**Press** Release

## DIASORIN LAUNCHES THE CLOSTRIDIUM DIFFICILE GDH ASSAY ON ITS LIAISON PLATFORMS

February 7, 2013 - Saluggia (VC) - **DiaSorin** (FTSE MIB:DIA) is pleased to announce the **launch of the Clostridium Difficile GDH assay on its Liaison analyzers family**.

The addition of the C. Difficile GDH assay to the DiaSorin Stool Menu, already including Clostridium Difficile Toxin A&B and Helicobacter Pylori, will allow DiaSorin customers to optimize this screening test with a unique automated solution.

The **C. Difficile GDH** Assay is a chemiluminescent immunoassay (CLIA) intended for use as a **screening assay to detect Clostridium difficile antigen**, glutamate dehydrogenase, **in human feces** from persons suspected of having C. Difficile disease. This assay does not distinguish toxigenic from non-toxigenic strains of C. Difficile.

Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.

Clostridium Difficile is a major cause of antibiotic-associated diarrhea and colitis Clostridium Difficile-Associated Disease (CDAD) can range from uncomplicated diarrhea to sepsis and even death. This nosocomial problem is in constant growth in the world.

Approximately 20-40% of patients hospitalized for more than 2 days become colonized with C. Difficile (1/3 will develop symptoms). Different studies performed in Canada, USA and Europe report increases, as much as two to four-fold, in CDI (Clostridium Difficile Infections) incidence in the past decade. Together with the increase in CDI incidence, the case fatality rate, total mortality rate, and colectomy rate for CDI significantly increased. The most recent data from European studies reported a mean incidence of healthcare-associated CDI of 4.1 per 10,000 hospital patient-days and CDI range from 6.9 to 46 cases per 100,000 person-years in the USA.

With almost 5 million patients tested every year in Europe and more than 20 million worldwide, Clostridium Difficile is by far the most important infectious parameter tested on stool.

The C. Difficile Glutamate Dehydrogenase (GDH) is highly correlated to the presence of C. Difficile bacteria and it is known as the common antigen. However, the GDH assays lacks specificity for the pathogenic toxin producing strains of C. Difficile, since the GDH assay detects the presence of both toxigenic and non-toxigenic strains of C. Difficile.



GDH is a parameter recognized worldwide for its NPV (Negative Predictive Value); it is accepted as the first step of all major algorithm recommended by the European and American society of microbiology for the diagnostic of C. Difficile.

REFERENCE TABLE FOR DIASO	RIN PRODUCTS			
Assay name	Clostridium Difficile GDH			
Diagnosis	Infectious Diseases			
Potential market	Every Year: 5 mln people tested in Europe, > 20 mln people WW			
Business segment	Immunodiagnostics	√	Molecular Diagnostics	
Technology	CLIA	1	Extraction	
	ELISA		Amplification/Detection	
	RIA		HLA Typying	
Clinical Area	Infectious Disease		Infectious Disease	
	Hepatites and Retroviruses			
	Oncology & Endocrinolgy			
	Bone & Mineral		Onco-hematology	
	Cardiac Markers			
	GI Stool Testing	√		

Mr. Carlo Rosa, Chief Executive Officer of DiaSorin Group, commented "I'm really proud to announce the launch of the C. Difficile GDH assay on our Liaison analyzer family. With this test DiaSorin is sending a clear message to the stool diagnostics market: <<we are allowing consolidation, workflow, and quality of results improvements where no one else have been able to, until now>>.

The launch of the C. Difficile GDH test on stool pursues our strategy in consolidating our leadership positioning on infectious diseases and places DiaSorin as the only provider in the world to allow those tests with a fully automated solution thanks to our LIAISON platforms family".

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