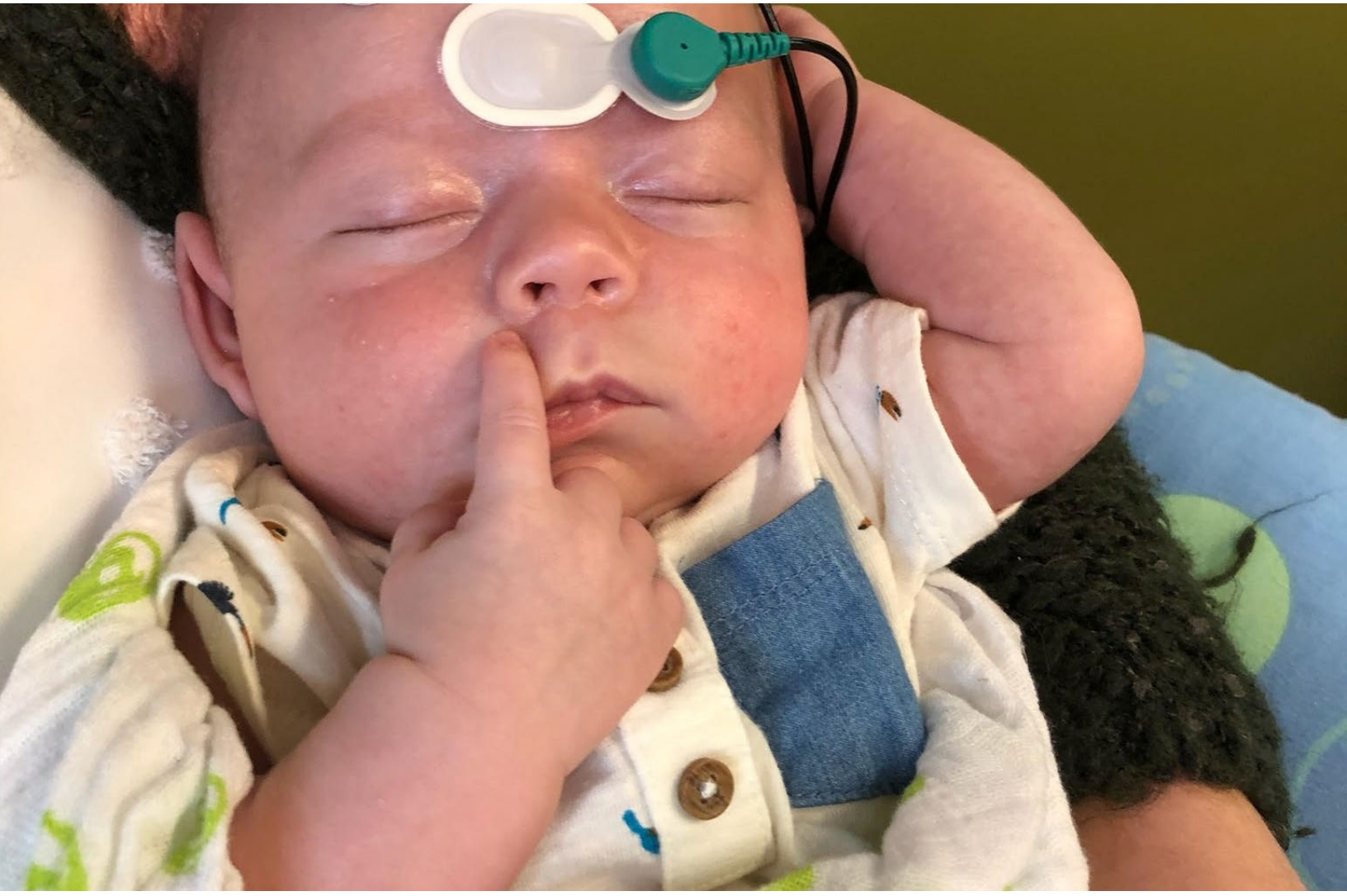
2024

Congenital Cytomegalovirus (cCMV) Policy and Procedure Manual

Guidance for Georgia Birthing Facilities and Medical Providers



GEORGIA DEPARTMENT OF PUBLIC HEALTH

The purpose of this manual is to provide standard policies and procedures for hearing-targeted congenital cytomegalovirus (cCMV) testing for birthing facilities and medical providers to ensure the health and well-being of newborns in Georgia. The manual provides information and tools for healthcare professionals to conduct cCMV testing effectively and efficiently for early detection and intervention of cCMV.

If you have any questions about the information in this manual, please email

DPH-NBS@dph.ga.gov

TABLE OF CONTENTS

SECTION 1. CCMV OVERVIEW

Congenital Cytomegalovirus (cCMV) infection is one of the most common congenital infections in the US, affecting around 3-6 per 1000 live born infants each year. 85-90% of infants with cCMV are born with clinically inapparent infections, and only 10-15% have symptomatic disease with detectable symptoms. These can include:

- Hearing loss
- Microcephaly
- Petechiae
- Hepatosplenomegaly
- Chorioretinitis
- Intrauterine Growth Restriction (IUGR)
- Brain abnormality

Testing newborns for cCMV infection is critical for early detection and prompt diagnosis of related long-term consequences, such as sensorineural hearing loss, retinitis, and neurodevelopmental delays. Early treatment, early intervention, and/or increased developmental monitoring can improve long-term outcomes for these infants.

Congenital CMV is the most common non-hereditary cause of sensorineural hearing loss in children. As part of routine newborn discharge protocols, initial newborn hearing screening should be conducted on all infants per hospital protocol. To ensure that affected infants are identified and receive adequate follow up care, targeted testing for cCMV is to be performed on all infants who fail their hearing screening prior to discharge. It is vital to test for cCMV with urine or saliva within the first 21 days of life to differentiate prenatally-acquired CMV, which can impact long-term development, from a postnatal infection which are usually harmless.

SECTION 2: ACRONYMS

ABR: Auditory Brainstem Response

CBC: Complete Blood Count

CPA: Conditioned Play Audiometry

cCMV: Congenital Cytomegalovirus

DBS: Dried Blood Spot

DPH: Georgia Department of Public Health

EHDI: Hearing Detection and Intervention

HCP: Healthcare Provider

HUS: Head Ultrasound

LAMP: Loop-Mediated Isothermal Amplification

NBS: Newborn Screening

NICU: Neonatal Intensive Care Unit

PCP: Primary Care Physician

PCR: Polymerase Chain Reaction

SendSS: State Electronic Notifiable Disease Surveillance System

SOP: Standard Operating Procedure

VRA: Visual Reinforcement Audiometry

SECTION 3: CCMV PROCESS OVERVIEW

Effective October 10, 2024, the Georgia Department of Public Health Rule 511-5-5-.06 requires that all infants born in Georgia must have their hearing screened unless parents refuse due to religious objection. If an infant does not pass the initial or final inpatient newborn hearing screening, in cases where a second screening is performed, the hospital or birthing center shall conduct cCMV testing before discharge or 21 days of age, whichever occurs earlier.

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

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

cCMV is a notifiable condition for infants ≤21 days of age. All positive results must be reported to DPH within 7 days of result.

HEARING-TARGETED cCMV SCREENING PROCESS MAP

Birthing Facility Responsibilities

SCREEN

All infants who fail/refer their final inpatient hearing screening MUST receive cCMV screening. Infants must be screened prior to 21 days of life or before discharge (whichever comes first).

COLLECT

Collect cCMV Urine PCR or Saliva PCR/LAMP. If saliva is used, wait 1-2 hours after consumption of breastmilk due to possible contamination resulting in false positives.

INFORM

Reporting Requirements at Time of Discharge: Inform parent/s and primary care physician on file in writing prior to discharge of newborn hearing screening results and status of cCMV screening (e.g. pending results, not completed, etc).

Best Practice: Provide parents with a copy of DPH's "Newborn Hearing Screening Results and Recommendation Form" and provide this information in the discharge summary.

REPORT

Reporting Requirements Upon Receipt of Results:

- All results (e.g. negative, positive, contaminated, etc) must be included in the patient's medical record.
- Positive results must be reported to DPH upon receipt so that timely follow-up care can begin.

Best Practice: Also contact the primary care physician on record to provide positive results. This will expedite follow-up.

LAMP: Loop-Mediated Isothermal Amplification
PCR: Polymerase Chain Reaction

For more information visit **www.dph.georgia.gov/EHDI/ccmv**

SECTION 4: HEALTH PROFESSIONAL ROLES AND RESPONSIBILITIES

4.1 Responsibility of the Birthing Facility

- Birthing facilities should designate a physician to oversee the medical aspects of both the newborn hearing screening program and the cCMV hearing-targeted testing program. Additionally, they should assign at least 1-2 employees to be primarily responsible for the hearing-targeted cCMV testing program. These individuals will serve as the main points of contact between the birthing facility and DPH.
- Birthing facilities should evaluate their current hearing screening referral rate to ensure quality hearing screenings are conducted and that infants are not being over-referred for hearing and cCMV testing. A hearing screening refer rate of ≤4% is considered within compliance with national standards. DPH can provide training and resources for hospitals with a high refer rate. Email DPH-NBS@dph.ga.gov to inquire about hearing screening refer rates and hearing screening resources.
- Birthing facilities must establish protocols for comprehensive data collection and recording to maintain data integrity. They should ensure strict quality control measures to meet reporting standards, especially when different staff members are responsible for testing and data entry. It is essential to permanently include testing status information in patients' medical records.
- Birthing facilities must ensure adequate training for all testing personnel to conduct hearing and cCMV testing effectively using recommended methods, and they should also ensure the maintenance of comprehensive training records.
- Birthing facilities must develop facility processes for placing the order for cCMV testing following a failed final hearing screening. Consider adopting a standing order policy to reduce delays and improve compliance.

For infants who fail their final newborn hearing screening or are tested for cCMV for any other reason, the birthing facility must obtain cCMV PCR test prior to discharge and before 21 days of age and complete the following:

1) Inform the parent in writing prior to discharge of their child's newborn hearing screening results and the status of their child's cCMV testing, including the recommendations for follow up.
2) Report the status of cCMV testing (e.g. pending results, not completed) along with any results, as applicable, to the Primary Care Physician (PCP) on file upon discharge. This should be included in the infant's discharge summary.
3) All results of the cCMV test (e.g. negative, positive, inconclusive, contaminated, etc.) must be included in the baby's clinical record.
4) In the event of a positive result on the cCMV test, the provider who completed the test must notify DPH within 7 days (best practice is within 72 hours of result).
5) In the event of an inconclusive or contaminated result after discharge, the provider who completed the test must notify DPH to ensure the child's medical home is informed of the need for a repeat specimen collection.

Birthing facilities must establish internal guidelines for the following:

1) Whether cCMV testing will be ordered after the initial or the second failed hearing screening. Note: cCMV testing must be completed prior to discharge and before 21 days of life.
2) Communication plan to ensure results of hearing screening are communicated to the medical provider responsible for ordering/conducting the cCMV testing
3) Whether a standing order policy is adopted to improve efficiency
4) What type of specimen will be collected (i.e. urine PCR or saliva PCR or LAMP)
5) Where laboratory testing will be completed (e.g. in-house or through an outside laboratory)

NOTE: cCMV testing will not affect discharge as only specimen collection is required prior to discharge, but results are NOT required to be obtained prior to discharge.

4.2 Responsibility of the Hearing Screener

Follow the policies and procedures for newborn hearing screening as outlined in the Newborn Screening Policy and Procedure Manual.

For infants who fail the final (first or second) inpatient hearing screening, ensure the results of the hearing screening are communicated to the medical provider responsible for ordering and/or conducting cCMV testing.

For infants who fail their initial hearing screening in an outpatient setting, ensure the results of the hearing screening are communicated to the medical home with recommendation that cCMV testing needs to be ordered.

Infants who test positive for cCMV must have a diagnostic Auditory Brainstem Response (ABR) evaluation rather than an outpatient hearing re-screen. If the child has not been discharged when a positive cCMV result is obtained, either complete diagnostic Auditory Brainstem Response (ABR) testing inpatient (best practice) or assist family in scheduling an ABR upon discharge.

If cCMV results are not known or if cCMV results are negative, a hearing re-screen should be recommended. Utilize DPH's Newborn Hearing Screening Results and Recommendations Form, as this includes a provider resource map.

4.3 Responsibility of the Medical Home

The primary Healthcare Provider (HCP) should review the hearing screening results and status of cCMV testing provided by the birthing facility to ensure that infants who failed the final inpatient hearing screening have received cCMV testing by 21 days of life. The results and status of these tests should be provided by the birthing facility.

The HCP may also access results of the newborn hearing screening via State Electronic Notification Surveillance System (SendSS) approximately 7-10 days after birth. Authorized providers can access newborn hearing screening results online through SendSS. When registering, request access for "SendSS Newborn: Newborn Testing Results." If you have difficulty obtaining the results, please complete and submit the Authorization for Release of Newborn Testing Report form to DPH-NBS@dph.ga.gov.

The "pediatrician after discharge" (primary HCP) listed on the NBS Dried Blood Spot (DBS) card at the time of delivery will be contacted by the state-designated follow-up program for infants with a reported positive cCMV result. DPH's designated follow-up program, Emory Newborn Screening Follow Up Program, will provide the provider on record with education, next steps, and assistance with referral coordination on all positive cases of cCMV reported to DPH prior to 21 days of life.

The HCP is responsible for contacting the family to arrange diagnostic testing and follow-up as indicated. If the infant is seeing a primary HCP that is not listed on the NBS DBS card, the family must inform DPH immediately (email DPH-NBS@dph.ga.gov) so the correct provider can be notified.

If the infant did not receive a newborn hearing screening for some reason (e.g. home birth, missed, etc.), the HCP should refer for an outpatient hearing screening prior to 21 days of age and obtain cCMV testing if the child fails that screening.

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

1. **Complete confirmatory testing (Urine PCR)** – Infants who received a positive result via initial saliva PCR or LAMP will need a confirmatory test via urine PCR to confirm diagnosis. This request will be included in the verbal and/or faxed report from the follow-up program.
2. **Complete appropriate referrals and the following tests**– Infants who test positive for cCMV via urine PCR should receive the following referrals and/or tests prior to 30 days of age to evaluate further for evidence/extent of cCMV disease:
    1. Referral to Infectious Disease
    2. Referral to Pediatric Audiology for Diagnostic ABR Evaluation (NOTE: Diagnostic testing is required, as opposed to a screening due to the high risk of hearing loss)
    3. Referral to Otolaryngology
    4. CBC with differential
    5. Liver function panel with Total and Direct (T/D) bilirubin
    6. Pediatric Ophthalmology for dilated retinal exam within 2-3 weeks of life
    7. Head Ultrasound (HUS)

3. **Respond to follow-up program with status of follow-up.** This communication will ensure families receive necessary care.

See Follow-Up Testing and Referral Section for additional information.

For routine questions regarding a positive cCMV case, please call Emory's NBS follow up team at 404-778-8560.
If there are clinical concerns, page genetics at 404-785-7778.

4.4 Responsibility of DPH

DPH will provide educational materials and policy and procedure resources to medical providers regarding the implementation of hearing-targeted cCMV testing, as well as next steps after diagnosis.

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

SECTION 5: SPECIMEN COLLECTION PROCEDURES

NOTE: cCMV testing will not affect discharge as only specimen collection is required prior to discharge, but results are NOT required to be obtained prior to discharge.

As per the Red Book® 2024-2027 Report of the Committee on Infectious Diseases, a urine PCR or saliva test (buccal swab PCR) is recommended for cCMV testing before discharge and/or no later than 21 days of life.

There are two primary cCMV testing options:

1) First-tier testing via **saliva PCR or saliva LAMP:**
    - Often easier to collect than urine

- Will require a confirmatory urine sample if results are positive
- No additional testing is required if negative; cCMV will be ruled out

2) Testing via **urine PCR:**
   - Often harder to collect than saliva
   - Does not require a catheterized specimen
   - Does not require a second cCMV test if results are positive
   - No additional testing is required if negative; cCMV will be ruled out

5.1 Saliva Collection Procedures:

These are general guidelines. Follow instructions provided by the specific test kit you are utilizing.

The saliva test can be used as a first-tier screen. Positive results from a saliva test require confirmatory urine PCR.

1) Confirm the baby has not breastfed within the last 1-2 hours. There is no wait time if the infant is formula-fed. For simplification, consider waiting 1-2 hours independent of the mode of feeding.
2) Insert a sterile cotton or polyester swab (do not use calcium alginate swab or wood shafted swab) into the baby's mouth between the gums and cheek and swirl for 10 seconds or until it is saturated with saliva.
3) Remove the swab and place it into the test tube containing 1 to 3 mL of Universal Transport Media (UTM).
4) Follow instructions regarding storage and transit times provided by the specific test kit you are utilizing. See laboratories that complete cCMV testing for more information.

5.2 Urine Collection Procedures:

These are general guidelines. Follow instructions provided by the specific test kit you are utilizing.

Sterile urine bag collection method is the recommended method of collection. NOTE: The urine collection DOES NOT REQUIRE catheterization.

1) Clean the genital area with water. Pat dry with a clean towel or gauze.
2) Place the urine bag on the baby.
3) Work with birth parent to monitor the urine bag from time to time to ensure that it stays in place to avoid any possible contamination as it may take some time for a specimen to be collected.
4) Gently remove the urine bag and pour the sample into a sterile urine cup.
5) Follow instructions regarding storage and transit times provided by the specific test kit you are utilizing. See laboratories that complete cCMV testing for more information.

SECTION 6: REPORTING REQUIREMENTS

In the event of a positive result on the cCMV test, the provider who completed the test must notify DPH within 7 days of receipt (best practice is within 72 hours of result). There are a few reporting options:

1. Report via SendSS Notifiable Condition Case Reporting - See SendSS Notifiable Condition Reporting – cCMV Overview for more information on setting up an account and entering case reports.
2. Ensure your facility's lab is sharing cCMV results with DPH via Electronic Lab Reporting (ELR) – Email DPH-NBS@dph.ga.gov to confirm if DPH is receiving ELRs from your facility's labs.
3. Fax completed cCMV Laboratory Case Report to (404) 657-2773 or email to DPH-NBS@dph.ga.gov.

It is best practice for the provider who completed the test also notify the patient's provider on record of the positive result so they can facilitate time-sensitive next steps.

Please provide DPH's contact information (DPH-NBS@dph.ga.gov) in case the HCP has management questions.

Once DPH is notified of the positive cCMV result, DPH's designated follow-up program will contact the child's provider on record to share results and provide next steps. See follow-up testing and referral procedures below.

Congenital Cytomegalovirus (cCMV) Laboratory Case Report Form

Instructions: All cCMV-positive laboratory results collected from infants <21 days of age must be reported to DPH within 7 days of the result. Submit this form to the Georgia Newborn Screening Program by faxing to (404) 657-2773 or email to DPH-NBS@dph.ga.gov

CHILD INFORMATION

Child's Name (Last)	(First)		**Date of Birth:** / / {MM/DD/YYYY}
Address	**City**	**State**	**ZIP**
Mother's Name (First and Last)	**Phone Number**		
Race: ☐ Asian/Polynesian ☐ Native Am/Alaskan ☐ Black ☐ White ☐ Multiracial ☐ Unknown	**Ethnicity:** ☐ Not Hispanic ☐ Hispanic ☐ Unknown	**Primary Language:** ☐ English ☐ Other _____	**Sex:** ☐ Male ☐ Female ☐ Other
Primary Care Physician (PCP) Name (First and Last)	**PCP Address** (Street, City, State, and ZIP)		**PCP Phone Number** **PCP Fax Number**
Multiple Birth? ☐ No ☐ Yes *If Yes, which order (e.g. 1,2,3):* _____	**Child's Birthing Facility:**	**Form/ Kit #** (if known) *Located on the NBS card*	**Is Child Currently Hospitalized?** ☐ Yes ☐ No ☐ Unknown

REPORTER INFORMATION

Reporter Name (First and Last)	**Reporting Facility**	**Reporter Phone Number**
Date of Report: / / {MM/DD/YYYY}		

TEST INFORMATION

Specimen Source ☐ Saliva ☐ Urine ☐ Other: _____	**Date of Specimen Collection** / / {MM/DD/YYYY}	**Specimen ID** (if known):
Test Type ☐ PCR ☐ LAMP ☐ Other: _____	**Laboratory Name**	**Test Result** ☐ Positive ☐ Negative ☐ Inconclusive. *If selected, indicate reason:*_____ ☐ Other: _____
Comments:		

SendSS ID: _____ *(Internal Use Only)*

Updated 8/24/2024

SECTION 7: FOLLOW-UP TESTING AND REFERRAL PROCEDURES

Negative saliva or urine result:

- No further cCMV testing is needed. cCMV has been ruled out.
- Refer for hearing re-testing or diagnostic ABR testing right away (if the infant also failed an outpatient hearing screening) as the infant still requires hearing follow-up testing.

Positive first-tier saliva result:

- Inform DPH of positive result
- This suggests possible congenital CMV; however, due to the possibility of false positive saliva from breastmilk contamination, testing with urine PCR is necessary to confirm.
- Ensure baby receives urine cCMV PCR prior to 21 days of life.
- Refer to a Pediatric Audiologist who is trained in diagnostic ABR testing. Infants who test positive for cCMV must have a diagnostic ABR evaluation rather than an outpatient hearing screen.

Positive urine result:

- No further cCMV testing is needed. cCMV has been confirmed.
- Complete the following before 30 days of age to evaluate further for evidence/extent of cCMV disease:
    - Refer to Pediatric Infectious Disease Physician
    - Refer to Pediatric Ophthalmology for dilated retinal exam
    - Refer to Pediatric Audiology for diagnostic Auditory Brainstem (ABR) Evaluation (hearing test)
    - Complete the following tests:
        - Complete Blood Count (CBC) with differential
        - Liver function panel with T/D bilirubin
        - Head Ultrasound (HUS)
- Long-term Monitoring:
    - Refer to Early Intervention (Babies Can't Wait). cCMV diagnosis automatically qualifies for enrollment.
    - Monitor speech, language, and other developmental milestones
    - Follow-up with Pediatric Audiologist for repeated hearing testing at least every 6 months until age 3, then annually until

age 10. See Section 9.2 Audiovestibular Monitoring Protocol for additional information.

- Routine vision testing

Inconclusive, Contaminated, or Missed result:

- Ensure infant receives urine PCR prior to 21 days of life.
- Refer for hearing re-screening or diagnostic ABR testing right away (if the infant also failed an outpatient hearing screening) as the infant still requires hearing follow-up testing.

CLINICAL ASSESSMENT AND MANAGEMENT

of Congenital Cytomegalovirus (cCMV) Flow Sheet

If Positive Saliva CMV PCR*:

- Send Urine CMV PCR before 21 days of age (Qualitative PCR will suffice)
- Consider consulting Infectious Disease Specialist

*Saliva Loop-Mediated Isothermal Amplification (LAMP) is also an acceptable test

↓

If Positive Urine CMV PCR:

PERFORM ALL THE FOLLOWING TESTS AND REFERRALS BEFORE 30 DAYS OF AGE TO EVALUATE FURTHER FOR EVIDENCE/EXTENT OF CCMV DISEASE:

- CBC with differential
- Liver function panel with T/D bilirubin
- Head Ultrasound (HUS)
- Pediatric Ophthalmology for dilated retinal exam within 3 wks of life
- Otolaryngology
- Consider ID Consultation
- Pediatric Audiology for Diagnostic Auditory Brainstem (ABR) Evaluation (hearing test)

↓ ↓ ↓

ASYMPTOMATIC if all of the following:

- Normal ophthalmology exam
- Normal ABR
- Normal HUS
- Normal platelet count
- No hepatosplenomegaly
- Normal liver function

↓

Refer to Audiology for routine diagnostic audiological testing by 3 months of age.

Recommended Hearing Testing Intervals:

- Every 3 months until 12 months of age.
- Every 6 months until 3 years of age.
- Every year thereafter.

→ **Long Term Monitoring:**

- Routine vision screening
- Monitor speech, language, and other developmental milestones.
- Referral to DPH for enrollment in Babies Can't Wait

Isolated Sensorineural Hearing Loss

COMPLETE THE FOLLOWING BEFORE 30 DAYS OF AGE.

- Refer to Infectious Disease

SYMPTOMATIC if ≥ 1 of the following:

- Thrombocytopenia
- Hepatomegaly
- Splenomegaly
- Intrauterine Growth Restriction (IUGR) or Small for Gestational Age (SGA)
- Microcephaly
- Abnormal HUS
- Hepatitis
- Sensorineural Hearing Loss

For more information visit **www.dph.georgia.gov/EHDI/ccmv**

References:

Park AH. Outcomes from an Expand-ed Targeted Early Cytomegalovirus Testing Program. J Ped Infect Dis. (2020) 15(04): 189-194 DOI: 10.1055/ s-0040-1709159.

This form was adapted with permission from the Virginia Department of Health.

SECTION 8: SPECIAL POPULATIONS

8.1: Neonatal Intensive Care Unit (NICU) Patients and Hospital Transfers

If an infant is transferred to another hospital or birthing center before the newborn hearing screening has been completed, then it is the responsibility of the second facility to assure that a newborn hearing screening and cCMV test are completed as indicated above. The transferring hospital must provide status of hearing and cCMV testing to the second facility upon transfer.

In special populations of newborns where newborn hearing screening cannot be accomplished before 21 days of age, testing for cCMV is left to the discretion of the medical practitioner caring for the newborn. If the infant has failed final newborn hearing screening after 21 days of life or has other risk factors of cCMV, consider consulting with Pediatric Infectious Disease Specialist to discuss next steps. Birthing facilities may determine it is advantageous to complete cCMV screening on NICU patients at risk of cCMV prior to completing their newborn hearing screening if the patient will be over 21 days of age at the time of hearing screening. The same recommendations for follow-up testing and monitoring listed in this policy and procedure manual should be followed if they test positive for cCMV.

In cases where newborn hearing screening cannot be completed before 21 days of age due to gestational age or medical instability, the decision to test for congenital CMV (cCMV) prior to a failed hearing screening is left to the discretion of the birthing facility and medical provider. Birthing facilities must determine whether to include cCMV testing for NICU babies at risk of cCMV. Birthing facilities may find it beneficial to conduct cCMV screening on NICU patients at risk for cCMV before completing their newborn hearing screening if the patient will be over 21 days old at the time of the hearing screening.

If an infant fails the final newborn hearing screening after 21 days of life or has other risk factors for cCMV, consider consulting with a Pediatric Infectious Disease Specialist to discuss the next steps.

8.2 Missed Hearing Screenings

If an infant did not receive a newborn hearing screening prior to discharge for some reason (e.g. home birth, missed, etc.), the HCP should refer for an outpatient hearing screening prior to 21 days of age and follow procedures outlined in this document based on those results.

8.3 Multiple Births

It is possible for one infant to be infected and the other may or may not be infected. However, if one infant test positive, the other infant/s are at a higher likelihood of also being infected, even if they pass their newborn hearing screening. Therefore, if one twin tests positive for cCMV, it is recommended to screen the other twin.

8.4 cCMV Testing Refusal

cCMV testing does not require parental consent; however, parents may refuse the cCMV test. Birthing facilities must obtain a signed refusal form at the time of screening and forward the completed form to DPH by faxing to (404) 657-2773 or email to DPH-NBS@dph.ga.gov. This form shall be retained in the child's medical record for the period of time defined by the hospital or provider policy.

SECTION 9: RESOURCES

9.1 Laboratories that Complete cCMV Testing

Many laboratories currently offer PCR or LAMP-based cCMV testing. Testing should be performed on urine or saliva, not blood. Each facility should submit specimens through their standard laboratory-testing process. NOTE: This list is meant to provide a general overview of options and is not exhaustive. Please follow collection and stability procedures as provided by the test kit.

Note: Urine collection will require the use of sterile urine collection bags.

ARUP https://www.aruplab.com/testing 800-522-2787	
Specimen Type: Saliva	
Test Name	Cytomegalovirus by Qualitative PCR, Saliva / CMVPCR SAL
Test Code	2008555
Specimen Collection	Collect and submit saliva in ORACollect OC-100 kit (ARUP supply #49295)
Stability of Specimen	Ambient: 7 days; Refrigerated: 7 days; Frozen: 3 months
Result Time	2-5 days
LOINC	83065-3 (cCMV PCR, Saliva) / 31208-2 (CMV PCR Source)
OraCollect OC-100 Saliva Collection Training Video: https://www.youtube.com/watch?v=XMdDeusQ_IY	
Specimen Type: Urine	
Test Name	Cytomegalovirus by Qualitative PCR (CMV PCR)
Test Code	0060040
Specimen Collection	Collect and submit 1 mL urine. Sterile urine container, no preservative.
Stability of Collection	Ambient: 8 hrs; Refrigerated: 72 hrs; Frozen 3 months
Result Time	2-5 days
LOINC	5000-5 (CMV DNA) / 31208-2 ('Specimen Source')

LabCorp https://www.labcorp.com/test-menu	
Specimen Type: Saliva	
Test Name	CMV Congenital Qualitative PCR, Saliva Swab
Test Code	139865
Specimen Collection	Saliva collected using a synthetic swab and placed in Universal Transport Media. Preferred collection kit is the "Copan UTM-RT, PeopleSoft No. 24674)

Stability of Specimen	Refrigerated swabs are stable for 7 days. Frozen swabs are stable for 14 days (-20°C).
Result Time	3 days
LOINC	83065-3
Specimen Type: Urine	
Test Name	CMV Qualitative PCR (CMV PCR)
Test Code	138693
Specimen Collection	Collect and submit in a sterile container, volume 0.5 mL, minimum 0.2 mL
Stability of Collection	Refrigerated or frozen, stable for 7 days
Result Time	Varies by lab; 3-4 days
LOINC	5000-5
Specimen Type: Urine	
Test Name	CMV Qualitative PCR (CMV PCR)
Test Code	139840
Specimen Collection	Collect and submit in a sterile container, volume 0.5 mL, minimum 0.2 mL
Stability of Collection	Frozen only; stable for 3 days (-20C)
Result Time	Varies by lab; 3-4 days
Causes for Rejection	Patients <21 days old
LOINC	4999-9
Specimen Type: Urine	
Test Name	Cytomegalovirus (CMV), Quantitative, Urine, PCR
Test Code	139144
Specimen Collection	Collect and submit in a sterile container, minimum 0.5 mL
Stability of Collection	Refrigerated or frozen, stable for 7 days
Result Time	Varies by lab; 3-4 days
Causes for Rejection	Patients <21 days old
LOINC	49347-8 and 53763-9

Mayo https://www.mayocliniclabs.com/test-catalog	
Specimen Type: Saliva	
Test Name	Congenital Cytomegalovirus (cCMV), Molecular Detection, PCR, Saliva
Test Code	CCMVS

Specimen Collection	Collect and send specimen per swab manufacturer instructions. Supplies needed: BD UVT with minitip flocked swab (T971)
Stability of Specimen	Frozen swabs are stable for 7 days.
Result Time	1-3 days
LOINC	83065-3
Specimen Type: Urine	
Test Name	**CCMVU / Congenital Cytomegalovirus (cCMV)**
Test Code	**CCMVU**
Specimen Collection	Collect and submit in a sterile container, volume 1 mL, minimum volume 0.1 mL. Supplies needed: Sarstedt Aliquot Tube, 5 mL (T914)
Stability of Collection	Ambient: Not stable; Refrigerated or frozen, stable for 7 days
LOINC	4999-9
Specimen Type: Urine	
Test Name	Cytomegalovirus (CMV) Molecular Detection, PCR, Varies
Test Code	CMVPV
Specimen Collection	Collect and submit in a sterile container, volume 1 mL, minimum volume 0.3 mL. Supplies needed: Sarstedt Aliquot Tube, 5mL (T914)
Stability of Collection	Ambient: Not stable; Refrigerated or frozen, stable for 7 days
Result Time	1-3 days
LOINC	5000-5 (CMV DNA) / 31208-2 ('Specimen Source')

Quest https://questdiagnostics.com	
Specimen Type: Saliva	
Test Name	Cytomegalovirus DNA, Qualitative Real-Time PCR, Saliva
Test Code	37010
Specimen Collection	Saliva collected in an ORACollection OCDC-100 collection device

Stability of Specimen	Ambient: 48 hours; Refrigerated: 14 days; Frozen: 30 days
Result Time	Unknown
LOINC	83065-3
Specimen Type: Saliva	
Test Name	Cytomegalovirus DNA, Quantitative Real-Time PCR, Saliva
Test Code	37017
Specimen Collection	Saliva collected in an ORACollection OCDC-100 collection device
Stability of Specimen	Ambient: 48 hours; Refrigerated: 14 days; Frozen: 30 days
Result Time	Unknown
LOINC	33006-8, 34720-3 and 96396-7
Specimen Type: Urine	
Test Name	Cytomegalovirus DNA, Qualitative, Real-Time PCR
Test Code	10601
Specimen Collection	Collect and submit in a sterile container, volume 1 mL, minimum volume 0.5 mL
Stability of Collection	Ambient: 48 hours; Refrigerated: 8 days; Frozen: 30 days
Result Time	Unknown
LOINC	5000-5 (CMV DNA) / 31208-2 ('Specimen Source')

Eurofins Viracor https://www.eurofins-viracor.com/our-testing/cmv/	
Specimen Type: Saliva	
Test Name	Cytomegalovirus (CMV) Saliva Real-Time PCR
Test Code	5571
Specimen Collection	Collect and submit swab in provided tube of 1 to 3 mL of Universal Transport Media (UTM)
Stability of Specimen	Ambient: 48 hours; Refrigerated or Frozen: 7 days
Result Time	Unknown
Specimen Type: Urine	
Test Name	Cytomegalovirus (CMV) Quantitative PCR

Test Code	5502
Specimen Collection	Collect and submit in a sterile container, volume 2 mL, minimum volume 0.8 mL
Stability of Collection	Ambient: Not stable; Refrigerated: 3 days; Frozen: 30 days (-80C)
Result Time	Unknown

Alethia CMV Assay (Loop-Mediated Isothermal Amplification, LAMP) https://www.meridianbioscience.com/diagnostics/disease-areas/pediatric-neonatal/cmv/alethia-cmv/?country=US%23product-info#support-documents	
Specimen Type: Saliva	
Test Name	Alethia CMV DNA
Test Code	481325
Specimen Collection	Collect and submit swab in provided tube of Universal Transport Media (UTM)
Stability of Specimen	Ambient: 48 hours; Refrigerated: 7 days; Frozen: 14 days
Result Time	<60 minutes

9.2 Audiovestibular Monitoring Protocol

Recommended Audiologic and Vestibular Monitoring Protocol for Children with Congenital Cytomegalovirus (cCMV)

Children diagnosed with cCMV require comprehensive monitoring for hearing and vestibular changes due to the progressive nature of the virus's impact on these systems. This protocol outlines the recommended audiologic and vestibular monitoring procedures, referral pathways, and management strategies to ensure timely interventions. It also emphasizes the importance of early intervention services and parental education to support optimal outcomes for children with cCMV.

1. Audiologic Monitoring:
Developmentally Appropriate Testing: Audiologic evaluations should be suited to the child's age and developmental abilities. Testing may include:

- Diagnostic Auditory Brainstem Response (ABR), to include high-intensity click and tone burst threshold testing
- Visual Reinforcement Audiometry (VRA)
- Conditioned Play Audiometry (CPA)
- Otoacoustic Emissions (OAEs)
- Acoustic Reflexes
- Tympanometry

Ear-Specific Testing: Always perform ear-specific testing at regular intervals, with adjustments based on the child's clinical status. More frequent testing should be considered if a change in hearing is detected.

Unilateral Hearing Loss Monitoring: Both ears should be monitored following the same protocols, as unilateral hearing loss often progresses to bilateral hearing loss in cases of congenital cytomegalovirus (cCMV). The poorer hearing ear is likely to decline faster.

2. Vestibular Monitoring:
Screening Protocol: Vestibular screening should be included at each audiologic diagnostic visit to assess the vestibular system's health. For younger children, developmental checklists may be used to screen vestibular function.

Specialist Referral: If there is a concern regarding vestibular function, refer to appropriate specialists, such as:

- Audiologist for detailed vestibular evaluation
- Ear, Nose, and Throat (ENT) provider
- Physical therapist

3. Ear, Nose, and Throat (ENT) Referral:
Children diagnosed with any form of hearing loss, whether permanent or transient, and/or vestibular concern should be referred to an ENT provider for further medical assessment.

4. Early Intervention Services:
All children diagnosed with cCMV qualify for Babies Can't Wait services whether they have a diagnosed permanent hearing loss or not. Refer the child for early intervention services using SendSS for newly identified permanent hearing loss or via the Children 1st Referral Form, submitted to the local health district Children 1st Coordinator.

5. Audiologic Management Recommendations for Children with Confirmed cCMV and Hearing Loss:
Amplification Management: Children should be fit with hearing aids that are adaptable to changes in hearing status. Audiologists may choose devices with a wider fitting range to accommodate potential worsening of hearing over time.

Cochlear Implant Consideration: For children with confirmed sensorineural hearing loss, cochlear implants should be evaluated based on their pure tone audiometry and word recognition capabilities.

6. Parent Education:
Understanding Hearing Status: Parents should be fully informed about their child's hearing status and educated on the possibility of changes as their child grows.

Home Monitoring: Parents should be vigilant in noticing any changes in their child's hearing between appointments and should request an earlier evaluation if concerns arise.

Ongoing Monitoring After Age 10: Even if a child does not show hearing loss by age 10, parents should continue to monitor hearing, especially if the child has tested positive for cCMV.

Audiological and Vestibular Testing Recommendations for Children with Confirmed or Presumed cCMV

NOTE: The below recommendations are for all children who are cCMV+, regardless of passed newborn hearing screening (NBHS) status.

Initial Evaluation	**Diagnostic Hearing Evaluation by 3 months of age.** Recommend diagnostic auditory brainstem response (ABR) testing (and additional tests, such as tympanometry and Otoacoustic Emissions (OAEs) take place within 1 month of confirmation of cCMV.

0 months – 12 months of age	**Diagnostic Hearing Evaluation every 3-6 months** Recommend second evaluation by 4-5 months of age. **Vestibular Function Screening** Consider using CDC's Milestone Checklist or Ages and Stages Questionnaire to monitor child's motor milestones. Encourage families to download CDC's Milestone Tracker App to monitor themselves.	
1-3 years of age	**Diagnostic Hearing Evaluation every 6 months** **Vestibular Function Screening** Consider using CDC's Milestone Checklist or Ages and Stages Questionnaire to monitor child's motor milestones. Encourage families to download CDC's Milestone Tracker App to monitor themselves.	
3-10 years of age	**Diagnostic Hearing Evaluation every 12 months** **Vestibular Function Screening** Consider using Single Leg Stance Screen* (ages 3+) or Pediatric Dizziness Handicap Inventory for Caregivers (DHI-PC) (ages 5+)	
10+ years of age	**If no signs of hearing loss are present**, annual evaluations can stop at recommendation of managing audiologist. Parents should be educated to schedule an additional evaluation if there are concerns of hearing loss after 10 years of age.	If **diagnosed with hearing loss,** complete Diagnostic Hearing Evaluation every 12 months **Vestibular Function Screening** Consider using Single Leg Stance Screen* or Pediatric Dizziness Handicap Inventory for Caregivers (DHI-PC).

*Single Leg Stance Screen: Complete on stable ground with eyes open and hands on hips. 36 months=2 sec, 42 months=4 seconds, 48 months=6 seconds, 54 months=8 seconds, 60 months=10 seconds, 72 months=12 seconds, 7 years=15 seconds, 9 years=30 seconds

Helpful Resources:

Centers for Disease Control and Prevention Milestone Checklist

Centers for Disease Control and Prevention Milestone Tracker App

Referral to Department of Public Health Child Health Programs (Babies Can't Wait, etc)

Vanderbilt Pediatric Dizziness Handicap Inventory (DHI-PC) (Age 5-12)

Part II: Vestibular Assessment for Children - Vestibular Disorders Association

Ages and Stages Questionnaire

National CMV Foundation "Congenital CMV: Support and Next Steps"

References:

American Academy of Audiology. (2023). *Position statement on early identification of cytomegalovirus in newborns*. https://www.audiology.org/wp-content/uploads/2023/03/American-Academy-of-Audiology-CMV-Position-Statement.pdf

Condon, C., & Cremin, K. (2013). Static balance norms in children. *Physiotherapy Research International, 19*(1), 1–7. https://doi.org/10.1002/pri.1549

Minnesota Department of Health. (n.d.). *Audiology guidelines for infants with congenital cytomegalovirus (cCMV)*. https://www.health.state.mn.us/docs/people/childrenyouth/improveehdi/audiogdlnccmv.pdf

Zumbrunn, T., MacWilliams, B. A., & Johnson, B. A. (2011). Evaluation of a single leg stance balance test in children. *Gait & Posture, 34*(2), 174-177. https://doi.org/10.1016/j.gaitpost.2011.04.005

Authors: Sarah Jones, Au.D., Darby Hightower, Au.D., Margaret Butler Gipson, Au.D., Alison Morrison, Au.D., Melanie Morris, Au.D.

SECTION 10: APPENDICES

10.1 Contact Information

Georgia Newborn Screening Program – *Protocol and reporting questions*
200 Piedmont Avenue, SE
West Tower, Suite 1502
Atlanta, Georgia 30334
Email: DPH-NBS@dph.ga.gov
Fax: (404) 657-2773
Webpage: www.dph.ga.gov/NBS

Emory Newborn Screening Follow Up Program – *Clinical follow-up questions*

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

10.2 GA Rules and Regulations Rule 511-5-5-.06 Hearing Screening and Rule 511-5-5-.08 Abnormal Test Results

https://rules.sos.ga.gov/gac/511-5-5

10.3 Helpful Resources

National Center for Hearing Assessment and Management (NCHAM) pre-recorded Congenital CMV Research and innovations Webinar Series

Georgia Department of Public Health cCMV Landing Page

National CMV Foundation

Georgia Mobile Audiology Find an Audiologist Map

SendSS Notifiable Condition Reporting – cCMV Overview

cCMV Policy and Procedure Overview Powerpoint Slides

10.4 Acknowledgements and Contributors

This cCMV Policy and Procedure Manual was developed through the combined efforts of a team of over 25 specialists from various fields. Their diverse expertise and dedication were instrumental in crafting a document that is both comprehensive and actionable. We extend our deepest gratitude to all who contributed their time, knowledge, and passion to this project.

Key contributors include:

Ingrid Camelo, MD, FAAP, MPH

Deepa Ranganathan, MD, MPH

Frank Berkowitz, MBBCh, MPH

Tom Adamkiewicz, MD

Lindsay Sternad, MD, MPH

Paula Harmon, MD, MBA, FACS, FAAP

Nandini Govil, MD, MPH

Kristan Alfonso, MD

Sharon Quary, MS

Fozia Khan Eskew, BA

Jessica Ashley, APRN, FNP-C

Melanie Morris, Au.D.

Sarah Jones, Au.D.

Suzanne Caruthers, M.A.

Darby Hightower, Au.D.

Margaret Butler Gipson, Au.D.

Brandt Culpepper, Ph.D.

Jose Rodriguez-Torres, MD

Megan Pesch, MD, MS

Jason Boyce, BSN, RN

Stephen Dryanksi, Au.D.

Eric Berg, MD

Eric Appelbaum, MD

Geoffrey Aaron, MD

Brian Wakeman, Ph.D., MS

10.5 REFERENCES

Ross, S. A., Ahmed, A., Palmer, A. L., Michaels, M. G., Sánchez, P. J., Stewart, A., Bernstein, D. I., Feja, K., Novak, Z., Fowler, K. B., Boppana, S. B., & National Institute on Deafness and Other Communication Disorders CHIMES Study (2015). Urine Collection Method for the Diagnosis of Congenital Cytomegalovirus Infection. *The Pediatric infectious disease journal*, *34*(8), 903–905. https://doi.org/10.1097/INF.0000000000000757

Council of State and Territorial Epidemiologists (CSTE). (2023). Standardized Surveillance Case Definitions for Congenital Cytomegalovirus (cCMV) Infection and Disease: A position statement from the Council of State and Territorial Epidemiologists. https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/ps_2023/23-ID-02_cCMV.pdf

Virginia Department of Health. (n.d.). Resources for professionals: Early Hearing Detection and Intervention (EHDI). Virginia Department of Health. https://www.vdh.virginia.gov/early-hearing-detection-and-intervention/resources-for-professionals/

Utah Department of Health and Human Services. (n.d.). Congenital Cytomegalovirus (CMV) resources. Utah Department of Health and Human Services. https://familyhealth.utah.gov/cshcn/cmv/

American Academy of Pediatrics (AAP). (2021). Cytomegalovirus infection. In Red Book: 2021–2024 Report of the Committee on Infectious Diseases (32nd ed.). https://publications.aap.org/redbook/book/347/chapter-abstract/5751423/Cytomegalovirus-Infection?redirectedFrom=fulltext


DPH
GEORGIA DEPARTMENT OF PUBLIC HEALTH