

DIASORIN LAUNCHES A NEW ANTI HBs ASSAY, A SECOND GENERATION TEST ABLE TO FULFILL THE STANDARDS REQUIRED BY THE WORLD HEALTH ORGANIZATION

January 12, 2012 - Saluggia (VC) - DiaSorin S.p.A. (FTSE MIB:DIA) is pleased to announce it has received the CE Marking in the European Union to market a new Anti HBs II assay, a standardized, higher reproducible, and sensitive diagnostic test for the quantitative detection of antibodies against hepatitis B surface antigen (Anti-HBs).

Hepatitis B is an inflammatory liver disease caused by the hepatitis B virus (HBV) that may result in liver cell damage. The World Health Organization (WHO) estimates there are more than 350 million people worldwide living with HBV. The liver cell damage can lead to scarring of the liver (cirrhosis) and increased risk of liver cancer. HBV is transmitted by contact with blood or other body fluids of an infected person and is 50 to 100 times more infectious than HIV.

Following clinical illness, the titre of HBsAg begins to decline and eventually falls below a detectable level. In approximately 10% of patients, HBsAg persists indefinitely in serum and anti-HBs does not appear, indicating a chronic carrier state.

The presence of anti-HBs in serum indicates previous exposure to HBV and long-lasting acquired immunity. That's why detection of anti-HBs is critical in establishing whether complete resolution of the infection has occurred as well as in establishing the acquisition of immunity, whether acquired as a result of natural HBV infection or vaccination.

The LIAISON® Anti-HBs II assay uses chemiluminescence immunoassay (CLIA) technology for the quantitative determination of antibody to hepatitis B surface antigen (anti-HBs) in human serum or plasma samples. The test is performed on DiaSorin's LIAISON® and LIAISON® XL systems.

As mentioned in the Journal of Clinical Virology 50 (2011) 297-302, "*Performance of the DiaSorin LIAISON® anti-HBs II for the detection of hepatitis B surface antibodies: Comparison with the Abbott Architect anti-HBs assay*", the DiaSorin LIAISON® anti-HBs II assay shows excellent standardization to the WHO standard and good linearity.

This assay complete and further reinforces DiaSorin Hepatitis portfolio currently available on its CLIA platforms, and as Mr. Carlo Rosa, CEO of DiaSorin Group, commented “*it is another differentiation element that, combined with our reputation in infectious diseases and the new instruments features, the Liaison XL, will support us in gaining a solid competitive position in the addressable 750 million Euros market of Hepatitis and Retrovirus tests*”

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