



NEWS RELEASE

FOR IMMEDIATE RELEASE

DiaSorin Molecular Receives FDA Clearance for Simplexa™ VZV Swab Direct Molecular Assay

Cypress, Calif. (December 17, 2019) – DiaSorin Molecular LLC announced today that it has received FDA clearance for its Simplexa™ VZV Swab Direct assay. The CLIA moderate-complexity assay is designed for use on the LIAISON® MDX instrument to quickly and accurately detect varicella-zoster virus (VZV) DNA from cutaneous and mucocutaneous swab specimens. The company also attained CE Marketing for the assay in September. This assay complements the company's Simplexa VZV Direct kit, which is for use with CSF samples.

Varicella-zoster virus infection causes two clinically distinct forms of disease, a primary infection (chickenpox) or a secondary infection (shingles). Although vaccines have been around since the 1990s, it is estimated that 90 percent of the population will acquire the diseases by the age of 15. These infections can affect different areas of the body including the skin, genitals, nasal cavities, and the eyes and can cause severe long-term disability or disfigurement depending on the affected site and treatment. It is not always possible to visually distinguish VZV lesions from HSV lesions as the clinical presentation can be similar. This makes it critical for labs to identify VZV infection for proper patient treatment and management.

“With this release, we now offer a comprehensive menu of VZV and HSV tests from cerebrospinal fluid, mucocutaneous swab specimens, and cutaneous swab specimens,” commented Michelle Tabb, chief scientific officer at DiaSorin Molecular. “Customers can also run these tests at the same time using the same disc. We are dedicated to providing products that streamline testing workflows and improve 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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