



Newborn Screening for Cytomegalovirus: Information for Healthcare Providers in New York State

Newborn screening for congenital Cytomegalovirus (cCMV)

All newborn screen samples received by the New York State Newborn Screening (NBS) Program between July 2023 and June 2024 will be screened for one extra condition for free: congenital Cytomegalovirus (cCMV) infection. We predict about one out of every 200 newborns may test positive for cCMV. Some babies who are born with cCMV may develop hearing loss and/or other health problems.

All babies will be tested for cCMV. Parents can choose to opt out of having their child's cCMV screen result reported in their newborn screen record. Opting out means that neither the parent(s), nor the baby's primary care provider will be contacted even if the result of the screen is positive. Parents should be advised to act quickly if they would like to opt out. Their baby's newborn screen report will be complete 5-7 days after birth. If the NBS Program does not hear from the parent before 5 days post birth, their child's cCMV result will be included in their newborn screen report. Parents do not need to do anything if they would like their baby's cCMV result included in their newborn screen report. For more information about how to opt-out, please see the "Opt-Out Mechanism" section below.

Note: Parents may only opt out of the extra cCMV test and they must do so within the 5 days following the baby's birth. If they opt out of the cCMV report, the baby's result will not be reported at all and that data will be expunged. Parents should be encouraged to act quickly!

Why is it important to screen for cCMV?

CMV is a very common virus. In the United States, nearly one in 3 children is infected with CMV by age 5. By the age of 40, over half of adults in the U.S. have been infected with CMV. Most adults do not know they have the virus because most persons show no symptoms. Some people with CMV experience cold-like symptoms such as sore throat, fever, tiredness, and swollen glands. While CMV is often harmless in adults, pregnant people may pass the virus to their unborn babies. If a person contracts the virus for the first-time during pregnancy, the baby has at least a 4 out of 10 chance of being infected. People are not routinely tested for CMV, so a person may not know that they contracted the virus during pregnancy. A pregnant person can pass CMV to their unborn baby due to either a new infection during pregnancy or reactivation of an earlier infection. The highest risk to a baby is if a first-time CMV infection occurs early in a pregnancy. Babies born with cCMV are at risk for symptoms and/or long-term health problems.

For NBS specimen collectors:

Please do the following when collecting newborn screen samples between July 2023 and June 2024:

1. Please tell parents/guardians that their child will have an extra test for cCMV.
2. Give the cCMV parent brochure to all families when collecting their child's sample. The brochure is available in the 13 most commonly spoke languages in NYS.
3. Direct questions to the NBS Program (contact info below).
4. If families fill out tear-off opt out form, send it in envelope with NBS specimens. It does not need to be attached to that child's sample.



Why is the NYS NBS Program doing this extra test for cCMV?

This statewide pilot for cCMV will help answer 3 questions:

- Can cCMV be detected by newborn screening?
- How many newborns will have cCMV in a diverse population?
- Is prospectively identifying cCMV at birth helpful?

Babies born with cCMV

We expect 1 out of every 200 babies will have cCMV. For those born with cCMV, the possible outcomes are:

- Most babies born with cCMV will be healthy at birth and never develop any health consequences.
- Some babies born with cCMV appear healthy at birth but develop hearing loss during childhood.
- Some babies born with cCMV may have hearing loss at birth. Babies and children with hearing loss are at risk for speech and developmental delays.
- About one in 10 babies born with cCMV will be sick at birth. The symptoms seen in these babies may include petechiae/purpura, jaundice, microcephaly, low birth weight, hepatosplenomegaly, seizures, and retinitis.

Because most babies with cCMV do not show any signs or symptoms at birth, it is important for doctors to follow the baby's hearing and developmental milestones. **Finding hearing loss early in life is important and can prevent developmental delays.**

Early detection of hearing loss

Hearing loss is the most common long-term health effect in babies born with cCMV. Hearing loss can affect a baby's language, speech, and social skills. NYS Public Health Law section 2500-g requires that all newborns receive a hearing screen shortly after birth. NYS Public Health Law 2500-a states that babies who fail their hearing screen should be tested for cCMV. If a baby fails their hearing screen, they should receive diagnostic testing for cCMV regardless of the result of their newborn screen.

In NYS, hearing screening results are reported to the Early Hearing Detection and Intervention (EHDI) Program. For more information on the EHDI Program visit their website:

www.health.ny.gov/community/infants_children/early_intervention/newborn_hearing_screening

How is the test done?

Dried blood spot newborn screening is performed via newborn heel stick. This is a routine test done for thousands of babies in the United States every day. The newborn screen (NBS) and cCMV screen will be done on the same blood sample. **An extra blood sample is not needed for the cCMV screen.** All blood samples are sent to the NYS Newborn Screening Program (our address is listed below).

cCMV screening will be performed using real-time polymerase chain reaction (PCR) to amplify and detect the genome of the virus in dried blood spots collected from each baby for newborn screening. The method is a modification of an FDA-approved assay.

What are the possible test results?

Most babies will have a negative result for cCMV; the expected incidence of the congenital infection is one in 200. We predict this screen will have approximately 75-80% sensitivity, therefore a negative screen result should not be used to rule out cCMV infection.



NBS Report Type	Description	Action Needed	Necessary Follow-up Actions
Negative	Normal result, patient likely does not have a cCMV infection	None	<ul style="list-style-type: none">• Primary Care Provider (PCP) communicates results with parent(s)• If baby has any symptoms concerning for CMV order a urine PCR; if positive, notify NBSP that the dried blood spot cCMV screen was a false negative
Positive	Abnormal result, patient likely has a cCMV infection	Prompt consultation needed with Infectious Disease Specialty Care Center (SCC)	<ul style="list-style-type: none">• NBSP staff notifies PCP and SCC of the result• PCP or SCC notifies parent(s) of the result• SCC or PCP orders urine PCR test for confirmatory testing as soon as possible• SCC discusses whether treatment is needed with parent(s), notifies PCP• SCC and/or PCP completes diagnosis form and returns it to NBSP

Positive test and next steps

This cCMV screen is not a diagnostic test; it cannot definitively determine if a baby has cCMV. As referenced above, if a newborn’s cCMV screen is positive, the parent(s) should be notified by their PCP and/or an Infectious Disease Specialist. Once the parent(s) is/are notified, a follow up appointment should be scheduled for confirmatory diagnostic testing. The recommended diagnostic test is a PCR (urine preferred), and it should be collected within 21 days of life. This timeframe is used to determine if the patient’s infection is congenital or acquired.

False positive results on the newborn screen are possible. Therefore, an independent PCR is needed to determine if the newborn has cCMV.

Treatment of cCMV infection

For infants with clinical signs/symptoms of cCMV at birth, treatment with the antiviral medications, ganciclovir or valganciclovir, may improve hearing and developmental outcomes. Treatments generally last from six weeks to six months. Treatments are administered orally or through an IV or PICC line. These treatment regimens have only been studied in infants with symptomatic cCMV disease. There is limited information on the effectiveness of ganciclovir or valganciclovir to treat infants with hearing loss alone.

Caution: treatment should only be initiated after consultation with a pediatric Infectious Disease specialist.

Registry

Parents/guardians of babies who are diagnosed with cCMV via their NYS newborn screen may be consented by a pediatric Infectious Disease specialist to participate in a long-term follow-up registry that will follow clinical outcomes over at least a 2-year period following diagnosis.

Health management



Infants diagnosed with cCMV should have regular hearing and vision tests. For children with hearing loss, early interventions, such as hearing aids, can help strengthen communication and language skills. A general recommendation for babies diagnosed with cCMV is to have a hearing assessment every three months in the first three years of life, then every six months from three years of age through six years of age. In addition, the Early Intervention (EI) Program offers a variety of therapeutic and support services, such as:

- Speech pathology and audiology
- Vision services
- Service coordination
- Home visits
- Parent support groups and more

More information about the New York State EI Program is available at https://www.health.ny.gov/community/infants_children/early_intervention/.

Opt-out mechanism

All babies born in New York State between July 2023 and June 2024 will be screened for cCMV as part of a pilot testing program. Parents have the option to opt out of receiving the cCMV screening results and having the results recorded in their baby's newborn screen record through several methods. To opt-out, parents may do any one of the following:

1. Scan QR code found on parent brochure which leads to NBSP website and opt-out portal.
2. Remove and fill out the opt-out form in the parent brochure, then give it to hospital staff to submit with the NBS specimen (this option must be done within 2 days of birth).
3. Email a picture of the completed opt-out form to cmvnbs@health.ny.gov
4. Call the NYS NBSP
Phone Number: 518-473-7552 (option 5)
*Language interpretation available upon request
5. Mail the opt-out form to:
Newborn Screening Program
NYS Department of Health
120 New Scotland Avenue
Albany, NY 12208

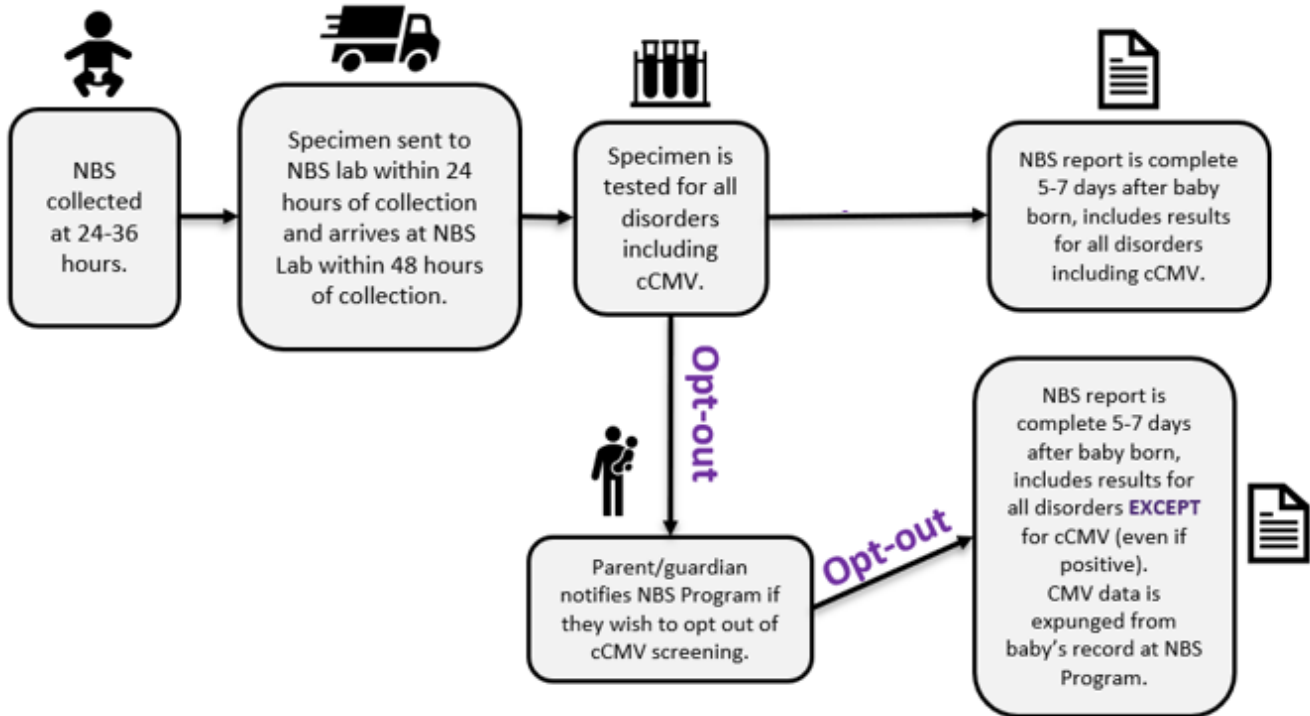
Parents should be advised to act quickly if they would like to opt out. Their baby's newborn screen report will be complete 5-7 days after their birth. If the NBSP does not hear from the parent(s) before their newborn screen report is complete, their child's cCMV result will be included in their newborn screen report. Once the report is complete the result cannot be removed. Parents do not need to do anything if they would like their baby's cCMV result to be reported.

Parents cannot opt back in after previously opting out. Patient data will be expunged upon opting out. Patients that require testing for clinical reasons, and had previously been opted out, may be retested.

Note: The choice of opting out only refers to opting out of receiving the cCMV screen result. If the parents choose to opt out of the cCMV screen, the baby's result will not be reported at all. **Opting out means that the parent(s) and the baby's primary care provider will not be contacted even if the result of the screen is positive.**



cCMV NBS Opt-Out Process/Timeline:



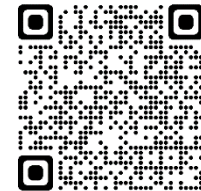
Contact us for questions or more information:

For questions or more information, contact us using one of these methods:

Phone: 518-473-7552 (option 5)

CMV email: cmvnbs@health.ny.gov

Website: www.wadsworth.org/newborn



References:

CDC CMV Fact Sheet. <https://www.cdc.gov/cmV/fact-sheets/healthcare-providers.html>

CDC CMV Clinical Overview. <https://www.cdc.gov/cmV/clinical/overview.html>

National CMV Foundation. <https://www.nationalcmv.org/resources/for-healthcare-professionals>

New York State Early Intervention Program (EIP). https://www.health.ny.gov/community/infants_children/early_intervention/

New York State Early Hearing Detection and Intervention Program (EHID). https://www.health.ny.gov/community/infants_children/early_intervention/newborn_hearing_screening/

Congenital CMV Disease Research Clinic & Registry. <https://www.bcm.edu/departments/pediatrics/sections-divisions-centers/cmVregistry/>