



alethia[™]
CMV

Improve outcomes for physicians by providing a convenient and timely result for congenital CMV in newborns.

Congenital CMV - The Unknown Threat to Newborns

Nearly 1 in 4 women are carriers of the most common virus passed from mother to babies during pregnancy^{1,2}. Every year 1 in 200 babies are born with cCMV³, and yet, the majority of pregnant women have never heard of it.

Alethia[™] CMV provides early detection of congenital CMV which is vital in guiding appropriate treatment for newborns.

- Report results with confidence with the First FDA cleared test for cCMV
- Utilizes saliva, an easy to collect and preferred sample type for congenital CMV testing⁴
- Obtain results in less than one hour with minimal hands on time
- High NPV provides confidence to physicians and piece of mind to parents before their baby goes home

Your lab can improve outcomes for newborns.

- How would an FDA cleared cCMV test with a simple procedure and results in less than one hour help improve turnaround time and overall lab workflow?
- Knowing cCMV is the leading cause of deafness in newborns, how would you implement a test in your health system that can impact patient care and reduce costs associated with potential disease complications?



Results That Matter

- The simple procedure of Alethia CMV provides flexibility to best fit the laboratory's workflow when compared to other testing technologies.
- Saliva is easy to collect and contains high viral load, allowing optimal detection and same day reporting for physicians and families.

Improving Outcomes For Newborns

- Implementing newborn testing strategies for cCMV have been increasingly recognized for their potential medical benefits and improved patient outcomes.⁵
- Congenital CMV testing empowers physicians and families with the full understanding of their newborn's health prior to leaving the hospital.



Product Specifications

Intended Use

The Alethia CMV Assay is an in vitro diagnostic molecular test for the detection of CMV from the saliva of newborns under 21 days. The test will provide an actionable result to enable the clinical team to develop an appropriate treatment plan.

Turnaround Time

< 60 minutes

Sample Type

Saliva from newborns younger than 21 days

Sample Storage

- Saliva swabs can be stored at 19 - 30 C up to 48 hours.
- Refrigerated at 2 - 8 C up to 7 days.
- Frozen at $\leq -20C$ up to 14 days.

Kit Storage

Kit should be stored at 19 - 30 C

Performance

100% PPA

99.8% NPA

Catalog Number

Alethia CMV - 481325

CPT Codes

87496

Alethia CMV

External Control - 479880

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,
4. Congenital cytomegalovirus infection in pregnancy and the neonate: consensus recommendations for prevention, diagnosis, and therapy William D Rawlinson, [www.thelancet.com/infection](http://dx.doi.org/10.1016/S1473-3099(17)30143-3) Published online March 10, 2017
5. JAMA Pediatr. 2016;170(12):1173-1180. doi:10.1001/jamapediatrics.2016.2016. Published online October 10, 2016. Corrected on October 31, 2016.

Ready to get a handle on CMV testing? Let's talk.

Contact a specialist at 1-888-763-6769.

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