

Press Release

DIASORIN EARNS FDA CLEARANCE EXTENDING SAMPLE CLAIMS FOR SIMPLEXA HSV 1 & 2 DIRECT MOLECULAR TEST

March 28th, 2018 - Saluggia (VC) - DiaSorin (FTSE Mid Cap: DIA) announced today that it has received FDA clearance extending the sample claims for its Simplexa HSV 1 & 2 Direct assay. CE Mark, for the same extended sample claims, was earned in September 2017.

The coverage of multiple sample types in a moderate complexity assay enables laboratories to easily manage various HSV testing needs with one assay.

The extension adds cutaneous and mucocutaneous lesion swabs to previously claimed specimen types of cerebrospinal fluid (CSF) and genital lesion swabs. The test, for use on the LIAISON MDX, is the only FDA cleared herpes simplex virus (HSV) molecular test for HSV-1 and HSV-2 DNA detection in CSF, cutaneous and mucocutaneous swab samples.

HSV 1 & 2 causes a variety of disease with multiple presentations, ranging from mucocutaneous and cutaneous lesions to fulminate encephalitis that can have devastating results.

"The FDA clearance on these additional sample types makes the Simplexa HSV Direct test the only kit in the U.S. that can test both CSF and mucocutaneous and cutaneous swab samples to meet the needs of today's laboratories," said Michelle Tabb, Vice President of Research and Development, DiaSorin Molecular. "Laboratories now have access to the most comprehensive HSV PCR test available, enabling consolidation of testing on multiple different sample types with one kit."

About DiaSorin

Headquartered in Italy and listed in the FTSE Italia Mid Cap Index, DiaSorin is a global leader in the In Vitro Diagnostic (IVD) field. For over 40 years the Company has been developing, producing and marketing reagent kits for IVD worldwide. Through constant investments in research and development, and using its own distinctive expertise in the field of immunodiagnostics to deliver a high level of innovation, DiaSorin offers today the broadest range of specialty tests available in the immunodiagnostics market and new tests in the molecular diagnostics markets, which identify DiaSorin Group as the "Diagnostic Specialist".

For additional information, please contact:

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