

DIASORIN LAUNCHES THE FIFTH MOLECULAR DIAGNOSTIC TEST FOR THE DETECTION AND QUANTIFICATION OF CYTOMEGALOVIRUS (CMV) ON ITS LIAISON IAM PLATFORM.

January 9, 2014 - Saluggia (VC) - **DiaSorin** (FTSE Mid Cap:DIA) is pleased to announce the launch of a **new molecular diagnostic test** for the detection and quantification of **Cytomegalovirus (CMV)** on human fluid samples, available on the market outside of the United States and Canada.

The new **IAM CMV** is the **fifth test** used on the **LIAISON IAM** after the first four assays already launched in 2012 and 2013 (IAM BKV, IAM VZV, IAM PARVO, IAM TOXO), which further strengthens DiaSorin's position as **Specialist leader in the Molecular Diagnostic market**.

The new molecular diagnostic test is of primary importance because it **detects and quantifies clinically relevant subtypes of CMV in human plasma, urine and cerebrospinal fluid (CSF)**. These features make the test a valuable tool for the diagnosis and monitoring of **CMV infection in transplant recipients** and other **immunocompromised individuals** as well as for the diagnosis of **maternal and foetal CMV infection in early pregnancy** and for monitoring CMV infection in **affected babies**.

Cytomegalovirus (CMV) is a DNA virus belonging to the herpes virus family. CMV infection is common throughout the world with a **seroprevalence of around 60% in the human population**. Primary infection, which typically occurs during childhood, is often asymptomatic but it can cause symptoms similar to glandular fever. Following primary infection, CMV can persist in a latent state throughout the lifetime of the host and reactivation can occur if the host becomes immunocompromised.

Concerning the market, CMV infection **can occur in immunocompromised individuals and pregnant women**. Regarding the first group, with increasing numbers of transplant recipients, the number of people at risk of CMV disease and related complications is increasing. The direct and indirect effects of CMV infection can have a significant impact on outcomes for transplant recipients. Furthermore, CMV is a major **cause of morbidity in AIDS patients** and in others with impaired immunity. Clinical manifestations amongst these patient groups include retinitis, pneumonitis, gastrointestinal disease and neurological disorders.

Regarding the second group, between **1-7% of pregnant women are infected** with CMV for the first time during their pregnancy. Although CMV infection is usually **mild or asymptomatic**, it poses a serious **risk to foetal development** if a pregnant woman acquires primary CMV infection in the first trimester or early in the second trimester. In around **40% of such cases, the virus is transmitted to the foetus** and can cause neurological damage, serious long-term complications and even death. Although 85-95% of infected infants are asymptomatic at birth, 10-15% of them go on to develop neurologic, auditory, visual, and/or dental defects in their early years.

REFERENCE TABLE FOR DIASORIN PRODUCTS

Assay name	Cytomegalovirus		
Diagnosis	Detection and quantification of clinically relevant subtypes of CMV		
Business segment	Immunodiagnosics		Molecular Diagnostics ✓
Potencial market	60% of world population		
Technology	CLIA		Extraction
	ELISA		Amplification/Detection ✓
	RIA		HLA Typing
Clinical Area	Infectious Disease		Infectious Disease ✓
	Hepatitis and Retroviruses		
	Oncology & Endocrinology		Onco-hematology
	Bone & Mineral		
	Cardiac Markers		
GI Stool Testing			

Paul Eros, Global VP Marketing Molecular Diagnostics of DiaSorin Group, commented: *“The potentially serious consequences of CMV infection in transplant and immunocompromised patients as well as in women in early pregnancy make IAM CMV an important addition to our infectious disease portfolio. The availability of real-time molecular diagnostic methods such as IAM CMV allows the rapid and sensitive diagnosis of active CMV infection. Furthermore, quantification of the viral load is invaluable for assessing the risk of CMV-related disease, to provide prognostic information, for guiding treatment decisions and for monitoring response to therapy”.*

Carlo Rosa, CEO of DiaSorin Group, commented: *“The launch of the IAM CMV assay on molecular diagnostics confirms our commitment to develop a strong portfolio of products related to infectious diseases also with this new technology and sets the basis for our further improvement into a new business area where DiaSorin wants to play a role in the future”.*

About DiaSorin

Headquartered in Italy and listed in the FTSE 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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