DiaSorin The Diagnostic Specialist

PRESS RELEASE

DiaSorin Simplexa® Congenital CMV Direct Assay received U.S. FDA 510(k) clearance

The Simplexa® Congenital CMV Direct Assay is:

- the first kit to receive FDA clearance in enabling direct detection of cytomegalovirus DNA in both saliva swab and urine specimens
- designed for use on the LIAISON® MDX platform and is run directly through the Direct Amplification Disc (DAD), enabling rapid detection

Saluggia, Italy, November 9, 2022 - DiaSorin (FTSE MIB: DIA) announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its Simplexa® Congenital CMV Direct kit.

This molecular diagnostic test enables direct detection of cytomegalovirus (CMV) DNA in both saliva swab and urine specimens from babies 21 days old or younger.

Saliva swab specimens are easy to collect for screening purposes and urine specimens are vital for confirmation. Simplexa Congenital CMV Direct is the first kit to receive FDA clearance for CMV detection from both saliva swab and urine specimens. 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, which occurs when the virus is passed from mother to unborn baby, can lead to dangerous, even fatal outcomes.

Many healthcare organizations globally are considering the need for universal CMV screening programs for newborns.

Congenital CMV is the most frequent infectious cause of neonatal malformation in developed nations. It is also 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 fast and accurate diagnosis of congenital CMV critical for optimal disease management.

"The Simplexa Congenital CMV Direct kit is the first FDA-cleared product for diagnosing congenital CMV from both saliva swab and urine specimens," said Michelle Tabb, Chief Scientific Officer for DiaSorin Molecular. *"Claims for both sample types allows users to follow CDC recommendations with the simplified workflow of Simplexa. This allows accurate and fast diagnosis with one test enabling early intervention and treatment. We are excited to offer this valuable test as part of our growing menu."*

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About DiaSorin

Headquartered in Italy and listed at the Italian Stock Exchange in the FTSE MIB Index, DiaSorin is a global leader in the In Vitro Diagnostic (IVD) field and is active since 2021 in the Life Science business. For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide.
The Group operates in 5 continents through 43 companies, 4 branches, 10 manufacturing facilities and 9 research and development centers. The extensive diagnostic testing and Life Science offer, made available through continuous investments in research, positions DiaSorin as the player with the broadest range of specialty tests available within the diagnostic market, and identifies the Group as the "Diagnostic Specialist".
More info at www.diasoringroup.com