FDA clears Simplexa Congenital CMV Direct assay

Nov. 11, 2022—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 Simplexa Congenital CMV Direct kit is the first FDA-cleared product for diagnosing congenital CMV from both saliva swab and urine specimens,” Michelle Tabb, chief scientific officer of DiaSorin Molecular, said in a press statement. “Claims for both sample types allow 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.”

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