

A close-up photograph of a woman smiling warmly as she holds a newborn baby. The woman is wearing a white patterned top, and the baby is wearing a blue and pink striped onesie. The background is softly blurred, suggesting an indoor setting with natural light.

alethia™

Everyone Wants To Take Their New Baby Home

With the comfort of understanding the challenges
and the reassurance of your clinical team

The Unknown Threat

According to the CDC, congenital CMV infection occurs when a baby is born with a Cytomegalovirus infection. It is the most common virus passed from mothers to babies during pregnancy.

In fact, nearly 1 in 4 women are carriers of CMV during pregnancy, with 1 in 200 babies born with cCMV each year, and yet, the majority of pregnant women have either never heard of it, or don't realize the danger it poses to their unborn child.

Congenital CMV infection can cause developmental disabilities such as hearing and vision loss, cerebral palsy, mental disability, and, in rare cases, death.

Early detection is integral to establishing appropriate treatment.

Congenital CMV can be diagnosed if the virus is detected in a baby's urine or saliva within 2 to 3 weeks from birth.

CMV is a public health issue, and legislation has been passed or is under consideration in numerous states regarding CMV education and testing for neonates.

At Meridian, we understand how this causes uncertainty about when and how to test.



“CMV causes disease in more children than anything else we screen pregnant women or newborns for. Every year there are several thousand babies in the US who are harmed by congenital CMV infections.”

DSoren Ganitt, MD, PhD, MPH, Associate Professor | Department of Pediatrics
Division of Infectious Diseases | University of British Columbia
Director of Clinical Research | BC Children's Hospital Research Institute
Vancouver, BC

A Point of View for Better-Managed cCMV

We are committed to supporting the healthy integration of care for both the needs of your patients and the needs of providers like you.

When considering the wide range of cCMV testing approaches, it can be agreed that early detection is critical to establish appropriate patient management.

At the time healthcare providers observe the possibility of a cCMV infection in a newborn, they are in the best position to call for a convenient and timely test.

Improving outcomes for newborns

Congenital cytomegalovirus-infected neonates might be asymptomatic or symptomatic at birth (JAMA 032017). Recent studies have demonstrated that the targeted approach, which focuses on neonates who have failed a newborn hearing screen, misses a significant number of infected neonates.

To facilitate early detection and intervention, consensus guidelines recommend that consideration be given to universal neonatal cytomegalovirus testing to enable early detection of neonates infected with congenital CMV.

Leading institutions and thought leaders have implemented a third approach that advocates that healthcare providers test for congenital CMV if the neonate has failed a newborn hearing test or in the presence of symptoms suggestive of a viral illness. These symptoms include, but are not limited to:

- Thrombocytopenia
- Petechiae
- Hepatomegaly
- Splenomegaly
- Intrauterine growth restriction
- Hepatitis (raised transaminases or bilirubin) or ventriculomegaly
- Intracerebral calcifications
- Periventricular echogenicity
- Cortical cerebellar malformations
- Abnormal cerebrospinal fluid indices for age
- Choroideritis
- Sensorineural hearing loss
- Cytomegalovirus DNA in cerebrospinal fluid
- Hepatomegaly or a single measurement of low platelet count or raised levels of alanine aminotransferase
- SGA (small gestational age)



The Healing Benefits of Convenience

The time has come for a convenient, accessible test for cCMV—a test that accomplishes multiple benefits for infected neonates, their parents and caregivers, healthcare practitioners, lab professionals and the system that serves everyone.

Consider the possibilities :

Imagine having test results in the same day

Having an opportunity to make informed patient care decisions sooner

The possibility of earlier intervention and avoidance of long-term complications

Healthcare systems working to improve both population health and resource utilization

At Meridian, we believe that “convenience and accessibility” aren’t merely improvements in efficiency—they can transform the future for children with cCMV.

“At this point, I think saliva is one of the best approaches just because of ease of collection and because of the high viral load that makes it the better specimen choice versus urine or dried blood spot.”



Congenital CMV Testing Challenges

Regardless of the clinical environment you work in or the role you play, at Meridian we know how tough it can be when faced with the need to identify cCMV.

If you're a healthcare professional with access to an academic lab or other institution that currently provides cCMV testing with a lab-developed test (LDT), you probably realize how fortunate you and your patients are. However, the burden on your lab to consistently provide that test is significant: Tight regulations, rigorous quality controls and staff

qualifications all combine to make cCMV testing genuinely challenging.

Additionally, if you're like many providers and lab staff who simply don't have access to or don't provide cCMV testing, you are providing care amid the emotional concern of missing a diagnosis that could prove devastating to a child and parents.

It's clear that the need exists for a simple, repeatable, accessible and convenient test for cCMV.



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