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Integrating Hearing-Targeted Congenital Cytomegalovirus Follow-Up into Existing Newborn Screening Infrastructure: Georgia's Experience

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Abstract

Congenital cytomegalovirus (cCMV) is the leading non-genetic cause of childhood sensorineural hearing loss. However, published descriptions of state-level approaches for integrating cCMV follow-up into existing Early Hearing Detection and Intervention (EHDI) and Newborn Blood Spot Screening (NBS) follow-up infrastructure are limited. In October 2024, hearing-targeted cCMV testing became required in Georgia through a change to the state's rules and regulations. The Georgia Department of Public Health (DPH) developed a follow-up protocol built on three core components: cCMV was designated a notifiable condition, triggering electronic laboratory reporting (ELR) to DPH alongside provider and facility reporting requirements; medical follow-up for cCMV cases was integrated into the state's existing NBS follow-up processes; and an audiologist-led protocol was established to facilitate timely diagnostic hearing evaluation and ongoing audiologic follow-up for confirmed cCMV cases. Between 10 October 2024 and 10 March 2026, DPH identified 103 newborns with an initial positive cCMV result. After excluding nine cases that did not enter the follow-up workflow at birth, 94 newborns were included in this analysis. Of these, 59 (62.8%) were laboratory-confirmed cCMV-positive, 33 (35.1%) were false positive, and 2 (2.1%) were presumptive positive. One newborn died before completing audiologic follow-up and was excluded from follow-up outcomes. Among the remaining 58 laboratory-confirmed cCMV cases requiring audiologic follow-up, 52 (89.7%) completed diagnostic Auditory Brainstem Response (ABR) evaluation and 6 (10.3%) were lost to follow-up; 14 of 52 (26.9%) evaluated newborns were diagnosed with sensorineural hearing loss (SNHL). This paper describes Georgia's cCMV follow-up strategy and reports preliminary outcomes from the program's first 18 months of implementation, offering an adaptable framework for integrating cCMV case follow-up and audiologic surveillance into existing state public health infrastructure.

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1. Introduction

Congenital cytomegalovirus (cCMV) is one of the most common congenital infections in the United States, affecting three to six per 1000 live-born newborns each year [1]. It is the leading cause of non-genetic sensorineural hearing loss (SNHL) in children, accounting for an estimated 15–25% of all moderate-to-profound SNHL [2,3]. Approximately 90% of newborns with cCMV are asymptomatic at birth, and among these asymptomatic newborns, 8–15% develop late-onset hearing loss [4].

A laboratory-confirmed diagnosis of cCMV requires detection of cytomegalovirus (CMV) in a specimen collected within the first 21 days of life. Congenital CMV infection occurs when the virus is transmitted from mother to fetus in utero and is associated with the well-described risks of congenital disease, including SNHL and neurodevelopmental sequelae. By contrast, CMV infection acquired after birth does not carry the same implications as congenital infection and does not require surveillance, hearing follow-up, or consideration of early antiviral treatment. Because a positive test obtained after 21 days cannot reliably distinguish between congenital and postnatally acquired infection, timely testing is essential to establish a definitive cCMV diagnosis.

Newborns who miss this narrow testing window may never receive a confirmatory cCMV diagnosis at all, even if they go on to develop cCMV-associated hearing loss months or years later. While retrospective testing of the newborn dried blood spot (DBS) can provide an opportunity to identify congenital infection after the 21-day window, DBS testing has lower sensitivity than urine or saliva, and a negative result does not rule out cCMV [5].

In addition to hearing loss, cCMV is associated with a spectrum of potential long-term outcomes affecting vision, vestibular function, and neurodevelopment, underscoring the importance of early identification. Early diagnosis enables timely surveillance, comprehensive follow-up, and referral to early intervention services to support affected newborns and optimize developmental and health outcomes [6,7]. Despite these known risks associated with cCMV, public health screening and clinical follow-up for cCMV remain inconsistent across the United States. As of late 2025, 13 states had enacted hearing-targeted cCMV screening laws or regulations, requiring or recommending cCMV screening for newborns who fail the newborn hearing screening [8]. Two additional states, Connecticut and Minnesota, mandate universal cCMV screening for all newborns regardless of hearing screening results. In many states without a statewide screening requirement, cCMV testing may only occur based on clinical suspicion or institutional practice. In 2026, the American Academy of Pediatrics (AAP) recommended a hearing-targeted plus expanded testing approach, in which newborns should be tested for cCMV if they do not pass the newborn hearing screen or have other risk factors or signs of cCMV: maternal human immunodeficiency virus (HIV) or CMV infection during pregnancy, birth weight or head circumference below the 10th percentile for gestational age, abnormal central nervous system imaging, intra-abdominal calcifications, unexplained hepatomegaly, splenomegaly, petechial rash, thrombocytopenia, elevated liver enzymes or conjugated bilirubin [7].

Although hearing-targeted cCMV screening policies exist in some states, published descriptions of how states operationalize cCMV follow-up within existing Early Hearing Detection and Intervention (EHDI) and newborn screening (NBS) follow-up systems are

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limited. Part of this complexity stems from the fact that the organizational relationship between EHDI and NBS itself varies across states. Programs may be housed within the same agency but operate as separate teams or may be in different agencies altogether. In Georgia, EHDI and NBS follow-up are housed within the Georgia Department of Public Health (DPH) but operate as distinct programs with separate follow-up teams and processes. Because hearing-targeted cCMV testing is performed by birthing facilities using urine or saliva rather than through the traditional newborn blood spot screening process, cCMV does not fit fully within the existing scope of either program. Georgia developed a coordinated follow-up model that routes different components of cCMV case management through existing public health processes, including notifiable disease reporting, NBS follow-up, and audiology outreach, rather than creating a parallel cCMV follow-up system. This paper describes Georgia's hearing-targeted cCMV follow-up protocol and reports outcomes during its first 18 months of implementation.

1.1. History of Hearing-Targeted cCMV Screening in Georgia

Following a formal request from the Georgia Chapter of the AAP in November 2018, Georgia's Newborn Screening and Genetics Advisory Committee (NBSAC) established a cCMV working group to determine if cCMV should be added to Georgia's NBS panel. The working group met regularly from 2019 through 2021, and in April 2021, they declined to recommend adding cCMV to the state's NBS panel due to insufficient evidence, recommending educational initiatives instead. The federal Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) reached a similar conclusion in August 2022, citing insufficient data.

The Georgia cCMV working group reconvened in 2023 to reassess feasibility, this time considering a hearing-targeted rather than universal screening approach. In September 2023, it recommended that DPH incorporate hearing-targeted cCMV screening into the state's rules and regulations, and the NBSAC and DPH Commissioner approved the recommendation [9]. A cCMV Taskforce was then established to draft the regulatory language and develop the state's cCMV policy and procedures. Effective 10 October 2024, birthing facilities in Georgia are required to conduct cCMV testing on all newborns who fail their final newborn hearing screening (NBHS), before discharge or 21 days of age, whichever comes first. cCMV became a notifiable condition effective the same date (see Section 2.1.1., Case Definition and Diagnostic Testing Criteria), which allows DPH's follow-up to extend to all positive reported cases, not only those identified through hearing-targeted screening. cCMV testing in Georgia occurs through three pathways: the mandated hearing-targeted screening; testing based on clinical indication (e.g., intrauterine growth restriction, brain abnormality); or universal testing protocols that a small number of birthing facilities have independently adopted.

1.2. Background on Georgia's Newborn Screening Programs

The Georgia NBS Program is a statewide public health program designed to identify conditions in newborns that may result in severe illness, physical or developmental disability, or death if not identified and treated early. Newborns in Georgia undergo three components of screening: DBS, hearing, and critical congenital heart disease (CCHD). DBS screening is performed using a blood specimen collected shortly after birth and submitted to the Georgia Public Health Laboratory (GPHL) for testing, which screens for 39 primary conditions. Hearing and CCHD screening are performed as point-of-care screenings prior to hospital discharge.

Follow-up for abnormal screening results is coordinated through established state-contracted programs according to the type of result. They communicate results to

providers and families, coordinate recommended follow-up, and connect newborns and their families with appropriate diagnostic and clinical services.

1.2.1. Emory University Newborn Screening Short-Term Follow-Up Program

The Emory University Newborn Screening Short-Term Follow-Up (Emory STFU) Program serves as the established state-contracted organization for managing follow-up of abnormal DBS results, excluding hemoglobinopathies, reported by GPHL. The program is staffed by licensed registered nurses who receive abnormal results through an electronic health database, notify the newborn's healthcare provider, and facilitate evaluation and confirmatory testing, while communicating directly with families to provide education and reinforce follow-up recommendations.

1.2.2. Early Hearing Detection and Intervention Program

Georgia's EHDI Program provides follow-up for newborns who fail their newborn hearing screening and supports timely progression from screening to diagnostic audiologic evaluation and appropriate intervention. Follow-up is coordinated through a network of 18 EHDI coordinators, with one located in each of Georgia's public health districts, who track newborns requiring hearing follow-up, communicate results and recommendations with families and medical providers, and ensure that children diagnosed with permanent hearing loss are referred to early intervention.

1.3. Pre-Existing Database Infrastructure

The NBS and EHDI follow-up programs described above are more easily able to coordinate cCMV follow-up because they utilize a shared data system. Hospitals initiate the newborn screening data flow by submitting an electronic birth certificate (EBC) to Georgia Vital Records within five days of birth, as mandated by Georgia law. Vital Records compiles a daily Health Level Seven (HL7) EBC file, which is sent to DPH's State Electronic Notifiable Disease Surveillance System (SendSS) database.

Newborn screening results, including DBS, CCHD, hearing, and, now, cCMV, are similarly routed into SendSS and automatically matched to the corresponding newborn's EBC record. This creates a single, statewide record for each newborn that NBS and EHDI follow-up staff can access and update in real time, minimizing duplication of effort. Because SendSS already functions as a central, cross-program repository for newborn screening results, it is an existing point of infrastructure that future public health initiatives could build on. The following section describes how DPH built Georgia's cCMV follow-up protocol within this existing infrastructure.

2. Materials and Methods

2.1. What cCMV Added

Georgia's cCMV follow-up protocol integrates case identification, reporting, and follow-up across the birthing facility where testing occurs, DPH (including Child Health Audiology), and Emory STFU. Once a case is confirmed, Emory STFU and DPH Audiology conduct case follow-up in parallel, managing medical and audiologic follow-up, respectively. Figure 1 provides an overview of this workflow, from initial specimen collection through confirmed diagnosis and follow-up. The sections below describe each component of this process in detail.

Hearing loss has long been a notifiable condition in Georgia, requiring healthcare providers to report confirmed or suspected permanent hearing loss in children under six years of age to DPH within seven days of diagnosis, as part of the state's EHDI surveillance system. [10] When cCMV was designated a notifiable condition in October 2024,

DPH's SendSS information technology (IT) development team built a new cCMV results section within the existing EHDI record in SendSS. Laboratories continue to report positive notifiable disease results using Electronic Lab Reporting (ELR), adding cCMV to the panel of conditions reported through that established channel. Building on the shared SendSS infrastructure described above, the SendSS IT development team built the connection linking each incoming reportable positive cCMV result to the newborn's corresponding EHDI record, automatically populating in the newly created cCMV section. This match triggers automatic state and district level electronic alerts, initiating DPH's cCMV follow-up protocol within both the EHDI program and Emory STFU. This data-transfer process allows DPH to link a positive cCMV result directly to a child's existing screening and follow-up record, streamlining case identification and enabling timely, coordinated follow-up.

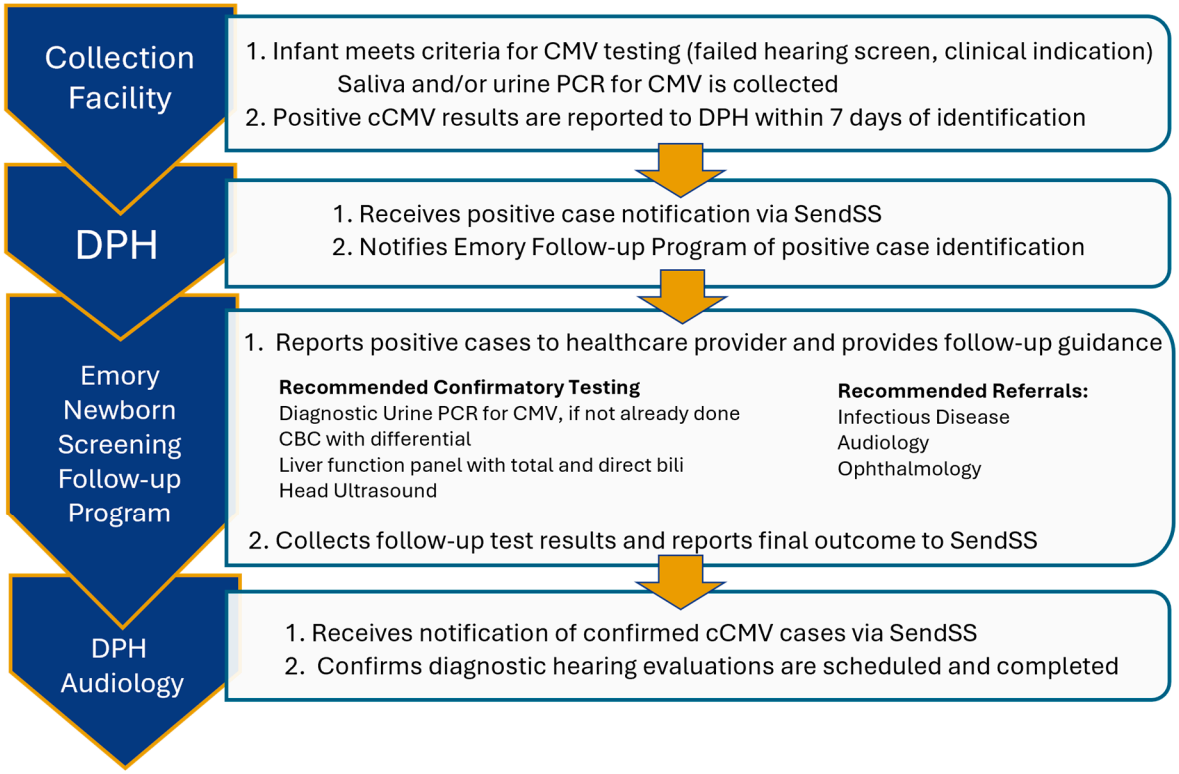


Figure 1. Georgia's cCMV follow-up protocol. CBC, complete blood count; cCMV, congenital cytomegalovirus; CMV, cytomegalovirus; DPH, Georgia Department of Public Health; PCR, polymerase chain reaction; SendSS, State Electronic Notifiable Disease Surveillance System.

A multidisciplinary cCMV Taskforce, including pediatricians, audiologists, geneticists, otolaryngologists, infectious disease, and public health nursing and program staff, contributed to protocol development and confirmatory testing recommendations (see Acknowledgments). Program roles and responsibilities were defined by DPH leadership.

2.1.1. Case Definition and Diagnostic Testing Criteria

cCMV is a notifiable condition in Georgia only when the specimen is collected at 21 days of age or younger; Georgia's follow-up protocol, including outcome classification, is scoped accordingly. The cCMV taskforce utilized the Council of State and Territorial Epidemiologists (CSTE) surveillance case definitions, as reflected in the Centers for Disease Control and Prevention (CDC) surveillance criteria, to establish confirmatory testing requirements and standardized outcomes for case resolution in Georgia [11]. The statewide mandate implemented in October 2024 required birthing facilities to test newborns who

fail the final inpatient newborn hearing screen for cCMV before 21 days of age. Per DPH's cCMV Policy and Procedure Manual, initial screening can be performed using urine polymerase chain reaction (PCR) or saliva PCR; saliva loop-mediated isothermal amplification (LAMP) is also an acceptable first-tier screening method. DPH does not mandate a specific specimen or initial test type, and testing methodologies vary across birthing facilities [12]. A positive saliva screening result requires confirmation with a urine PCR specimen within the 21-day diagnostic window. Newborns with positive urine PCR collected as the initial testing method within 21 days of age enter the workflow with a cCMV diagnosis already established. Medical follow-up recommendations are based on CSTE/CDC surveillance criteria, which specify urine PCR as the required confirmatory test following a positive saliva screen.

Using these same CSTE/CDC criteria, outcome status is assigned based on the results and timing of confirmatory testing. Because this paper describes outcomes of Georgia's cCMV follow-up protocol, it is limited to newborns who screened positive on at least one specimen and therefore entered the protocol. Newborns with a negative initial screening result, though sometimes reported to DPH, did not enter follow-up and are not described here. Positive saliva cases with confirmatory urine PCR within 21 days of age resulting as "not detected" were classified as false positive. Positive saliva cases with confirmatory urine PCR within 21 days of age resulting as "detected" were classified as confirmed positive, as were cases with a positive nucleic acid amplification test (NAAT) or culture result from an alternate specimen type recognized under CSTE/CDC criteria (e.g., whole blood, cerebrospinal fluid) collected within 21 days of age, provided no negative urine test was obtained.

2.1.2. Integrating Audiology Follow-Up into Existing EHDI Infrastructure

In the typical EHDI workflow, newborns who fail their newborn hearing screening are automatically added to the district EHDI coordinator's follow-up list. EHDI coordinators contact families and physicians regarding the need for follow-up testing, typically through a combination of phone calls, faxes, and/or letters. Because cCMV carries a significant risk of SNHL regardless of the newborn hearing screening result, DPH established a parallel, audiologist-led pathway for these cases. A positive cCMV result triggers an alert to the DPH Child Health audiologist, who assumes the lead role for hearing-related follow-up in place of the standard EHDI coordinator process. While EHDI coordinators are well-versed in tracking newborns who need diagnostic versus screening follow-up, cCMV introduces a layer of medical complexity that falls outside this standard role. Because a cCMV-positive newborn may have passed the newborn hearing screening, families and physicians frequently question why a diagnostic auditory brainstem response (ABR) is being recommended at all, a question that requires audiologic and medical knowledge to answer credibly. The Child Health audiologist is positioned to field these questions directly, explaining the delayed-onset and progressive nature of cCMV-associated hearing loss.

The Child Health audiologist does not perform hearing testing directly. Their role is to help families identify a qualified pediatric audiologist, coordinate with the newborn's physician to obtain appropriately specified orders, address barriers such as transportation, and when families or physicians are difficult to reach, coordinate with Emory STFU to support outreach. The audiologist's clinical background also allows for evaluation of the appropriateness of care a newborn has already received and intervention when necessary. Community audiologists vary in their familiarity with cCMV, and families are not always equipped to recognize when the advice they receive is inadequate. In one case, a community audiologist advised a family to delay diagnostic testing for several months following an inconclusive attempt. The Child Health audiologist recognized this as

inconsistent with the diagnostic urgency of cCMV, counseled the family accordingly, and helped connect them with a provider who could complete testing immediately. Testing resulted in an SNHL diagnosis by three months of age rather than substantially delaying the diagnosis.

Together, this clinical and system-level expertise helps ensure that newborns with confirmed cCMV receive the correct diagnostic hearing evaluation and ongoing audiologic follow-up.

2.1.3. Integrating Medical Follow-Up into Existing NBS Infrastructure

DPH expanded its existing contract with Emory to include cCMV medical follow-up, requiring only limited modification to the established workflow and communication pathways. Because of cCMV's narrow diagnostic window, positive cCMV results are reported to Emory as critical result notifications, a designation reserved for cases requiring immediate action and accelerated follow-up. Emory's follow-up team tracks cCMV cases every two days until specimen collection is confirmed.

Once a case outcome is established, it is reported through SendSS, where it is accessible to both Emory and the Child Health audiologist. A case is closed by the Emory STFU team once the newborn has completed an infectious disease referral or consultation, confirming connection with appropriate specialty care. Infectious disease specialists classify disease severity and determine eligibility for antiviral therapy, which is recommended for moderate-to-severe cCMV disease and may be offered for cCMV with isolated SNHL when begun within 13 weeks of birth [7].

2.2. Early Intervention Eligibility

Because newborns with confirmed cCMV are at increased risk of SNHL and neurodevelopmental delay, they qualify automatically for early intervention (EI) services through Babies Can't Wait (BCW), Georgia's Part C EI program under the federal Individuals with Disabilities Education Act (IDEA), which provides developmental and therapeutic services (e.g., speech-language, audiologic, and developmental therapy) to newborns and toddlers with disabilities or developmental delay. Referral to and enrollment in Part C EI services among confirmed cases were tracked as part of this protocol (see Section 2.3, Data Analysis) and are reported in Section 3.4.

2.3. Data Analysis

All positive cCMV results reported to DPH from 10 October 2024 through 10 March 2026 were queried in SendSS and exported into an Excel line list for analysis. Because a newborn may have multiple positive test results (initial and confirmatory) reported, duplicates were removed to obtain a list of unique cases. This line list was compared and linked to the line list maintained by Emory, which contained clinical details and timeliness metrics for cCMV screening, follow-up initiation, and diagnosis for each case. The cases were linked to their birth records by their unique SendSS personal identification number to obtain their demographic data. The positive predictive value of the initial cCMV saliva screen was calculated as follows: [# confirmed positive/(# confirmed positive + # false positive)] × 100. The mean and median days from birth to first screen, follow-up initiation, and diagnosis were calculated, as was the range of days.

NBHS and diagnostic ABR evaluation records that were already linked in SendSS to the confirmed positive cases were analyzed to track their audiology follow-up. The sensitivity of the hearing-targeted cCMV screening was calculated as follows: [# failed NBHS/(# failed NBHS + # passed NBHS)] × 100. Finally, confirmed positive cases were queried individually in the Babies Information and Billing System (BIBS) to determine if they were referred to and subsequently enrolled in Part C EI services. Because of small sample sizes,

Fisher's exact test was used to test the significance of associations between NBHS results and audiology follow-up, referral to Part C EI, and enrollment in Part C EI. All data analyses were conducted using Microsoft Excel and SAS Enterprise Guide 8.3 (SAS Institute Inc., Cary, NC, USA).

2.4. Exclusion Criteria

Nine cases were excluded from this analysis. Three cases were confirmed positive for cCMV at the birthing facility but were never reported to DPH through the required notifiable condition pathway. DPH became aware of these cases only when the EHDI system identified them independently, such as through EHDI failed hearing referrals noting a positive cCMV status. DPH contacted the submitting facilities, analyzed root causes for the lack of reporting, and re-educated the facility. Four cases were excluded because testing occurred out of state and were not reported to DPH until after the 21-day diagnostic window had passed. The remaining two cases were affected by ELR delays. In one, the positive result was confirmed but the report to DPH was transmitted late. In the other, the delay prevented confirmatory testing from being completed within the 21-day diagnostic window, and the case was classified as presumptive positive. Because none of the nine cases entered DPH's established cCMV follow-up workflow at or near birth, they were excluded from analysis. Although all nine of these newborns ultimately received the same audiology-led follow-up as other confirmed cases, they were excluded from this analysis because the timeliness intervals reported here (see Section 3.2) are anchored to birth and reflect performance of the follow-up process beginning near birth.

3. Results

3.1. Case Identification and Demographics

From 10 October 2024 through 10 March 2026, a total of 94 newborns who initially screened positive for cCMV were reported to DPH, after removal of duplicate records and exclusion of nine cases (Figure 2). Table 1 shows their demographic characteristics and Table 2 shows their clinical characteristics. Of these 94 newborns, 59 were confirmed positive. Among the confirmed cases, 46% had a history of neonatal intensive care unit (NICU) admission, 42% had a low birth weight <2500 g, and 34% failed NBHS.

Table 1. Demographic characteristics of 94 newborns who initially screened positive for cCMV and were reported to the Georgia Department of Public Health, 10 October 2024–10 March 2026.

Demographic Characteristic	Total (*n* = 94)		Confirmed Positive (*n* = 59)		
	n	%	*n*	%	Prevalence Per 10,000 Live Births
Sex					
Male	55	58.5	28	47.5	3.1
Female	39	41.5	31	52.5	3.5
Maternal age, y					
14–19	17	18.1	14	23.7	17.5
20–29	53	56.4	31	52.5	3.7
30–39	19	20.2	11	18.6	1.4
40–49	3	3.2	1	1.7	1.5
Unknown	2	2.1	2	3.4	N/A
Maternal race/ethnicity					
White, not Hispanic/Latino	40	42.5	25	42.4	3.3
Black, not Hispanic/Latino	34	36.2	25	42.4	4.7

Hispanic/Latino, any race	16	17.0	6	10.1	1.8
Multiracial, not Hispanic/Latino	3	3.2	2	3.4	4.4
Other, not Hispanic/Latino	1	1.1	1	1.7	8.3

cCMV, congenital cytomegalovirus; N/A, not applicable.

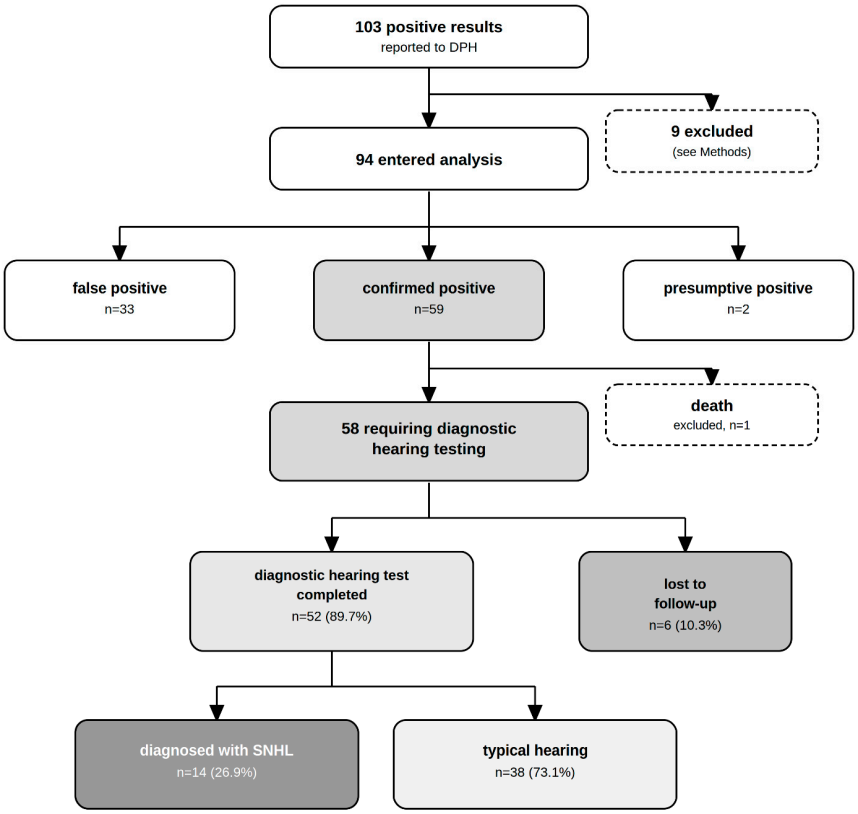


Figure 2. Case identification and outcome flow for 94 newborns who initially screened positive for cCMV and entered Georgia's follow-up protocol, 10 October 2024–10 March 2026. cCMV, congenital cytomegalovirus; DPH, Georgia Department of Public Health; SNHL, sensorineural hearing loss.

Table 2. Clinical characteristics of 94 newborns who initially screened positive for cCMV and were reported to the Georgia Department of Public Health, 10 October 2024–10 March 2026.

Clinical Characteristic	Total (*n* = 94)		Confirmed Positive (*n* = 59)	
	n	%	*n*	%
Risk factors				
Neonatal intensive care unit (NICU) admission	37	39.4	27	45.8
Low birthweight (<2500 g)	34	36.2	25	42.4
Small for gestational age/intrauterine growth restriction	10	10.6	10	16.9
Prenatal CMV exposure	4	4.3	4	6.8
Newborn hearing screening results at time of cCMV screen				
Passed	30	31.9	17	28.8
Failed	34	36.2	20	33.9
Not done (in NICU)	21	22.3	17	28.8
Unknown	9	9.6	5	8.5
First cCMV screening specimen type				
Saliva	64	68.0	30	50.8
Urine	25	26.6	25	42.4
Blood	3	3.2	3	5.1

Blood and urine	1	1.1	1	1.7
Blood IgG antibody	1	1.1	0	0.0

cCMV, congenital cytomegalovirus; CMV, cytomegalovirus; IgG, immunoglobulin G.

Of the 94 newborns with positive cCMV screening results, 65 required confirmatory testing because their initial testing did not meet diagnostic laboratory criteria. Of these, 63 (96.9%) completed confirmatory specimen collection within the 21-day diagnostic window. Only two newborns did not complete confirmatory testing within this timeframe due to collection-related barriers, resulting in classification as presumptive positive (Table 3).

Table 3 shows the outcome status of the 94 newborns who initially screened positive for cCMV. Among the 64 newborns who screened positive for cCMV by saliva, 30 were confirmed positive and 32 were false positive, resulting in a positive predictive value of [30/(30 + 32)] × 100 = 48%.

Table 3. Outcome status of 94 newborns who screened positive for cCMV and were reported to the Georgia Department of Public Health, by specimen type, 10 October 2024–10 March 2026.

Outcome Status	Saliva	Urine or Blood	Blood IgG Antibody	Total	%
Confirmed positive	30	29	0	59	62.8
False positive	32	0	1	33	35.1
Presumptive positive	2	0	0	2	2.1
Total	**64**	**29**	**1**	**94**	**100.0**

cCMV, congenital cytomegalovirus; IgG, immunoglobulin G.

3.2. Timeliness of First cCMV Screen, Follow-Up Initiation, and Diagnosis

Table 4 shows timeliness markers of the 94 newborns who initially screened positive for cCMV, from birth to first screen, follow-up initiation, and diagnosis. The median time from birth to initiation of medical follow-up was 7 days, representing one-third of the 21-day diagnostic window and leaving approximately 14 days to obtain a confirmatory specimen. During this interval, several steps must occur before a positive result enters the medical follow-up workflow, including specimen collection, laboratory processing and reporting, and electronic transmission of the result to DPH. The range of days from birth to follow-up initiation was 2 to 21, reflecting variation in the timing of cases entering the follow-up process.

Table 4. Intervals in days between birth, first cCMV screen, follow-up initiation, and diagnosis for 94 newborns who initially screened positive for cCMV and were reported to the Georgia Department of Public Health, 10 October 2024–10 March 2026.

Interval	*n*	Mean	Median	Range
Birth to first screen	94	3.15	2	0–15
Birth to follow-up initiation	94	7.91	7	2–21
Birth to diagnosis	64	9.78	9.5	0–28
Follow-up initiation to diagnosis	36	6.19	6	0–21
Diagnosis to follow-up initiation *	28	3.61	3	1–12

cCMV, congenital cytomegalovirus.* If follow-up was initiated after diagnosis.

3.3. Audiologic Follow-Up Outcomes

Table 5 shows the audiologic follow-up of the 59 newborns with confirmed positive cCMV. Among these newborns, 25 failed NBHS and 31 passed NBHS, resulting in a sensitivity of [25/(25 + 31)] × 100 = 44.6%. Among the 25 newborns who failed NBHS, 20

(80.0%) received a diagnostic hearing evaluation within 90 days (3 months) of birth as recommended, compared to only 19 (61.3%) of the 31 newborns who passed NBHS, although this was not statistically significant (p = 0.18) [13]. Among the 25 newborns who failed NBHS, 14 (56.0%) were diagnosed with permanent hearing loss.

Table 5. Audiologic follow-up of 59 newborns with confirmed positive cCMV reported to the Georgia Department of Public Health, by NBHS result, 10 October 2024–10 March 2026.

NBHS Result	Total	Evaluation < 90 Days		Evaluation > 90 Days		Permanent Hearing Loss		Lost to Follow-Up	
		n	%	*n*	%	*n*	%	*n*	%
Passed	31	19	61.3	9	29.0	0	0.0	3	9.7
Failed	25	20	80.0	3	12.0	14	56.0	2	8.0
Missed *	2	0	0.0	1	50.0	0	0.0	1	50.0
Total	**58**	**39**	**67.2**	**13**	**22.4**	**14**	**24.1**	**6**	**10.3**

cCMV, congenital cytomegalovirus; NBHS, newborn hearing screening. * Excludes 1 death.

3.4. Early Intervention (Part C) Referral and Enrollment

Table 6 shows referrals to and enrollment in Part C EI services among the 59 newborns with confirmed positive cCMV. A higher percentage of newborns who failed NBHS were referred to Part C EI services (92.0%) than were newborns who passed NBHS (87.1%), although this was not statistically significant (p = 0.68). Similarly, a higher percentage of newborns who failed NBHS subsequently enrolled in Part C EI services (52.0%) than did newborns who passed NBHS (35.5%), although this also was not statistically significant (p = 0.28).

Table 6. Referrals to and enrollment in Part C EI services among 59 newborns with confirmed positive cCMV reported to the Georgia Department of Public Health, by NBHS result, 10 October 2024–10 March 2026.

NBHS Result	Total	Referred to Part C EI		Enrolled in Part C EI	
		n	%	*n*	%
Passed	31	27	87.1	11	35.5
Failed	25	23	92.0	13	52.0
Missed *	2	0	0.0	0	0.0
Total	**58**	**50**	**86.2**	**24**	**41.4**

cCMV, congenital cytomegalovirus; EI, early intervention; NBHS, newborn hearing screening. * Excludes 1 death.

4. Discussion

4.1. Observed Prevalence vs. National Estimates

Disparities by maternal age and race/ethnicity in the prevalence of confirmed positive cCMV observed in this study reflect national estimates, albeit at much lower rates due to under-detection of cases, as discussed in the limitations below. Newborns of the youngest mothers aged 14–19 (n = 14) had the highest prevalence by maternal age of 17.5 per 10,000 live births in this study (Table 1). Estimates based on 2022 national birth data similarly indicate that newborns of mothers aged 15–19 had the highest prevalence of 47 per 10,000 live births [14]. Prevalence decreased among newborns of successively older maternal age groups in this study, similar to 2022 national estimates [14]. Newborns of Black, not Hispanic/Latino mothers (n = 25) had the highest prevalence by maternal race/ethnicity of 4.7 per 10,000 live births in this study (Table 1; while Other, not Hispanic/Latino had a higher rate of 8.3 per 10,000 live births, this was based on only one case). Multiyear

national estimates similarly indicate that Black newborns had the highest prevalence of 93–95 per 10,000 live births [15,16]

4.2. Working Together in Existing Systems

Implementation of cCMV screening created an opportunity to strengthen collaboration between two established public health programs, NBS and EHDI, that previously operated independently. Integrating cCMV follow-up into these existing systems established new communication pathways and allowed each program to contribute its existing expertise. NBS brought established infrastructure for managing time-sensitive abnormal results and for provider and family outreach. EHDI, through development of audiologist-led follow-up, contributed expertise in audiologic surveillance and in coordinating services for newborns with or at risk for hearing loss. This collaboration was further supported by DPH's SendSS IT development team, who built a cCMV-specific data section and automated alerting within the state's existing notifiable-conditions infrastructure (see Section 2.1, What cCMV Added). This efficient approach to case identification and communication illustrates how a new screening requirement can strengthen, rather than duplicate existing public health systems, and it may offer a template for future cross-program initiatives beyond cCMV.

Georgia's EHDI program also functioned as a partial safety net for cCMV cases missed by the notifiable-condition reporting pathway, identifying them independently through newborn hearing screening follow-up and coordination, as discussed below in Limitations. This may be an underappreciated strength of embedding cCMV follow-up within existing multi-program infrastructure rather than building a single, stand-alone surveillance channel.

Georgia's experience implementing hearing-targeted cCMV screening illustrates how existing newborn screening infrastructure can be adapted to accommodate a new condition without building a separate system from the ground up. As the scope of newborn screening continues to expand, cCMV offers a useful model for reorganizing established public health functions, such as notifiable disease reporting, follow-up case management, and hearing surveillance, to be reorganized around a new screening requirement while preserving the systems already in place.

4.3. What the Data Suggests Is Working

The high rate of timely confirmatory cCMV testing (96.9%) observed among newborns requiring confirmatory urine PCR suggests that integrating cCMV medical follow-up into existing NBS infrastructure supports completion of recommended testing within the narrow diagnostic window. Direct communication with healthcare providers, families, and laboratories further supports identification and resolution of barriers that might otherwise delay testing. In September 2025, the Emory STFU program began routine phone outreach directly notifying families of abnormal results and next steps. Anecdotally, family engagement is believed to have contributed to the success with timely follow-up; both cases that did not obtain confirmatory testing within the 21-day window occurred before the family outreach strategy was implemented.

Additionally, the audiologist-led hearing follow-up pathway appears to be a meaningful driver of the diagnostic completion rates reported above. Of the 58 confirmed cCMV cases requiring audiologic follow-up, 52 (89.7%) completed diagnostic ABR evaluation, and 39 (67.2%) did so within the recommended three-month window (Table 5). Standard EHDI follow-up relies on a district coordinator to track appointment completion. The cCMV pathway instead places an audiologist in direct contact with families and providers, allowing case-specific clinical judgment rather than administrative tracking alone. This is particularly relevant for cCMV, where a passed newborn hearing screening

can create the false impression that no further evaluation is warranted. The Child Health audiologist's ability to explain the delayed-onset and progressive nature of cCMV-associated hearing loss directly to families and physicians appears to support continued follow-up despite a reassuring initial hearing screen (see Section 2.1.2.).

4.4. Hearing-Targeted cCMV Screening Alone Would Have Missed the Majority of Cases

More than half (55%) of confirmed cCMV cases in this cohort were identified outside Georgia's rule-mandated hearing-targeted pathway, either through universal screening adopted independently by some birthing facilities or through testing prompted by clinical indications unrelated to hearing screening status. Limiting testing to newborns who failed their NBHS would have identified only 45% of confirmed cases (sensitivity = 44.6%), meaning a hearing-targeted-only approach would have missed the majority (55%) of cCMV cases in Georgia during this period. Notably, all 14 newborns diagnosed with permanent hearing loss had failed their NBHS. However, the cases missed by hearing-targeted screening are at risk for late-onset or progressive hearing loss, as well as cCMV disease that may warrant antiviral treatment, which is time-limited to the first 13 weeks after birth [7].

These findings are consistent with the 2026 AAP clinical report, which recommends hearing-targeted plus expanded testing [7]. Several characteristics of confirmed cases in this cohort correspond to the AAP's expanded testing criteria, including small for gestational age or intrauterine growth restriction (n = 10, 16.9%) and documented maternal CMV infection during pregnancy (n = 4, 6.8%) (Table 2). In addition, 17 of 59 confirmed cases (28.8%) were in neonatal intensive care and had not yet completed newborn hearing screening at the time of cCMV testing. The AAP notes that many pre-term newborns cannot complete hearing screening before 21 days of age and recommends considering cCMV testing before that point. Because Georgia's rule requires cCMV testing for newborns who fail their final inpatient hearing screening before discharge or 21 days of age, whichever comes first, newborns who remain in intensive care without a completed hearing screen may reach the end of the cCMV diagnostic window before becoming eligible for hearing-targeted testing.

Among confirmed cCMV cases, newborns who passed their NBHS completed diagnostic ABR evaluation within three months of birth at a lower rate (61.3%) than those who failed (80.0%). Anecdotally, program staff encountered instances in which healthcare providers advised families that a passed hearing screening meant no further evaluation was needed, despite a confirmed cCMV diagnosis, reflecting a potential misperception regarding the need for continued evaluation following a cCMV diagnosis. These findings suggest that a hearing-targeted approach does not simply under-identify cCMV; it may also shape provider and family expectations in ways that undermine follow-up even after a case is correctly identified. Programs considering hearing-targeted cCMV screening should weigh this dual effect and consider provider education emphasizing that a normal hearing screen does not rule out cCMV-related hearing loss or other sequelae.

4.5. Notifiable Condition Reporting as the Safety Net

Because Georgia's notifiable condition reporting requires laboratories to report all positive cCMV results to DPH regardless of the reason testing was ordered, cases identified through universal screening or clinical indication entered the same follow-up workflow as those identified through the hearing-targeted pathway. Had cCMV follow-up been triggered only by the hearing-targeted screening rule itself, these additional cases would likely have gone unidentified by DPH entirely.

This has a direct implication for other programs: a hearing-targeted testing requirement alone does not guarantee case capture outside the hearing-targeted pathway, but

pairing it with notifiable-condition reporting does. Programs adopting hearing-targeted cCMV screening should consider notifiable-condition designation not as a separate policy choice but as the mechanism that determines whether cases identified outside the mandated pathway are reported to public health follow-up at all.

4.6. Specimen Type and the Burden of False Positives

Saliva was the most common initial specimen type (68.0%) but, due to its low positive predictive value (48%), it requires confirmatory testing with urine. Roughly half (52%) of the newborns who screen positive by saliva ultimately proved to be false positives, which is a real burden of repeat testing, family anxiety, and follow-up coordination. Because saliva samples collected shortly after breastfeeding can be contaminated with maternal breast milk leading to false-positive results, hospital-level education on proper collection timing, along with encouraging urine testing when feasible, may help reduce this burden. Additionally, this high false-positive rate underscores the importance of clear provider and family communication about what a positive saliva screen does and does not mean, as a screen-positive result is not equivalent to a confirmed diagnosis.

5. Limitations

5.1. Data and Analytic Limitations

This analysis is limited to newborns with a reported positive cCMV result. Because Georgia's surveillance system requires reporting of positive results only, we cannot calculate the true sensitivity or specificity of cCMV screening against the full birth cohort, including newborns who screened negative or were never tested. The positive predictive value reported here reflects only the subset of cases that entered DPH's follow-up workflow, not the performance of cCMV screening as a whole. Additionally, this analysis reflects the program's first 18 months of implementation. Outcomes may shift with improved reporting to DPH, increased provider awareness of cCMV screening, and an increased number of children screened for cCMV. The modest sample size limited statistical power to detect differences between the passed versus failed NBHS groups that may nonetheless be clinically meaningful.

5.2. Diagnostic Window and Specimen Collection

The limited diagnostic window for cCMV presents an inherent challenge for medical follow-up. As demonstrated by the observed screening and reporting intervals, approximately one week of the 21-day diagnostic window may elapse before a positive screening result reaches the Emory STFU, leaving roughly 14 days to obtain a confirmatory specimen. This shortened timeframe leaves little tolerance for additional delays and highlights the importance of rapid result transmission, timely notification, and close case monitoring to ensure that confirmatory testing is completed while congenital infection can still be established.

Unlike DBS newborn screening, which relies on a single centralized state laboratory, cCMV testing in Georgia is decentralized across multiple commercial and hospital-based laboratories using different platforms and specimen types. This decentralization, combined with limited provider familiarity with the distinct role of each test in screening versus diagnostic confirmation, contributed to errors in test ordering and specimen collection. Contributing issues included collection of incorrect specimen types (e.g., blood instead of urine), performance of an incorrect laboratory test despite correct test orders, inappropriate specimen handling, and limited availability of necessary collection supplies (e.g., specimen cups, urine bags). Each of these issues can require repeat specimen collection and additional coordination among Emory STFU, healthcare providers, families, and

laboratories, all of which can contribute to additional delays. Beyond the diagnostic consequences, these delays also place an additional burden on families, for whom repeat visits and time away from home and work can have far-reaching effects.

5.3. Gaps in Reporting

Electronic reporting also introduced the potential for additional delays and, in some instances, the inability to confirm congenital infection within the required timeframe. ELR mapping and file transmission errors resulted in delayed reporting in two excluded cases, preventing the ability to establish a diagnosis of congenital cCMV in one of those cases. All commercial laboratories performing cCMV testing added cCMV to their notifiable conditions list immediately upon the rule's effective date. However, birthing facilities that rely on in-house laboratories for cCMV testing were separately responsible for adding cCMV to their own facility's notifiable conditions list to route results through ELR. We have identified instances in which this step had not yet been completed. Although uncommon, these events point to the importance of ongoing monitoring of electronic reporting processes to ensure timely and reliable data exchange. ELR likely improves the speed and completeness of case reports compared to manual reporting, but it is not fail-proof. Mapping errors and facility reporting gaps still allow individual cases to fall outside the system entirely.

Out-of-state testing represented a disproportionate share of the identified reporting gaps: four of the nine excluded cases were initially tested for cCMV in a state outside of Georgia. These cases were identified only when Georgia's EHDI program encountered them through referrals, family contact, or coordinator follow-up. While this is a small number of cases, the proportion suggests that out-of-state testing may be an underrecognized source of missed cases, warranting attention alongside in-state reporting gaps. However, addressing this gap is complicated by the fact that not all states have adopted cCMV screening requirements, and among those that have, screening criteria, notifiable condition status, and reporting obligations vary. This inconsistency limits the extent to which any single state can rely on receiving positive results from another. Even so, Georgia's experience highlights the importance of establishing protocols with neighboring states or regions with high patient crossflow, to improve notification of positive out-of-state results where possible.

5.4. Separation of Early Intervention Data Systems

Although DPH administers the BCW program, Georgia's Part C EI program, eligibility and enrollment data are tracked in a system separate from SendSS called BIBS. EI records fall under education-record confidentiality protections distinct from the health-record framework governing NBS, EHDI, and cCMV data, so integrating them may not be legally allowable [17]. As a result, EI referral and enrollment outcomes for confirmed cCMV cases required individually querying BIBS for each case (see Section 2.3) rather than the automated, cross-program record used elsewhere in this protocol. This manual step is a challenge worth noting given that EI referral and enrollment are important downstream outcomes for cCMV-confirmed newborns.

5.5. Generalizability

Georgia's experience suggests that implementation of cCMV medical follow-up may be feasible within existing newborn screening infrastructure without development of a separate follow-up system. Programs considering a similar model would first need to evaluate their existing follow-up infrastructure and identify opportunities to incorporate cCMV into established processes for result notification, provider and family outreach, case management, and outcome tracking.

Successful replication requires clearly defined roles and communication pathways among public health programs, NBS follow-up teams, EHDI, EI programs, healthcare providers, and laboratories. Identifying mechanisms for rapid transmission of positive screening results is particularly important given the 21-day diagnostic window. Prioritization of cCMV as a time-sensitive result, frequent case tracking until confirmatory specimen collection is verified, and processes for identifying and addressing laboratory or collection barriers are also important components of the model.

Programs would also need a mechanism for sharing case outcomes across different systems to support continuity from screening and diagnostic confirmation to ongoing hearing surveillance and intervention. Existing infrastructure and organizational structures will vary across jurisdictions. Therefore, specific workflows will require adaptation to the local context. Leveraging established newborn screening and hearing screening workflows, rather than introducing additional systems, may provide a practical framework for coordinated cCMV follow-up across the continuum of care while minimizing the need for additional infrastructure.

6. Conclusions

Georgia's experience demonstrates that hearing-targeted cCMV follow-up can be built into existing newborn screening and EHDI infrastructure without establishing a parallel surveillance or case-management system. Georgia integrated cCMV follow-up into two existing follow-up functions—notifiable disease reporting and NBS medical follow-up—and built a new, audiologist-led hearing surveillance pathway utilizing an existing DPH audiology position. This approach achieved high rates of timely confirmatory testing and diagnostic ABR completion during the program's first 18 months.

These findings also carry a specific policy implication for other states considering hearing-targeted cCMV screening. More than half of Georgia's confirmed cases were identified outside the hearing-targeted pathway and were captured only because cCMV had also been designated a notifiable condition. Hearing-targeted testing requirements alone, the model most commonly adopted nationally, cannot be assumed to identify the majority of cCMV cases. Pairing such a mandate with notifiable-condition reporting is what allowed Georgia's existing infrastructure to function as a safety net for cases identified through individual hospitals' universal screening protocols or clinical indication. States considering hearing-targeted cCMV screening should consider pairing it with notifiable-condition designation.

This early experience also points to several areas for continued study: (1) the full characteristics of hearing loss over time in this cohort, particularly among newborns who had typical hearing on early diagnostic evaluation but remained at risk for late-onset or progressive loss; (2) strategies for reducing gaps in reporting to support more complete case capture; and (3) the relationship between diagnostic follow-up and Part C EI enrollment, given that strong audiologic follow-up in this cohort was not matched by comparably strong EI enrollment.

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Abbreviations

The following abbreviations are used in this manuscript:

AAP	American Academy of Pediatrics
ABR	Auditory Brainstem Response
ACHDNC	Advisory Committee on Heritable Disorders in Newborns and Children
BCW	Babies Can't Wait
BIBS	Babies Information and Billing System
CBC	Complete Blood Count
CCHD	Critical Congenital Heart Disease
cCMV	Congenital Cytomegalovirus
CDC	Centers for Disease Control and Prevention
CMV	Cytomegalovirus
CSTE	Council of State and Territorial Epidemiologists
DBS	Dried Blood Spot
DPH	Georgia Department of Public Health
EBC	Electronic Birth Certificate
EHDI	Early Hearing Detection and Intervention
EI	Early Intervention
ELR	Electronic Laboratory Reporting
Emory STFU	Emory University Newborn Screening Short-Term Follow-Up Program
GPHL	Georgia Public Health Laboratory

HHS	U.S. Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HL7	Health Level Seven
HRSA	Health Resources and Services Administration
IDEA	Individuals with Disabilities Education Act
IgG	Immunoglobulin G
IT	Information Technology
LAMP	Loop-Mediated Isothermal Amplification
NAAT	Nucleic Acid Amplification Test
NBHS	Newborn Hearing Screening
NBS	Newborn (Blood Spot) Screening
NBSAC	Newborn Screening and Genetics Advisory Committee
PCR	Polymerase Chain Reaction
PHIP	Public Health Information Portal
SendSS	State Electronic Notifiable Disease Surveillance System
SNHL	Sensorineural Hearing Loss

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