



NEWS RELEASE

FOR IMMEDIATE RELEASE

DiaSorin Molecular Receives FDA Clearance for Bordetella Test

Cypress, Calif., January 8, 2019 – DiaSorin Molecular LLC announced today that it has received FDA clearance for its new Simplexa[®] Bordetella Direct test. This CLIA moderate-complexity assay is designed for use on the LIAISON[®] MDX to quickly provide qualitative detection and differentiation of both *Bordetella pertussis* and *Bordetella parapertussis* in nasopharyngeal swabs (NPS). The assay is performed directly from NPS samples without extraction and provides results in about an hour.

Pertussis, or whooping cough, is a highly contagious disease of the respiratory system caused by small, gram-negative *B. pertussis* and *B. parapertussis* bacteria. While most of the cases are caused by *B. pertussis*, some milder cases have been linked to *B. parapertussis*. Pertussis can lead to more severe symptoms such as hypoxia, permanent brain damage or death, particularly in infants.

Since the late 1990s, there has been a marked increase in the number of reported pertussis cases in developed countries in spite of high vaccination rates. There were 48,227 cases reported in the United States in 2012, the highest number of reported cases since 1955. The World Health Organization estimates that there are 50 million whooping cough cases worldwide each year, resulting in 350,000 deaths.

“Whooping cough can be detected among all age groups and has seen a resurgence in recent years,” said Michelle Tabb, chief scientific officer for DiaSorin Molecular. “We are very excited about our addition of the Simplexa Bordetella Direct assay as it will help in the detection and appropriate treatment of this infectious disease. The assay meets the needs of today’s laboratories by detecting both *B. pertussis* and *B. parapertussis* with a simple workflow.”

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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Enclosed: Photo

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