



NEWS RELEASE

FOR IMMEDIATE RELEASE

DiaSorin Molecular Attains CE Mark for Simplexa™ HSV 1/2 & VZV Universal Direct Molecular Assay

Cypress, Calif. (May 16, 2019) – DiaSorin Molecular LLC announced today that it has received CE marking for its new Simplexa™ HSV 1/2 & VZV Universal Direct assay. The new molecular diagnostic test enables the direct detection and differentiation of herpes simplex virus (HSV)-1, HSV-2 and varicella-zoster virus (VZV) DNA from cutaneous and mucocutaneous swab specimens. The assay was designed for use on the LIAISON® MDX instrument and generates comprehensive and actionable insight for patients with lesions.

A herpes simplex virus infection can cause cutaneous or mucosal lesions that are usually self-limited, but severe disease can occur in immunocompromised patients, pregnant woman and infants. HSV-1 is typically characterized by oral lesions, infectious keratitis and eczema herpeticum, in addition to growing incidents of genital lesions. HSV-2 infection is one of the most common sexually transmitted diseases causing vesicular genital lesions. Worldwide, approximately 90 percent of people are infected with HSV, 60 to 80 percent of whom have HSV-1 and 16 to 25 percent have HSV-2.

VZV causes two clinically distinct forms of disease. Chickenpox is typically a mild disease, but can cause complications, and is characterized by lesions on the face, trunk and extremities. After initial infection, VZV becomes latent in sensory nerve ganglia. Reactivation occurs with increased age or immunosuppression and causes herpes zoster (shingles), a painful condition associated with complications including post-herpetic neuralgia and CNS infections. It is estimated that greater than 90 percent of the population will acquire the disease by the age of 15 and each of these persons is at risk for complications such as encephalitis.

HSV-1, HSV-2 and VZV are human herpes viruses that can cause genital vesicular lesions. Although a majority of genital lesions are caused by HSV-1 and/or HSV-2, up to

2.9 percent of genital lesions are associated with VZV. For many individuals, VZV genital infection is associated with a childhood primary infection rather than sexual transmission. Inclusion of VZV along with HSV-1 and HSV-2 testing may enable clinicians to provide improved therapeutic decisions and advice.

“Our HSV and VZV assay delivers answers for these related herpes viruses in a single reaction in about an hour, features an easy workflow with minimal hands-on time and does not require upfront extraction,” commented Michelle Tabb, chief scientific officer at DiaSorin Molecular. “We are excited to continue offering products that meet the needs of clinicians all over the globe.”

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

Contacts for the media:

Jennifer Dahlgren
Dahlgren Communications
530-263-6817
dahlgrenpr@comcast.net

Mona Gross, Director of Market Development
DiaSorin Molecular LLC
562-240-6146
Mona.gross@diasorin.com