



NEWS RELEASE

FOR IMMEDIATE RELEASE

## **DiaSorin Molecular Receives FDA Clearance for Simplexa™ VZV Direct Molecular Assay**

Cypress, Calif. (May 30, 2019) – DiaSorin Molecular LLC announced today that it has received FDA clearance for its new Simplexa™ VZV Direct assay for use with cerebrospinal fluid (CSF) samples. The new molecular diagnostic test enables the detection of varicella-zoster virus (VZV) DNA from CSF and serves as an effective tool to aid in the diagnosis of meningitis and encephalitis. Requiring only 50µL of patient CSF per test, the assay was developed for use on DiaSorin Molecular’s LIAISON® MDX instrument and complements DiaSorin Molecular’s Simplexa HSV 1 & 2 Direct assay.

VZV causes varicella (chickenpox), a highly communicable disease that is usually contracted in early childhood and is also known to cause some types of acute aseptic meningitis. After initial infection, VZV becomes latent in sensory nerve ganglia. Reactivation of the latent virus can occur with increased age or immunosuppression and causes herpes zoster (shingles), a painful condition associated with complications including post-herpetic neuralgia and central nervous system infections such as encephalitis.

It is estimated that greater than 90 percent of the population will acquire VZV by the age of 15 and they are subsequently at risk for developing VZV encephalitis. The two most prevalent human herpes viruses identified in encephalitis cases are HSV 1 and VZV, which commonly occur in middle-aged adults.

“HSV 1, HSV 2 and VZV CSF PCR are part of the diagnostic algorithm for encephalitis in adults,” commented Michelle Tabb, chief scientific officer at DiaSorin Molecular. “Our new VZV Direct assay, together with our HSV 1 & 2 Direct assay, provides physicians the answers they require in a timely manner for patient management.”

## **About DiaSorin Molecular**

DiaSorin Molecular LLC manufactures and distributes innovative molecular diagnostic products for hospital and reference laboratories. The company's products help laboratories consolidate their testing, streamline processes and increase efficiency. DiaSorin Molecular's Simplexa molecular diagnostic kits are designed for use on the company's versatile LIAISON MDX platform. The company provides service and support solutions for its kits and instruments through a global network of offices and distributors. DiaSorin Molecular also markets a range of ASRs (analyte-specific reagents) for use in lab-developed tests.

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Enclosed: Photo

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