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# Everyone Wants To Take Their New Baby Home

Empowered with a full understanding of their baby's  
health and the support of their 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<sup>1</sup>.

**In fact, nearly 1 in 4 women are carriers of CMV during pregnancy<sup>2</sup>, and 1 in 200 babies are born with cCMV each year<sup>3</sup>, 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<sup>4</sup>.

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<sup>5</sup>.

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<sup>6</sup>.

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







# The Challenge Of Congenital CMV Testing

Regardless of the clinical environment 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 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 challenging.

And, if you're like many providers and lab staff who simply don't have access to or don't provide cCMV testing, a diagnosis may be missed 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.

# Improving Outcomes For Newborns

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

When considering the wide range of cCMV testing approaches, one can agree 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.

**“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.”**

*Soren Gantt, MD PhD MPH,  
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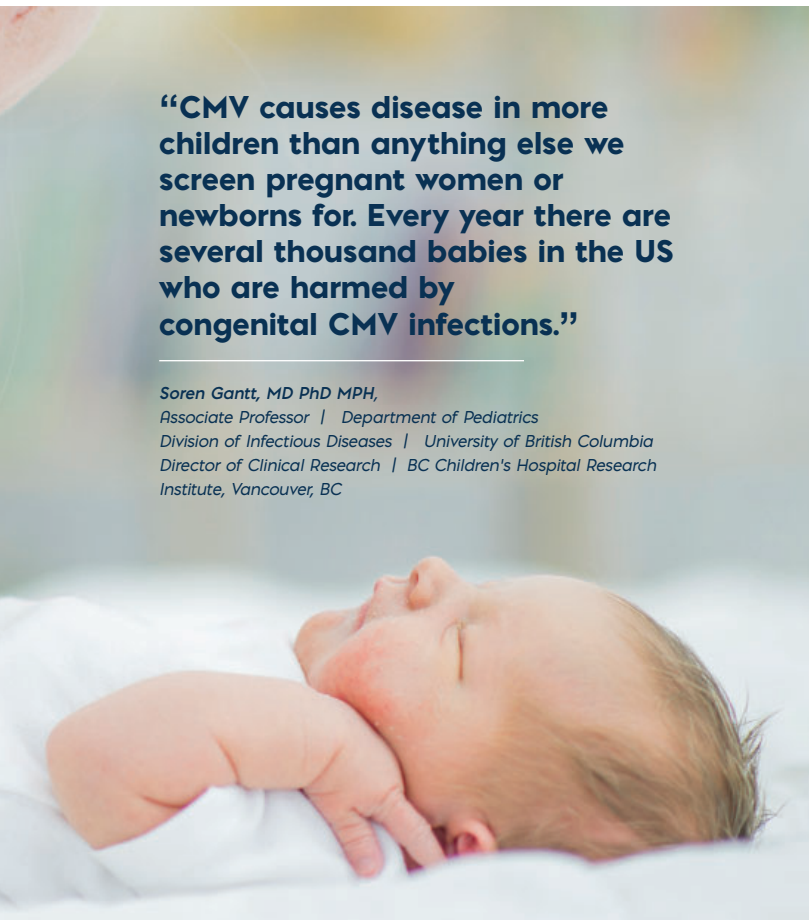
## Point of Views For Better Managed cCMV

Congenital cytomegalovirus-infected neonates might be asymptomatic or symptomatic at birth (JAMA 032017)<sup>7</sup>. 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<sup>8</sup>:

- Sensorineural hearing loss (SNHL)
- Small gestational age (SGA)
- Petechiae
- Seizures
- Thrombocytopenia
- Hepatomegaly
- Splenomegaly
- Hyperbilirubinemia (jaundice)
- Intracerebral calcifications
- Chorioretinitis
- Microcephaly







# 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 health system that serves them.

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

## 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 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.”**

*Karen Fowler, DrPH, Department of Pediatrics | Division of Infectious Diseases  
University of Alabama at Birmingham*

## References

1. Silasi M, Cardenas I, Racicot K, Kwon J-Y, Aldo P, Mor G. VIRAL INFECTIONS DURING PREGNANCY. American journal of reproductive immunology (New York, NY : 1989). 2015;73(3):199-213. doi:10.1111/aji.12355.
2. Marchofdimes.org. (2018). Cytomegalovirus and pregnancy. [online] Available at: <https://www.marchofdimes.org/complications/cytomegalovirus-and-pregnancy.aspx> [Accessed 13 Oct. 2018].
3. Congenital CMV Facts. Centers for Disease Control and Prevention. <https://www.cdc.gov/features/cytomegalovirus/index.html>. Published 2018. Accessed October 17, 2018.
4. Nationalcmv.org. (2018). Congenital CMV Outcomes | National CMV Foundation | National CMV Foundation. [online] Available at: <https://www.nationalcmv.org/congenital-cmv/outcomes> [Accessed 13 Oct. 2018].
5. <https://www.cdc.gov/cmv/congenital-infection.html>
6. Nationalcmv.org. (2018). CMV Legislation | National CMV Foundation | National CMV Foundation. [online] Available at: <https://www.nationalcmv.org/cmv-research/legislation.aspx> [Accessed 13 Oct. 2018].
7. Lourdes, M. (2017). Universal New Born Screening for Congenital CMV Infection – Who Really Benefits? 1st ed. [ebook] Singapore: J Clin Pathol Diagn, p.1. Available at: <http://www.imedpub.com/articles/universal-new-born-screening-for-congenital-cmv-infection--who-really-benefits.pdf> [Accessed 13 Oct. 2018].
8. Rawlinson, W., Boppana, S., Fowler, K., Kimberlin, D., Lazzarotto, T., Alain, S., Daly, K., Doutré, S., Gibson, L., Giles, M., Greenlee, J., Hamilton, S., Harrison, G., Hui, L., Jones, C., Palasanthiran, P., Schleiss, M., Shand, A. and van Zuylen, W. (2017). Congenital cytomegalovirus infection in pregnancy and the neonate: consensus recommendations for prevention, diagnosis, and therapy. The Lancet Infectious Diseases, 17(6), pp.e177-e188.



**For more information** on Meridian

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