

DIASORIN HAS CE MARKED ITS MOLECULAR'S SIMPLEXA™ CONGENITAL CMV DIRECT ASSAY

Saluggia - June 12, 2020 - DiaSorin (FTSE MIB: DIA) announced today that it has CE marked 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.”*

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About DiaSorin

Headquartered in Italy and listed in the FTSE MIB Index, DiaSorin is a global leader in the In Vitro Diagnostic (IVD) field. For over 50 years, the Company has been developing, producing and marketing reagent kits for IVD worldwide. The Group has a presence on the 5 continents with 26 companies, 4 foreign branches, 5 manufacturing facilities and 5 research and development centers throughout the world. Through constant investments in research and development, and using its own distinctive expertise in the field of immunodiagnosics to deliver a high level of innovation, DiaSorin offers today the broadest range of specialty tests available in the immunodiagnosics market and new tests in the molecular diagnostics markets, which identify DiaSorin Group as the “Diagnostic Specialist”.