

## Ga. Comp. R. & Regs. r. 511-5-5-.02 Definitions

### Georgia Administrative Code

### Department 511. RULES OF GEORGIA DEPARTMENT OF PUBLIC HEALTH

### Chapter 511-5. Georgia Department of Public Health

### Subject 511-5-5.

*Current through September 9, 2015*

#### **Rule 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, double-outlet right ventricle, D-transposition of the great arteries, Ebstein 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 **NewbornScreening** 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.

**Ga. Comp. R. & Regs. r. 511-5-5-.03 Testing Required of **Newborn** Babies**

**Georgia Administrative Code**

**Department 511. RULES OF GEORGIA DEPARTMENT OF PUBLIC HEALTH**

**Chapter 511-5. Georgia Department of Public Health**

**Subject 511-5-5.**

*Current through September 9, 2015*

**Rule 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 ground 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) methylmalonic 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.

**Ga. Comp. R. & Regs. r. 511-5-5-.06 Hearing Screening**

**Georgia Administrative Code**

**Department 511. RULES OF GEORGIA DEPARTMENT OF PUBLIC HEALTH**

**Chapter 511-5. Georgia Department of Public Health**

## **Subject 511-5-5.**

*Current through September 9, 2015*

### **Rule 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 or birthing center or in an 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 a 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 assure 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 given to the parents or legal guardians along with any follow-up recommendations, in accordance with the Georgia **Newborn Screening** Policy and Procedure Manual.

### **Ga. Comp. R. & Regs. r. 511-5-5-.08 Abnormal Test Results**

**Georgia Administrative Code**

**Department 511. RULES OF GEORGIA DEPARTMENT OF PUBLIC HEALTH**

**Chapter 511-5. Georgia Department of Public Health**

**Subject 511-5-5.**

*Current through September 9, 2015*

### **Rule 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 the 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.