

Simplexa Congenital CMV Direct kit gets CE mark

August 2020—DiaSorin Molecular announced it has received the CE mark for its Simplexa Congenital CMV Direct kit. The molecular diagnostic test enables direct detection of cytomegalovirus DNA in saliva swab and urine specimens from babies up to 21 days old.

“We are excited to offer the first CE-marked congenital CMV test performed directly using saliva swab and urine specimens,” Michelle Tabb, chief scientific officer for DiaSorin Molecular, said in a press release. “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.”

The assay is designed for use with the Liaison MDX instrument.

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