



**Early Hearing Detection
and Intervention Program**

Congenital Cytomegalovirus Testing

Frequently Asked Questions

July 2024



Congenital Cytomegalovirus (cCMV) Testing Frequently Asked Questions

GENERAL

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

The [cCMV Screening Guidelines](#), published in June 2024, are available to view and download on the cCMV webpage on FloridaNewbornScreening.com.

LEGISLATION

Question 2: *Is cCMV testing 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 testing before discharge or before 21 days of age, whichever occurs earlier, for newborns who meet any of the following criteria:

- Fail the newborn hearing screening.
- Born before 35 weeks gestation.
- Have an anticipated neonatal intensive care unit (NICU) stay of 21 days or more.
- Are transferred to another facility for a higher level of care.

Legislation also requires licensed birth centers to conduct the newborn hearing screen prior to discharge. Birth centers providing newborn care should order a cCMV test for newborns who do not pass the hearing screen.

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 test.

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

Per [section 383.145, Florida Statutes](#), results of newborn hearing loss screening, cCMV testing, and any related diagnostic testing, must be reported to the Florida Newborn Hearing Screening (NBHS) Program within seven days after receipt of such results. Results must be reported electronically through the NBHS Program's eReports™ system. eReports™ account requests can be made by completing the [eReports™ Registration Form](#).

Question 4: *Which hospital, the transferring or the receiving hospital, is required to complete the cCMV test when a newborn is transferred for a higher level of care?*

Per [section 383.145, Florida Statutes](#), if a newborn requires transfer to another hospital for a higher level of care, the receiving hospital must initiate the cCMV test if it was not already performed by the transferring hospital or birthing facility.

In cases where the birth hospital conducts the cCMV test prior to transferring a newborn, the birth hospital should consider how to:

- Track results.
- Document results.
- Report results to the NBHS Program.
- Notify the receiving hospital and PCP of results.

Question 5: *Are cCMV tests required for newborns who transfer into a facility, but do not have an anticipated NICU stay of 21 days or a failed hearing screen?*

Yes. Regardless of anticipated length of NICU stay or hearing screening status, cCMV tests must be completed on all newborns transferred for a higher level of care.

Question 6: *Is a cCMV test required for a newborn readmitted to the NICU or cardiac care unit?*

Per [section 383.145\(3\)\(a\)2., Florida Statutes](#), hospitals that provide NICU services shall administer a test to screen for cCMV in each newborn admitted to the hospital requiring an anticipated stay of three weeks or longer or who have a failed hearing screen. The legislative requirements apply to newborns readmitted to hospitals. Such testing must be initiated before the newborn becomes 21 days of age. Testing infants readmitted to the hospital who do not meet the legislative requirements is at the discretion of the hospital. The National CMV Foundation recommends testing newborns under 21 days of age who have any of the symptoms found at [Physician and OB-GYN Resources | National CMV Foundation | National CMV Foundation](#).

TESTING

Question 7: *What kind of cCMV test can be used?*

Each facility is responsible for selecting the cCMV test that will be used. Per [section 383.145, Florida Statutes](#), 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](#).

Question 8: *Can cCMV results from a blood test be reported in place of a saliva or urine test?*

Saliva and urine are the recommended testing methods for cCMV testing and are the only methods that can be reported through eReports. In cases where a blood test is performed and is positive, a confirmatory urine test should be completed before the newborn is 21 days of age. The result of the urine confirmatory test should be reported in eReports.

Question 9: *Is there a minimum age requirement for administration of the cCMV test?*

The NBHS Program recommends collecting the cCMV specimen after the infant is 24 hours of age, which is consistent with collection times for other newborn screening (NBS) conditions.

Question 10: *Should a facility test a newborn for cCMV after failure of the first (initial) hearing screening or the second (repeat) hearing screening?*

Per [section 383.145, Florida Statutes](#), hospitals must complete a cCMV test when a newborn is being discharged with a final failed hearing screening.

Question 11: *Is a cCMV test required for newborns with a prolonged NICU stay who pass the newborn hearing screen?*

Per [section 383.145\(3\)\(a\)2., Florida Statutes](#), cCMV tests are required for all newborns admitted to NICU with an anticipated stay of three weeks or longer, no

matter the results of the hearing screen.

Question 12: *Are hospitals required to complete a cCMV test for newborns with an ear-related malformation (microtia, atresia, cleft palate) that prevents hearing screening in one or both ears?*

Yes, a cCMV test 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 13: *What should be done when a cCMV test comes back inconclusive?*

If a newborn is still inpatient when a cCMV test 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 tests must be completed prior to 21 days of age to determine if the newborn acquired the virus during pregnancy. Inconclusive test results are required to be reported to the NBHS Program within seven days of receipt of results.

Question 14: *Is cCMV testing required if the parents opt out of the hearing screen?*

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

Question 15: *Since hearing screening and cCMV testing are required, are there repercussions for parents who decline?*

[Section 383.145\(3\)\(c\), Florida Statutes](#), allows the parent or legal guardian of a newborn to decline the hearing screening. The parent must sign a document that confirms their choice to decline, which should be included in the infant's medical record, and the hearing screening should be reported as a refusal to the NBHS Program.

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.

Question 16: *Should a newborn remain inpatient until the results of the cCMV testing are confirmed?*

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

Question 17: *When a saliva cCMV specimen is positive, is a confirmatory urine test required?*

Although not legislatively mandated, the NBHS Program recommends confirmatory urine tests be completed as soon as possible for all newborns who test positive with a saliva test. Confirmatory urine testing should be completed by 21 days of age for newborns.

For newborns who remain in the hospital following receipt of positive saliva results, complete a confirmatory urine test. For newborns discharged from the hospital prior to completion of the confirmatory test, notify the PCP of the initial positive test, and the need for confirmatory urine testing.

Question 18: *Who is responsible for conducting cCMV testing for infants born in birth centers and at home?*

Newborns born at a birth center or at home and who do not pass the newborn hearing screen are required to be screened for cCMV. Audiologists are encouraged to prioritize hearing screenings for newborns born at home to facilitate timely cCMV testing for infants who fail the hearing screening. The provider responsible for newborn care for infants born at birth centers and at home must ensure newborns who do not pass the newborn hearing screening are tested for cCMV.

REPORTING

Question 19: *How are cCMV test results reported to the NBHS Program?*

All cCMV test results must be submitted through the electronic reporting portal, eReports.™ eReports™ account requests can be made by completing the [eReports™ Registration Form](#). cCMV test results are required to be reported to the NBHS Program within seven days of receiving the results.

Question 20: *What results are required to be reported to the NBHS Program?*

All positive, negative, inconclusive, unsatisfactory, missed, parent refusals, and transfers 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](#) and [cCMV Data Entry At-A-Glance](#).

Question 21: *Is it required to report cCMV results that were collected for reasons outside of legislative requirements?*

Reporting cCMV test results is not required for infants tested for reasons outside of legislative requirements. However, reporting results ensures the NBHS Program can provide follow-up and resources to parents, when appropriate. It also provides the NBHS Program a more complete understanding of the incidence of cCMV statewide.

FOLLOW-UP AND TREATMENT

Question 22: *What are the next steps if a newborn tests positive for cCMV?*

The timing of medical intervention is crucial to treatment efficacy. Facilities and PCPs should consult with an infectious disease specialist upon diagnosis 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 test positive for cCMV. Other provider information and resources are available at [the National CMV Foundation website](#).

Question 23: *How can a pediatric infectious disease physician be located?*

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

Question 24: *Are newborns who test positive for cCMV eligible for Early Steps?*

A newborn with cCMV automatically qualifies for Early Steps services. Medical documentation of the positive cCMV test should be included with a 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 [the Early Steps website](#).

Question 25: *What is the recommendation for repeat hearing screenings for ongoing monitoring of a child's hearing level after a positive cCMV test?*

The American Academy of Audiology recommends all children who test positive for cCMV receive:

- A complete diagnostic hearing evaluation no later than 3 months-of-age.
- Diagnostic evaluations every three to six months until the age 1 year.
- Diagnostic evaluations every six months between the ages of 1 and 3 years.
- Diagnostic evaluations annually between the ages of 3 and 6 years.
- Diagnostic evaluations at shorter intervals based on parent concerns.