



**Early Hearing Detection
and Intervention Program**

Congenital Cytomegalovirus Screening

Frequently Asked Questions

September 2023



Congenital Cytomegalovirus (cCMV) Screening Frequently Asked Questions

GENERAL

Question 1: *Where can I find general recommendations for implementing targeted cCMV screening?*

The [cCMV Screening Guidelines](https://floridanewbornscreening.com/), published in November 2022, are available to view and download on <https://floridanewbornscreening.com/>.

LEGISLATION

Question 2: *Is cCMV screening state-mandated just like the newborn hearing screening?*

Per [section 383.145, Florida Statutes](#), hospitals that provide maternity and newborn care are required to conduct cCMV screening prior to discharge for newborns who fail the newborn hearing screening. Birthing centers are required to refer newborns for a hearing screening prior to discharge and home birth providers are required to refer newborns for a hearing screening within seven days of birth. Primary care providers (PCP) are required to refer newborns born at birthing centers and at home who fail an initial outpatient hearing screening for a cCMV screening.

Question 3: *What are the reporting requirements for cCMV screening?*

Per [section 383.145, F.S.](#), results of newborn hearing loss screening, cCMV screening, and any related diagnostic testing, must be reported to the Florida Newborn Hearing Screening (NBHS) Program within seven days after receipt of such results.

SCREENING

Question 4: *What kind of cCMV test can we use?*

Each facility is responsible for selecting the cCMV test that will be used. Per [section 383.145, F.S.](#), a test approved by the U.S. Food and Drug Administration (FDA) or another diagnostically equivalent test can be used to test for cCMV. FDA approved tests can be found using the Clinical Laboratory Improvement Amendments search database at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>.

Question 5: *Should a facility screen a newborn for cCMV after failure of the first (initial) hearing screening or the second (repeat) hearing screening?*

[Section 383.145, F.S.](#), requires hospitals to complete a cCMV screening when a newborn is being discharged with a failed hearing screening, whether it be the first or second inpatient hearing screening. Each facility is responsible for creating a protocol for cCMV screening, including which inpatient hearing screening will trigger cCMV screening.

Examples of screening flows have been provided in the cCMV Guidelines.

- Page 6 of the guidelines is a screening flow designed for facilities who choose to use the initial inpatient screening as the trigger for a cCMV screening.
- Page 7 of the guidelines is a screening flow designed for facilities who choose to use the repeat inpatient screening as the trigger for a cCMV screening.

Question 6: *Is a cCMV screening required for newborns who have not had a hearing screening prior to discharge or within 21 days of birth and remain inpatient (e.g., very low birthweight infants)?*

Hospitals are not required to conduct a cCMV screening for newborns who have not had a hearing screening prior to discharge or within 21 days of birth and remain inpatient. Facilities should consider completing cCMV screening for newborns with prolonged neonatal intensive care (NICU) stays, especially low birthweight infants. cCMV positive very low birthweight infants have significantly higher rates of sensorineural hearing loss, abnormal neuroimaging, and poor motor outcomes when compared with cCMV negative very low birthweight infants.

Question 7: *Are hospitals required to complete a cCMV screening for newborns with an ear-related malformation (microtia, atresia, cleft palate) that prevents hearing screening in one or both ears?*

Yes, a cCMV screening is required for newborns with ear-related malformations. Infants with ear-related malformations are considered to have failed the hearing screening during the visual inspection portion of the hearing screening.

Question 8: *What should be done when a cCMV screening comes back inconclusive?*

If a newborn is still inpatient when a cCMV screening comes back inconclusive, it is recommended that the facility retest the infant. If the newborn has been discharged when the result comes back inconclusive, it is recommended that the facility inform the PCP of the need for a retest or bring the newborn back for an outpatient retest. All cCMV screenings must be completed prior to 21 days of age to determine if the newborn acquired the virus during pregnancy.

Question 9: *Is cCMV screening required if the parents opt out of the hearing screen?*

Legislation does not require hospitals to screen for cCMV if a parent opts-out of a hearing screening on behalf of their newborn. However, each facility should develop procedures to address the circumstance.

Question 10: *Since hearing and cCMV screening are required, are there repercussions for parents who decline?*

[Section 383.145\(3\)\(c\), F.S.](#), allows the parent or legal guardian of a newborn to decline the hearing screening. Per [Florida Guidelines for Newborn Hearing Screening](#), a parent who declines the hearing screening should be provided with educational materials regarding hearing loss and potential delays in speech and oral language milestones. Additionally, the parent must sign a document that confirms their decline, which will be included in the infant's medical record, and the hearing screening should be reported as a refusal to the NBHS Program.

Question 11: *Should a newborn remain inpatient until the results of the cCMV testing are confirmed?*

Delaying discharge solely to wait for the cCMV screening results is not recommended.

Question 12: *When a saliva cCMV specimen is positive, is a urine test required?*

Each facility is responsible for creating a screening protocol. All cCMV screenings must be completed prior to 21 days of age to ensure the newborn did not acquire the virus after birth.

Question 13: *Who is responsible for conducting cCMV screenings for infants born in birthing centers and at home?*

The PCP is responsible for referring newborns who do not pass an initial outpatient hearing screening for cCMV screening. Audiologists are encouraged to prioritize hearing screenings for newborns born at birthing centers and at home to facilitate timely cCMV screening for newborns who fail the hearing screening.

REPORTING

Question 14: *How will cCMV screening results be reported to the NBHS Program?*

All cCMV screening results must be submitted through the electronic reporting portal, eReports™. Account requests can be made by completing the eReports Online Registration Form. cCMV screening results required to be reported to the NBHS Program within seven days of receiving the results.

Question 15: *What results are required to be reported to the Newborn Hearing Screening Program?*

All positive, negative, inconclusive, unsatisfactory, missed, and parent refusals are required to be reported to the NBHS Program through eReports. For detailed instructions on reporting cCMV results, visit [eReports Training - How to Enter cCMV Screening Results](#).

Question 16: *Is it required to report cCMV results that were collected without a hearing screening (e.g., infants with prolonged NICU stays)?*

Reporting cCMV screening results is not required for infants who receive a cCMV screening without a hearing screening. Reporting results for infants at higher risk of cCMV and hearing loss ensures the NBHS Program can provide follow up and resources to parents. It also provides the NBHS Program a more complete understanding of the incidence of cCMV statewide.

FOLLOW-UP AND TREATMENT

Question 17: *What are the next steps if a newborn tests positive for cCMV?*

Facilities and PCPs should consult with an infectious disease specialist for recommendations for medical management. Additionally, the National CMV Foundation developed a [Roadmap for Newborn Congenital CMV Work-up](#) and other resources to assist providers with medical management of newborns who screen positive for cCMV. Other provider resources are available for download at under the Resources section.

Question 18: *How can a pediatric infectious disease physician be located?*

To locate an infectious disease physician by city or region, search the Department of Health's [Practitioner Profile Search](#).

Question 19: *Are newborns who screen positive for cCMV referred to Early Steps?*

The hospital may make a referral to Early Steps when a newborn screens positive for cCMV. A newborn with cCMV automatically qualifies for Early Steps' services. Medical documentation of the positive cCMV screening should be included with the referral. The NBHS Program will follow-up with the Early Steps Program to ensure families are contacted. For more information about making a referral to Early Steps, visit [FloridaEarlySteps.com](#).

Question 20: *What are the next steps when a newborn screens positive for cCMV?*

If the infant is still inpatient, the hospital will develop a plan of care for the child. If the infant has been discharged, the infant's PCP will develop a plan for medical management.

Question 21: *What is the recommendation for repeat hearing screenings for ongoing monitoring a child's hearing level after a positive cCMV screening?*

Currently, there is not universal consensus on the timing and frequency of monitoring hearing levels for a child with cCMV. [The Joint Committee on Infant Hearing 2019 Position Statement](#) recommends newborns diagnosed with cCMV receive a diagnostic follow-up no later than three months of age and every 12 months to age three or at shorter intervals based on parent concerns.