



NEWS RELEASE

FOR IMMEDIATE RELEASE

## **DiaSorin Molecular's Simplexa™ Congenital CMV Direct Assay Attains CE Mark**

Cypress, Calif. (June 15, 2020) – DiaSorin Molecular LLC announced today that it has received CE marking for its Simplexa™ Congenital CMV Direct kit. The new molecular diagnostic test enables direct detection of cytomegalovirus DNA in both saliva swab and urine specimens from babies up to 21 days old. It is the first CE marked assay that can be run directly from both saliva swab and urine. The assay is designed for use with the LIAISON® MDX instrument.

CMV infection in otherwise healthy individuals is common and usually results in a mild, non-specific illness. However, congenital CMV (cCMV), which occurs when the virus is passed from mother to unborn baby, can lead to dangerous, even fatal outcomes. Approximately 60,000 neonates are born every year with congenital CMV infection in the United States and the European Union combined.

Congenital CMV is the leading cause of non-genetic childhood hearing loss and a significant cause of neurodevelopmental delays that, if not diagnosed early, can lead to lifelong impairment. This makes timely diagnosis of congenital CMV critical for disease management and intervention. The need for universal screening is under consideration by many health organizations globally.

"We are excited to offer the first CE marked congenital CMV test performed directly using saliva swab and urine specimens," said Michelle Tabb, chief scientific officer for DiaSorin Molecular. "The test quickly provides actionable results to help ensure early intervention for newborns infected with CMV. We look forward to continually serving customer needs with our growing menu of direct assays."

### **About DiaSorin Molecular**

DiaSorin Molecular LLC manufactures and distributes innovative molecular diagnostic products for hospital and reference laboratories. The company's products help laboratories consolidate their testing, streamline processes and increase efficiency. DiaSorin Molecular's Simplexa molecular diagnostic kits are designed for use on the company's versatile LIAISON MDX platform. The company provides service and support solutions for its kits and instruments through a global network of offices and distributors.

DiaSorin Molecular also markets a range of ASRs (analyte-specific reagents) for use in lab-developed tests.

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Enclosed: Photo

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