

DIASORIN LAUNCHES THE NEW HELICOBACTER PYLORI IgG CLIA TEST

June 7, 2016 - Saluggia (VC) - DiaSorin (FTSE Italia Mid Cap: DIA) is pleased to announce the launch of the new LIAISON test for the qualitative determination of IgG antibodies to *Helicobacter pylori* in human serum, available only for the market outside the USA.

The new assay enlarges the Company Infection Diseases panel on CLIA technology: it is the fastest fully automated solution on the market, which allows an accurate and correct diagnosis of the *H. pylori* infection.

Helicobacter pylori is one of the most common bacterial infections in humans, affecting nearly 50% of the world's population. *Helicobacter pylori* has been associated with the development of serious upper gastrointestinal (GI) conditions including chronic gastritis, peptic ulcer disease, gastric cancer, and mucosa-associated lymphoid tissue (MALT). According to a research of the Centre for Disease Control, *H. pylori* causes more than 90% of duodenal ulcers and up to 80% of gastric ulcers.

Serological testing is the first choice for the detection of *H. pylori* infection because it is easy to perform compared to the more invasive diagnostic tests.

The *H. pylori* worldwide market size is estimated to exceed € 100 million as a combination of non-invasive methods, such as serological assay, Urea Breath Test and fecal antigen detection.

The *H. pylori* IgG estimated testing volume is equal to ca. 1 million tests per year in Europe.

In the US market, approximately 25 million of people suffer from peptic ulcer disease at some point in their lifetime. Consequently the *H. pylori* IgG testing volume is estimated to exceed 6 million tests per year.

Francesco Colotta, Chief Medical Officer of DiaSorin Group, commented: *"Our new fully automated immunoassay CLIA test for the detection of H. pylori IgG antibody on human serum enriches our existing GI stool panel available on our LIAISON platforms. This new assay together with the fully automated test for the detection of H. pylori Stool Antigen on our LIAISON analyzers represent a reliable solution for the detection of H. pylori infection, for correct therapy, successful treatment monitoring and additionally for eradication programs"*.



REFERENCE TABLE FOR DIASORIN PRODUCTS

Assay name	LIAISON® H. pylori IgG		
Diagnosis	Qualitative determination of IgG antibodies to <i>H. pylori</i> in human serum		
Business segment	Immunodiagnosics	x	Molecular Diagnostics
Potential market	Around €10 mIn worldwide		
Technology	CLIA	x	Extraction
	ELISA		Amplification/Detection
	RIA		
Clinical area	Infectious Disease	x	Infectious Disease
	Hepatitis and Retrovirus		
	Oncology & Endocrinology		
	Bone & Mineral		
	Cardiac Markers		
	GI Stool Testing		Onco-hematology

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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