

**NOTICE OF PROPOSED RULEMAKING**  
**Revision to Newborn Screening Specimen Cards and Laboratory Analysis**  
**Rule 511-5-5-.04**

The Georgia Department of Public Health proposes the attached amendment to revise Rule 511-5-5-.04 "Newborn Screening Specimen Card and Laboratory Analysis" pursuant to its authority under O.C.G.A. § 31-2A-6 and O.C.G.A. §31-12-5 through -7.

The purpose of the proposed rulemaking is to extend the number of days by which specimens are designated as satisfactory for collection from seven (7) days to ten (10) days from the date of collection. This will reduce the need for parents to take their infants out of the home for a recollection, particularly for those parents who are hesitant due to the risk of exposing their newborns to COVID-19. Many other states have a submission period of 10-14 days, and processing specimen cards within ten (10) days of the date of collection will not impact the validity of the test.

The proposed amendments have been posted to the Department's website at <https://dph.georgia.gov/regulationsrule-making>. Interested persons may submit comments on these proposed revisions in writing addressed to:

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Written comments must be submitted on or before September 16, 2020. Comments may also be presented in person at a public meeting scheduled for 10:00 a.m. on Tuesday, September 1, 2020 in Room 9-260 at 2 Peachtree Street, NW, Atlanta, Georgia 30303. To dial in, please call (605) 313-4100 and enter access code 246-866. The Commissioner of Public Health will consider the proposed rules for adoption on or about September 21, 2020, to become effective on October 21, 2020.



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Associate General Counsel  
Georgia Department of Public Health

**RULES OF THE  
DEPARTMENT OF PUBLIC HEALTH  
CHAPTER 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 a 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 Department's 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 Public Health Laboratory within ~~seventeen~~ (10) 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 into 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 \$80.40 per baby, for screening, patient retrieval and diagnosis, in order to meet or defray the Department's actual 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, healthcare provider, or parent or legal guardian to arrange for the second specimen.

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