



NEWS RELEASE

FOR IMMEDIATE RELEASE

DiaSorin Molecular LLC's Simplexa[®] HSV 1 & 2 Direct Assay Receives FDA Clearance for Extended Swab Sample Claims

Cypress, Calif. (June 21, 2018) – DiaSorin Molecular LLC announced today that the company has received FDA clearance extending the sample type claims of its Simplexa[®] HSV 1 & 2 Direct assay. The clearance expands the type of samples that can be tested, from genital swabs to all cutaneous and mucocutaneous swab samples. FDA clearance of the assay for testing cerebrospinal fluid (CSF) samples was received in 2014. With these additional sample types, the DiaSorin Molecular Simplexa HSV 1 & 2 assay now has the most comprehensive sample type coverage for HSV testing in the market. CE Marking for these extended sample claims was attained late last year.

The Simplexa HSV 1 & 2 Direct kit real-time PCR assay, for use on DiaSorin Molecular's LIAISON[®] MDX instrument, is intended for the in vitro qualitative detection and differentiation of HSV-1 and HSV-2 DNA in cerebrospinal fluid (CSF) and swab samples. The test does not require a DNA extraction step and processes up to eight samples per run in about one hour.

HSV-1 and HSV-2 cause a variety of diseases with multiple presentations, ranging from mucocutaneous and cutaneous lesions to fulminate encephalitis, a high-mortality central nervous system infection. Rapid detection of HSV infection through molecular testing can be critical to decision-making for life-saving therapeutics. Clinical studies on patients of all age groups - from infants to adulthood – demonstrated accurate results. The coverage of multiple sample types in a moderate complexity assay enables laboratories to easily manage various HSV testing needs with one test.

“With this FDA clearance, we are able to meet our goal of offering the most comprehensive HSV molecular test available,” said Michelle Tabb, vice president of research and development for DiaSorin Molecular. “We are continually growing our test menu and expanding what the individual tests can do. This makes our molecular platform very attractive to clinical laboratories.”

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 laboratory developed tests.

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