorized by the Georgia Department of Public Health for reporting and treatment purposes. We recommend using the Laboratory portal to obtain the most complete information possible for your files. For information on using the web portal, call 404-327-7950.

Please enter the kit number you are searching for:

**Expanded Search:** kit number is unknown, please click the plus icon to open expanded search criteria

Infant DOB:(mm/dd/yyyy):

Mother's Last Name:

Mother's Phone:

### (3) How to obtain an NBS report from the Georgia NBS Program

a. To obtain an NBS blood specimen result from the Georgia NBS Program, it is necessary for the Program to verify the identify the individual making the request. Using the “Newborn Screening Authorization Release Form” enter the following information to allow for a thorough search for the report:

1. Requestor’s Name and/or Facility
    - i. For parent’s or legal guardians a valid state issued photo ID must accompany the request
  2. Mother’s first and last name at the time of delivery
    - i. If the parent or legal guardian's name does not match that on the NBS Report, additional information will be required
  3. Mother’s date of birth
  4. Child’s date of birth
  5. Child’s gender
  6. If a multiple birth, order of birth (Twin A/B/C)
  7. Hospital of birth
- b. Receiving the Report by Fax
1. Complete the release form and fax the form along with your facility’s fax cover sheet to the number at the bottom of the request form.
  2. The requestor’s fax number must be clear and legible.
- c. Receiving the Report by Mail
1. Complete the release form and mail the form along with a copy of the legal guardian’s photo ID.
- Attention: Newborn Screening Program**  
**2 Peachtree Street, NW 11<sup>th</sup> Floor Atlanta, GA 30303**
2. The return address must be clear and legible

(4) Newborn Screening Authorization Release Form

This form can be viewed in Section 5.5, Form no. 4

## 5.5 Forms

This section contains NBS forms used for the collection or retrieval of screening information:

1. Newborn Screening Specimen Card (NBS card) DPH Form 3491
2. Newborn Screening Data Dictionary: Reference guide to completing the NBS card
3. Delayed Screening Report Form
4. Request for Newborn Screening Report Form

### (1) Newborn Screening Specimen Card (NBS card) DPH Form 3491

PerkinElmer 226 Ahlstrom LOT 102277 / 314132 IVD 2017-06	<b>PEDIATRICIAN SUBMITTER</b>		Submitting Healthcare Provider (Report and Invoice to):		Submitter Code		<b>For GA State Lab Use Only</b>		
	Submitting Facility's Address				City				County
	Street				City		State		
	ZIP Code				Submitter Code		Pediatrician's Phone Number		
	Pediatrician After Discharge				Area Code		Number		
	Pediatrician's Mailing Address (Report Copy To)				City		County		
	Street				City		State		
	ZIP Code				Submitter Code		Pediatrician's Phone Number		
	Area Code				Number		State Lab Use Only		
	<b>Reason for Test</b>				<input type="checkbox"/> 1 <sup>st</sup> Test <input type="checkbox"/> Routine Retest <input type="checkbox"/> Retest - Prior Unsatisfactory <input type="checkbox"/> Retest - Prior Abnormal		<input type="checkbox"/> If Retest, Previous Lab Number:		<input type="checkbox"/> Unsat Code:
Chart Number/Medical Record Number		Hospital Lab Access No.		Birth Weight (Grams)		Collection Weight (Grams)		Gestational Age (Weeks)	
Infant's Last Name		Birth Date (Month, Day, Year)		Birth Time (Military)		NICU		Adoption	
Infant's First Name		Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown		Collection Date (Month, Day, Year)		Collection Time (Military)		Collected By (initials)	
<input type="checkbox"/> Single Birth <input type="checkbox"/> Multiple Birth A B C D		Transfusion: <input type="checkbox"/> Yes <input type="checkbox"/> No           Date of Last:		Protein Feed: <input type="checkbox"/> Breast <input type="checkbox"/> Formula <input type="checkbox"/> Both		Parenteral Nutrition: <input type="checkbox"/> Yes <input type="checkbox"/> No		Formula Trade Name:	
Infant's Race: <input type="checkbox"/> White <input type="checkbox"/> Black <input type="checkbox"/> Asian <input type="checkbox"/> American Indian/Alaskan Native <input type="checkbox"/> Multiracial <input type="checkbox"/> Unknown		Hispanic: <input type="checkbox"/> Yes <input type="checkbox"/> No		Mother's Last Name		Mother's Birth Date (Month, Day, Year)		Mother's or Contact's Number (Area Code, Number)	
Mother's First Name		Emergency Contact Number (Area Code, Number)		Mother's Address		City		County	
State		Zip Code		<b>HEARING</b>		<b>Date Tested:</b>		<b>CCHD Results</b>	
Right Ear: <input type="checkbox"/> Pass <input type="checkbox"/> Refer		Left Ear: <input type="checkbox"/> Pass <input type="checkbox"/> Refer		Screen Method: <input type="checkbox"/> aABR <input type="checkbox"/> aOAE <input type="checkbox"/> aABR and aOAE		Not Screened: <input type="checkbox"/> Delayed/WBN <input type="checkbox"/> Delayed/NICU <input type="checkbox"/> Transfer (Hospital: _____)		Parental Refusal <input type="checkbox"/> Equipment Down	
Other: <input type="checkbox"/>		Initial: Right Hand _____ Foot _____ Time _____		Repeat #1: Right Hand _____ Foot _____ Time _____		Repeat #2: Right Hand _____ Foot _____ Time _____		Final Outcome: <input type="checkbox"/> Pass <input type="checkbox"/> Fail Transferred To:	
<b>LAB DATA ENTRY COPY</b>									

Revised October 15, 2015

## (2) Newborn Screening Data Dictionary: Reference guide to completing the NBS card

Section	Field Label	Description
Submitter	Submitting Healthcare Provider (Report & Invoice)	Name of the facility where the specimen was collected
Submitter	Submitter Code	Unique identifier for the facility (three digits/letters "123/ABC")
Submitter	Submitting Facility's Street	Street of the Submitting Facility
Submitter	Submitting Facility's City	City of the Submitting Facility
Submitter	Submitting Facility's County	County of the Submitting Facility
Submitter	Submitting Facility's State	State of the Submitting Facility
Submitter	Submitting Facility's Zip Code	Zip Code of the Submitting Facility
Pediatrician	Pediatrician After Discharge	Name of Pediatrician given by parent or guardian whom will administer care after discharge
Pediatrician	Submitter Code	Unique identifier for the Pediatrician (six digits "123456") <b>if known add</b>
Pediatrician	Pediatrician's Phone Number	Named pediatrician's phone number
Pediatrician	Pediatrician's Street	Street of the Pediatrician's Facility
Pediatrician	Pediatrician's City	City of the Pediatrician's Facility
Pediatrician	Pediatrician's County	County of the Pediatrician's Facility
Pediatrician	Pediatrician's State	State of the Pediatrician's Facility
Pediatrician	Pediatrician's Zip Code	Zip Code of the Pediatrician's Facility
Baby	Reason for Test	Select 1 <sup>st</sup> Test if this is the initial screen for newborn.
Baby	Reason for Retest (Place each once it is known how coded), <b>Please Select one Response</b>	Select Routine Retest for infants in NICU.
Baby	Reason for Retest (Place each once it is known how coded), <b>Please Select one Response</b>	Select Retest-Prior Unsatisfactory if there is a technical collection error
Baby	Reason for Retest (Place each once it is known how coded), <b>Please Select one Response</b>	Select Retest Prior Abnormal for out of range result.

<b>Section</b>	<b>Field Label</b>	<b>Description</b>
Baby	If Retest, Previous Lab Number	Enter Laboratory form number This number is the ten digit number in red on the submitter copy. If retest was checked, and the number is known (optional).
Baby	Chart Number/Medical Record Number	Place the chart number/medical record number here.
Baby	Hospital Lab Access Number	If your hospital uses a lab access number to log the specimens, lab will place that number here
Baby	Birth Weight (grams)	Weight taken at birth <b>(critical information)</b>
Baby	Collection Weight (grams)	Current weight at the time of collection if the newborn is older than 7 days.
Baby	Gestational Age	Gestation determined by a physician or based on the dates of pregnancy.
Baby	NICU	Check yes if the newborn has been admitted to a Level II or III special care nursery.
Baby	Infants Last Name	Last Name of Newborn <b>(Critical Information)</b>
Baby	Birth Date	Enter Newborn's birthdate (MM/DD/YR) <b>(Critical Information)</b>
Baby	Birth Time (military)	Newborn's Time of Birth <b>(Critical Information)</b>
Baby	Adoption	If adopted check yes, if not select no
Baby	Infant's First Name	Infant's first name. Can be listed as: Baby Boy, Baby Girl or Twin A boy/girl if first name is not known.
Baby	Sex	Indicate if newborn is a male, female or unknown
Baby	Collection Date	The date the specimen was collected <b>(Critical information)</b>
Baby	Collection Time (military)	Time the specimen was collected <b>(Critical Information).</b>
Baby	Collected By	The nurse or lab tech that collected the specimen (initials only).
Baby	Birth Plurality	If the mother delivered a single baby check single birth. If the mother delivered more than one baby check multiple births and indicate what order this baby was delivered (A=1st, B=2 <sup>nd</sup> , C=3 <sup>rd</sup> , D=4 <sup>th</sup> etc.).
Baby	Transfusion	Did the newborn have a transfusion? Yes or No. If yes indicate the date of the last transfusion.

Section	Field Label	Description
Baby	Infant's Race	Indicate the race of newborn. Ask mother.
Baby	Ethnicity	Indicate if the newborn is Hispanic (yes/no)
Mother	Mother's Last Name	Last name of the birth mother (Critical Information)
Mother	Mother's Birth Date	Birth date of the birth mother
Mother	Mother's Contact Number	Mother's number where she can be reached after discharged. Either house phone or cell phone. <b>(Critical Information)</b>
Mother	Emergency Contact Number	Friend or relative of the mother that can be contacted if the mother cannot be reached.
Mother	Mother's First Name	Birth mother's first name
Mother	Mother's Street	Residing street of the mother.
Mother	Mother's City	Residing city of the mother.
Mother	Mother's County	Residing county of the mother.
Mother	Mother's State	Residing state of the mother.
Mother	Mother's Zip Code	Residing Zip Code of the mother.
Hearing	Final Screen Date	Write the date of the final screen. <b>(If screened twice the date of the second screen)</b>
Hearing	Right Ear	Check pass/refer of the final screen for the right ear
Hearing	Left Ear	Check pass/refer of the final screen for the left ear
Hearing	Screen Method	Check the screening instrument (aABR, aOAE, aABR and aOAE) used for the final screen.
Hearing	Not Screened	If infant not screened before the card was submitted indicate the reason: delayed/wbn (well baby nursery), delayed/NICU (neonatal intensive care unit), transfer/hospital, parental refusal, equipment down and other
CCHD Results	Date	Enter date the CCHD screen was completed
CCHD Results	Initial	Enter pulse ox results and the time the test completed for the right hand and either foot <b>(Both right hand and either foot must be tested).</b>

<b>Section</b>	<b>Field Label</b>	<b>Description</b>
CCHD Results	Repeat #1	If the results are inclusive. Retest in one hour and enter 2 <sup>nd</sup> test results for the right hand and either foot.
CCHD Results	Repeat #2	If the results are inclusive. Retest in one hour and enter 3 <sup>rd</sup> test results for the right hand and either foot.
Final Outcome	Pass	Indicate if the infant passes with a check in the box.
Final Outcome	Fail	Indicate if the infant fails with a check in the box.
Final Outcome	Referred To	Please indicate if the infant was referred to a cardiologist or hospital (please write the full name of the cardiologist or hospital). No abbreviations, please.

(3) Delayed Screening Report Form



Maternal Child Health | Newborn Screening  
 2 Peachtree St., Atlanta, Georgia | 11th Floor  
 Phone: 404-657-4143 | Fax: 404-657-2773

**Delayed Screening Report**

*When an infant is screened for hearing loss and CCHD, and the results were not documented on the NBS card, the hospital or birthing facility must complete this form and fax to the NBS program.*

Complete a separate form for each screening report

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
 Date

**Place Hospital Label Here**

\_\_\_\_\_  
 Submitting Facility (print)

**Hearing Screening Results**

<b>Hearing Screen Date:</b> _____/_____/_____		
<b>Right Ear</b>	<b>Left Ear</b>	<b>Screen Method</b>
<input type="checkbox"/> Pass <input type="checkbox"/> Refer	<input type="checkbox"/> Pass <input type="checkbox"/> Refer	<input type="checkbox"/> aABR <input type="checkbox"/> aOAE <input type="checkbox"/> aABR and aOAE

**CCHD Screening Results**

<b>Initial Screening:</b> (If rescreen is required proceed to second screening):	<b>Second Screening:</b> (1 hour following initial screening if rescreen is required):	<b>Third Screening:</b> (1 hour following second screening if rescreen is required):
Time and Date:	Time and Date:	Time and Date:
Pulse Ox Saturation of Foot:	Pulse Ox Saturation of Foot:	Pulse Ox Saturation of Foot:
Pulse Ox Saturation of Right Hand:	Pulse Ox Saturation of Right Hand:	Pulse Ox Saturation of Right Hand:
Difference (right hand – foot): <input type="checkbox"/> Fail <input type="checkbox"/> Pass <input type="checkbox"/> Rescreen	Difference (right hand – foot): <input type="checkbox"/> Fail <input type="checkbox"/> Pass <input type="checkbox"/> Rescreen	Difference (right hand – foot): <input type="checkbox"/> Fail <input type="checkbox"/> Pass

Referred To (Physician or Hospital): \_\_\_\_\_

CCHD Screener's First Initial/Last Name: \_\_\_\_\_

Please fax this form to the Georgia Newborn Screening Program at 404-657-2773.

MCH.CH.1208  
 Revised: March 2015

## (4) Request for a Newborn Screening Report Form



NAME OF INDIVIDUAL/PATIENT	
DATE OF BIRTH	
ADDRESS	CITY/STATE/ ZIP

**AUTHORIZATION FOR RELEASE  
OF NEWBORN SCREENING REPORT**


---

- I hereby voluntarily authorize **DPH** to disclose the medical information indicated below to \_\_\_\_\_.
- The purpose for this disclosure is for \_\_\_\_\_.
- The information to be disclosed includes:
  - Newborn Screening Report
  - Follow-up Notes
  - Other (specify) \_\_\_\_\_
- Additional Information:
  - Mother's Name: \_\_\_\_\_
  - Mother's Date of Birth: \_\_\_\_\_
  - Hospital of Birth: \_\_\_\_\_
  - Patient's Gender: \_\_\_\_\_
- 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.

Page 1 of 1

 \_\_\_\_\_  
 Print Patient's Name

 \_\_\_\_\_  
 Patient's Signature

 \_\_\_\_\_  
 Authorized Guardian or Representative

 \_\_\_\_\_  
 Authorized Guardian or Representative Signature

**Fax request form along with your office fax cover sheet to:  
 Georgia Newborn Screening Program  
 Fax# 404-657-2773  
 For more information call: 404-657-4143**

## 5.6 Newborn Screening Fee

According to Georgia Rule 511-5-5, the Newborn Screening (NBS) program currently charges a \$50 fee for screening, patient retrieval and diagnosis to meet and defray the Department's costs.

There **will not** be a fee for the following circumstances:

1. Repeat requested by GPLH or NBS Follow-Up Program
2. Repeat due to a GPLH error
3. Pediatrician or other provider mandatory collection, including
  - o Repeat specimen: 1st specimen taken before 24 hours
  - o Repeat specimen: prior abnormal result
  - o Repeat specimen: Neonatal Intensive Care Unit (NICU) - submitting 2 repeat specimens after initial specimen
  - o Infant has had blood transfusion- submitting 2 repeat specimens after transfusion
  - o Repeat screen collected from a Pediatrician or provider for an initial unsatisfactory specimen collected from a birthing facility.

There **will** be a fee for the following circumstances:

1. Prior unsatisfactory specimen from the **same** submitter
2. General provider request, (see above exceptions)
3. Failure to use the UPS transportation system in a timely manner resulting in specimen arrival at GPLH more than seven (7) days after collection (batching specimens, for example)

## 5.7 Parent Education

Parents must receive DPH Form 5506 (“Georgia Newborn Screening Program: What Every Parent Should Know”) prior to screening in the hospital or birthing center. Parents should know:

- the importance of newborn screening,
- the importance of having a follow-up physician for the newborn screen, and,
- religious grounds are the only valid reason for refusal of newborn screening.
  - If a parent objects to testing based on religious grounds, a hospital official is to inform the parent of the consequences of refusal (possible infant death or intellectual disability) and require the parent to complete a statement indicating their refusal of newborn screening for religious reasons.

### Frequently Asked Questions

#### **What is the Newborn Screening Program?**

- Newborn Screening is a public health program created by Georgia law in 1968. Its goal is to test all babies born in Georgia for conditions that can cause major illness, intellectual disability, or even death if not found early and not treated.

#### **What are the legal requirements for newborn screening?**

- The legal requirements for newborn screening are that every baby in Georgia must have a specimen collected prior to discharge from the hospital regardless of the age of the baby or the status of feeding. If the baby is discharged before 24 hours after birth, the baby must be tested again prior to one week of age. The only legal reason for not collecting a specimen is if the parents object to such testing for religious reasons.

#### **But my baby looks healthy. Are the tests still necessary?**

- **YES!** Most infants with a condition found by newborn screening show no signs of the condition right after birth and can usually be identified before the baby becomes sick. If an infant has a condition, and there is a need for special care, your baby’s healthcare provider can be informed.

#### **Do I have to give permission for my baby to be tested?**

- **No.** The law says that all babies born in Georgia must be tested. You may refuse testing only if it is against your religion. If you do not want to have the test done, you will be asked to sign a statement that says you do not want to have your baby tested.

#### **When is the testing done?**

- The Georgia law says that the hospital of birth must do this test before your baby goes home from the hospital. If you plan to have your baby at home, the test still has to be done. The doctor or nurse that delivers your baby has to tell you where and when to get your baby tested.

#### **How is the test done?**

- The heel of your baby’s foot will be pricked to get several drops of blood. The blood is put on a newborn screening test card and shipped to the Georgia Public Health Laboratory in Decatur, Georgia.

**Will I be told the tests results?**

- Your baby's doctor should be able to give you the test results. Results are mailed to the hospital of birth and to the doctor listed on the screening card. You may also contact the Georgia NBS Program for a copy of your baby's report.

**What happens if a newborn has an abnormal blood test result?**

- The retrieval, diagnosis, medical management and counseling of affected individuals is through cooperative or contractual arrangements between the Newborn Screening Program, Emory University, Georgia Regents University Hospital, and the Sickle Cell Foundation of Georgia, and the county health departments.

**If a re-test is requested, does it mean my baby may have a condition?**

- **No.** There are several reasons why a repeat test may be needed. Sometimes there was an error in the collection of the specimen or a delay in the specimen arriving at GPHL. A positive screen does not say "yes" or "no" to whether or not your child has a condition. Instead, it finds those few babies out of all those tested who may need more specific testing.

**Where can I go to have the re-test done?**

- Your baby's doctor may be able to do repeat tests at their office. If not, your local hospital lab or local county health department should be able to do the test. The Sickle Cell Foundation of GA and the Hemoglobin Follow-up Program will also do repeat tests for abnormal hemoglobin results.

**If my child has one of the conditions, can it be treated?**

- There are treatments for each of these conditions. The treatment may be a medication, special diet, or both.

**What is my role as a parent?**

- Make sure you give your correct address and phone number to the hospital where your baby is born. If you do not have a telephone, give the phone number of someone who knows how to reach you. If possible, give the name and phone number of the doctor who will take care of your baby after leaving the hospital. It is important that your baby's doctor be able to contact you quickly if a re-test is needed. If you are asked to bring your baby in for re-testing, do so as soon as you can. If your child does have a condition, quick action is very important.

**Do I have to pay for this test?**

- A fee of \$50 is currently billed to hospitals for specimens submitted for screening. Hospitals, medical offices, and health departments may also charge a small fee to do and send the test. If you are told that your child cannot have this test because you cannot pay the fee, please call the Newborn Screening Program at (404) 657-4143.

**Where can I get more information?**

- For general information about the Georgia Newborn Screening Program, call (404) 657-4143, or visit <http://dph.georgia.gov>
- For general information about the Georgia Public Health Laboratory, contact

The Newborn Screening Section  
Georgia Public Health Laboratory  
1749 Clairmont Road  
Decatur, GA 30033-4050  
Phone: (404) 327-7950  
Fax: (404) 327-7919

## CCHD FAQs

### **How common is CCHD?**

- About three percent of all babies are born with a birth defect.
- Overall, nearly one percent of all newborns have a congenital heart defect (CHD).
- CHDs are the leading cause of birth defect associated infant illness and death.

### **Won't CCHD be detected prenatally or by exam in the nursery?**

- Prenatal ultrasounds can detect fewer than half of the cases of CCHD
- Predicting saturations based on visual examination of color is unreliable.
- Prior to discharge, some babies with CCHD will have normal exams and not appear cyanotic.
- The ductus arteriosus may provide a significant amount of blood flow to the lungs or body.
- Babies with CCHD can quickly decompensate when the ductus arteriosus closes.
- Pulse oximetry can accurately detect the lower oxygen saturations associated with CCHD with ductal-dependent systemic or pulmonary blood flow.

### **Who will pay for the CCHD screening?**

- Presently, there is not a separate reimbursement available for CCHD screening.
- CCHD screening is part of the bundled services that all newborns should receive.
- Services provided after a failed CCHD screening (e.g., echocardiograms) are typically reimbursed.

### **Should babies be screened in primary care offices if they were not screened in the nursery?**

- Because CCHD screening can be performed in the primary care office, screening can be considered at the first newborn outpatient visit for those babies who were not screened. However, babies should be screened prior to discharge regardless of the age at discharge. Pediatricians who opt to perform CCHD screening in the office should have a plan in place for further evaluation for infants who need repeat pulse-oximetry measurements or who have a failed screen.

## 5.8 Genetic Counseling/Carriers

### Genetic Counseling

The goals of genetic counseling are to increase the understanding of genetic diseases, discuss disease management options, and explain the risks and benefits of testing. Counseling sessions focus on giving vital, unbiased information and non-directive assistance in the patient's decision-making processes.

Emory University Newborn Screening Follow-up Program and the Sickle Cell Foundation of Georgia offers genetic counseling to families of children diagnosed with a disorder and those with children carrying a mutation identified through newborn screening.

For additional information, please contact:

**Emory Follow-Up Program: 404-778-8560**

**Sickle Cell Foundation NBS Coordinator: (404) 755-1641 or 1-800-326-5287 (toll-free)**

### Carrier Status

Everyone has two copies of each gene, one from their mom and one from their dad. Being a carrier means that one copy of the gene mutated (changed) and had been passed on to a person but the other copy is normal and functioning fine. Since carriers still have one working copy of the gene, they typically do not have any health problems associated with carrying a mutation.

Therefore, many people are carriers of a disease-causing mutation without even knowing it. Being a carrier, however, means there is an increased chance that your child could be born with a genetic disease. Anyone can be a carrier of a genetic disease, even if no one in your family is affected.

## 5.9 Other Resources

[Baby's First Test](#) houses the nation's newborn screening clearinghouse.

[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.

[Centers for Disease Control and Prevention](#) serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the people of the United States.

[ACT Sheet](#): <https://www.acmg.net> provides immediate steps for physicians to take upon receiving a positive screen for an infant in his or her practice.

[American Academy of Pediatrics \(Georgia Chapter\)](#) work to improve the health and welfare of all the 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.](#) 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 Information Center](#) provides sickle patient and provider education.

[Sickle Cell Foundation of Georgia](#)

[National Newborn Screening and Genetics Resource Center \(NNSGRC\)](#)

[Cystic Fibrosis Foundation](#)

[National Organization for Rare Disorders \(NORD\)](#)

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