

**DIASORIN LAUNCHES ITS FIRST MOLECULAR TEST WITH THE NEW BUSINESS DIVISION, DIASORIN MOLECULAR: THE NEW SIMPLEXA C. DIFFICILE DIRECT MOLECULAR TEST**

**November 2, 2016 - Saluggia (VC)** - DiaSorin (FTSE Italia Mid Cap: DIA) is pleased to announce the launch of the new *Clostridium difficile* molecular test, available for the market outside the USA.

The new assay, developed by DiaSorin Molecular, the new molecular division based in Cypress, CA (previously Focus Diagnostics), has been designed for use on the *Liaison MDX*, a small bench-top instrument able to provide reliable, clinically validated, real-time PCR results for quantitative, qualitative, multi-analyte and sample-to-answer detection.

The *Liaison MDX* system, targeted for medium-to-large laboratories, uses two different discs to run tests: the 8-well Direct Amplification Disc and the 96-well Universal Disc.

The new *Clostridium difficile* test is run on the Direct Amplification Disc and is intended for sample-to-answer detection of the organism in patients with signs and symptoms of *Clostridium difficile* Infection in about 1 hour. The test is yet another addition to the test menu available on the Direct Amplification Disc which includes influenza A/B & RSV, herpes simplex virus and Group A Streptococcus. With this launch, DiaSorin Molecular now offers *C. difficile* testing in both the Universal Disc and Direct Amplification Disc formats, giving DiaSorin the chance to enlarge its penetration into medium-sized labs, ensuring fast turnaround time and reduced hands on time together with high quality real-time detection.

*Clostridium difficile* Infection (CDI) is a major cause of antibiotic-associated diarrhea and colitis. The pathogen is reported to cause up to one-third of antibiotic-associated diarrhea cases, 50 to 75% of all cases of antibiotic associated colitis, and 90 to 100% of antibiotic-associated pseudomembranous colitis cases. Illness ranges from uncomplicated diarrhea to sepsis and even death.

*C. difficile* is transmitted from person to person, by the fecal-oral route or is acquired from environmental sources that have been contaminated. Once introduced into environments such as hospitals or nursing homes, *C. difficile* forms highly resistant spores that are able to survive for extended periods of time and are resistant to many disinfectants. While CDI occurs in all age groups, the populations at highest risk are prolonged hospitalized and immunocompromised patients, and institutionalized elderly patients receiving antibiotic therapy. Approximately 20-40% of patients hospitalized for more than 2 days become colonized with *Clostridium difficile* and 1/3 will develop symptoms. This nosocomial problem is in constant growth in the world. Together with the increase in CDI incidence, the case fatality rate, total mortality rate, and colectomy rates have significantly increased.

In USA, 500,000 people have been affected by CDI, with a recurrence rate in the range of 15%-35% and 29,000 people have been killed. CDI-related costs for health care expenditure had exceeded \$6 billion per year.

The size of the diagnostic market for *Clostridium difficile* is estimated to exceed \$450 million worldwide for a total of approximately 16 million tests annually.

## Press Release

Carlo Rosa, Chief Executive Officer of DiaSorin Group, commented: *“The Clostridium difficile molecular assay developed in our laboratories in Cypress (CA) enlarges our molecular infectious disease product portfolio and confirms the strength of DiaSorin Molecular in the diagnostics field. This launch, which comes only a few months after the acquisition of Focus Diagnostics, also confirms the value of our new division and the good execution of the integration process that will allow DiaSorin Molecular to take an active role in deploying our molecular business expansion strategy.”*

### REFERENCE TABLE FOR DIASORIN PRODUCTS

<b>Assay name</b>	Clostridium difficile
<b>Diagnosis</b>	Detection of Clostridium difficile bacterium in human stool sample
<b>Business segment</b>	Molecular Diagnostics
<b>Potential market</b>	\$ 450 million worldwide
<b>Clinical area</b>	Infectious Disease

#### **About DiaSorin**

Headquartered in Italy and listed in the FTSE Italia Mid Cap Index, DiaSorin is a global leader in the In Vitro Diagnostics (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 immunodiagnosics to deliver a high level of innovation, DiaSorin offers today the broadest range of specialty tests available in the immunodiagnosics market and new tests in the molecular diagnostics markets, which identify DiaSorin Group as the IVD “diagnostics specialist”.

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