



## DIASORIN HAS BEEN GRANTED DE NOVO AUTHORIZATION IN THE U.S. FOR THE FIRST FULLY AUTOMATED LABORATORY TEST FOR HEPATITIS DELTA VIRUS (HDV) ON THE LIAISON XL

- THE NEW LIAISON XL MUREX ANTI-HDV ASSAY IS THE FIRST FULLY AUTOMATED IMMUNOASSAY THAT HAS BEEN GRANTED DE NOVO AUTHORIZATION FOR HDV DETECTION IN THE U.S.
- THIS NEW ASSAY ADDRESSES A SIGNIFICANT GAP IN FDA-CLEARED TESTING FOR INDIVIDUALS WITH ACUTE OR CHRONIC HEPATITIS B (HBV) AT RISK FOR DEVELOPING ACTIVE HEPATITIS D (HDV) INFECTION
- THE DEVELOPMENT OF THE ASSAY HAS BEEN SUPPORTED BY GILEAD SCIENCES

**Saluggia, Italy – January 29, 2026** - Diasorin (FTSE MIB: DIA) announced today it has secured U.S. Food and Drug Administration (FDA) De Novo authorization for the first fully automated diagnostic test for hepatitis delta virus (HDV) on the Diasorin LIAISON XL immunoassay system. Designated as a Breakthrough Device by the FDA, the test aids in the diagnosis of HDV in individuals living with acute and chronic hepatitis B virus (HBV). The development of the automated diagnostic assay has been supported by Gilead Sciences.

*“Marking a major advancement for patients with hepatitis B, the FDA De Novo authorization of an automated total anti-HDV test provides clinicians with a standardized and reliable routine method for detecting HDV co-infection and super-infection - a key driver of accelerated progression to cirrhosis and liver failure,” said Dr. Robert Gish, Medical Director of the Hepatitis B Foundation. “Broad access to accurate HDV testing will enable earlier identification and more informed clinical management across U.S. practices”.*

Hepatitis delta, also known as hepatitis D, is caused by the hepatitis delta virus. It is a viral liver infection that can result in one of the most severe forms of viral hepatitis.

Occurring as a co-infection or a superinfection in individuals with HBV, HDV can progress to chronicity, cirrhosis, liver failure, and cancer. Mortality rates are up to 50% within 5 years in cirrhotic patients. It is estimated that the global hepatitis delta virus epidemic affects more than 15 million individuals worldwide, with many cases going undiagnosed in both endemic and non-endemic geographies.

The Diasorin LIAISON Murex Anti-HDV Immunoassay is the first fully automated FDA-authorized immunoassay for HDV detection in the U.S., addressing current availability and testing limitations to improve patient identification.

*“We are proud to announce this new milestone in HDV testing, that confirms our ability to grow Diasorin’s offering of innovative specialty tests” commented Chen Even, PhD, CCO of Diasorin. “We believe that this new innovative diagnostic solution will support future critical clinical decisions, aiding in the prevention of Hepatitis Delta severe complications.”*

HDV is known as a “satellite virus” of HBV because it depends on it for viral replication and dissemination in liver cells. It is important that individuals with HBV infection get tested for HDV, as they are most at risk. Getting tested for HDV can help improve patient outcomes by ensuring infected individuals receive appropriate and prompt medical care and treatment.

The fully automated HDV immunoassay test on the Diasorin LIAISON XL is available in the United States starting February 2026.



#### **About 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 and is active since 2021 in the Life Science business. For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide.

The Group operates in 5 continents through 30 companies, 4 branches, 10 manufacturing facilities and 9 research and development centers. The extensive diagnostic testing and Life Science 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.diasorin.com](http://www.diasorin.com)

#### **FOR ADDITIONAL INFORMATION, PLEASE CONTACT:**

##### **INVESTOR RELATIONS**

###### **Riccardo Fava**

*Corporate VP Communication, ESG & Investor Relations*  
[riccardo.fava@diasorin.com](mailto:riccardo.fava@diasorin.com)

###### **Eugenia Ragazzo**

*Corporate Investor Relations & ESG Senior Analyst*  
[eugenia.ragazzo@diasorin.com](mailto:eugenia.ragazzo@diasorin.com)