FDA clears Simplexa Congenital CMV Direct assay

January 2023—DiaSorin announced it has received FDA 510(k) clearance 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 21 days old or younger. It 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.

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