



SPAFID
CONNECT

Informazione Regolamentata n. 0957-88-2020	Data/Ora Ricezione 01 Ottobre 2020 07:44:54	MTA
--	---	-----

Societa' : DiaSorin
Identificativo : 137581
Informazione
Regolamentata
Nome utilizzatore : DIASORINN02 - Fava
Tipologia : REGEM
Data/Ora Ricezione : 01 Ottobre 2020 07:44:54
Data/Ora Inizio : 01 Ottobre 2020 07:44:55
Diffusione presunta
Oggetto : DiaSorin received FDA approval on 6
Hepatitis B tests, completing its Hepatitis
offer in the US market

Testo del comunicato

Vedi allegato.



DIASORIN RECEIVED FDA APPROVAL ON 6 HEPATITIS B TESTS, COMPLETING ITS HEPATITIS OFFER IN THE US MARKET

Saluggia - October 1, 2020 - DiaSorin (FTSE MIB: DIA) announces that it has received FDA approval for the 6 assays that complete the LIAISON® XL Hepatitis menu offering in the US. DiaSorin's full offering of the Hepatitis B (HBV) panel will allow a complete HBV testing solution that is key, not only to identify infected individuals, but also to diagnosing the presence of the virus, avoiding the spread of the infection and optimizing patient management.

HBV is a vaccine-preventable liver infection. For some people, it is an acute or short-term illness, but for some others it can become a long-term chronic infection, which leads to serious health issues, like cirrhosis or liver cancer.

Worldwide, approximately 2 billion people are infected by HBV.

HBV infection represents the third leading cause of death due to liver cancer. In the U.S. specifically, the number of reported acute hepatitis B cases has remained stable in the last years, with around 20,000 new cases per year and a total number of people living with HBV of more than 900,000 people. Moreover, low rates of hepatitis B vaccination coverage among adults and increasing rates of injection drug use are fueling a rise in acute HBV infections in the U.S. and CDC estimates that half of the people with chronic HBV infection do not know they are infected.

The World Health Organization recommends that testing should be offered to all people at risk of hepatitis B and that the implementation of HBV testing is the best way to reduce the spread of the infection and to optimize the management of patients. Universal access to testing and treatment is key to eliminating viral hepatitis and testing is important to diagnose acute and/or chronic hepatitis B and begin treatment, when necessary.

According to Centers for Disease Control and Prevention (CDC) recommendation, the best way to prevent hepatitis B is by being vaccinated while the implementation of HBV testing improves the knowledge about one's status of infection. Offering a complete Hepatitis B testing solution is key not only to identify infected individuals, but also to discriminate immune subjects.

Through the approval of the full HBV panel, DiaSorin is now able to offer a complete testing solution for Hepatitis A (HAV total, HAV IgM), Hepatitis B (Anti-HBs, Anti-HBc, Anti-HBe, HBeAg, HBcIgM, and HBsAg), and Hepatitis C (HCV Ab) in the U.S. market.

"The approval of our full Hepatitis menu in the U.S. is consistent with our strategy to address the hospital labs' market, reinforcing our positioning as a supplier of both mainstream and specialty infectious diseases tests", commented Chen Even, Chief Commercial Officer of the DiaSorin Group. "We are one of the only two vendors in the U.S. to offer a complete hepatitis solution on a single platform, including a fully automated HBe antibody assay for the best patient management and we continue to be a leader in innovation with our HBsAg assay, which detects all genotypes, serotypes and mutations for the most accurate diagnosis of HBV".

DiaSorin's hepatitis testing solution combines over 40 years of experience in hepatitis serology with the full automation of the Group's CLIA technology. The tests are designed to be performed on the more than 5,000 LIAISON® XL platforms installed worldwide.



The Diagnostic Specialist

PRESS RELEASE



Hepatitis testing will be consolidated with the largest specialty infectious disease menu already available in the U.S. market, including ToRCH and Treponema markers, for comprehensive patient management.

The approval of the Hepatitis B panel falls within the agreement signed with Beckman Coulter back in 2016, when the two groups formed a strategic partnership to bring the LIAISON XL Hepatitis and HIV products to the U.S. market. Since then, the companies are working together for the FDA approval and commercialization in the U.S. of the full line Hepatitis (A, B, C) and HIV assays already available to DiaSorin customers outside the U.S. territory.

"I'm proud that the U.S. Food and Drug Administration has approved the commercialization of our six HBV tests, recognizing again our ability to provide innovative, high quality and highly technological diagnostic solutions" commented Carlo Rosa, CEO of the DiaSorin Group. *"These new tests will be manufactured in our Italian and U.K. facilities and will be added to our existing and already available hepatitis panel in the U.S., strengthening our positioning as diagnostic specialists at service of hospital laboratories".*

For additional information, please contact:

Riccardo Fava

Corporate Vice President Communication & Investor Relations

Tel: +39.0161.487988

riccardo.fava@diasorin.it

Emanuela Salvini

Investor Relator

Tel: +39.0161.487567

emanuela.salvini@diasorin.it

DiaSorin

Headquartered in Italy and listed at the Italian Stock Exchange in the FTSE MIB Index, DiaSorin is a global leader in the In Vitro Diagnostic (IVD) field, with 26 companies, 4 branches, 5 manufacturing facilities and 5 research and development centers.

For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide. The extensive diagnostic testing offer, made available through continuous investments in research, positions DiaSorin as the player with the broadest range of specialty tests available within the diagnostic market, and identifies the Group as the "Diagnostic Specialist".

More info at www.diasoringroup.com

Fine Comunicato n.0957-88

Numero di Pagine: 4