ABL Diagnostics Announces Availability of UltraGene Viral Meningitis Following CE-IVD Registration by ABL SA Luxembourg

WOIPPY, FRANCE, July 28, 2026 /EINPresswire.com/ -- ABL Diagnostics (Euronext Paris – Compartiment B – ISIN: FR001400AHX6), a company specialized in molecular diagnostic solutions for infectious diseases, announces the commercial availability of UltraGene Viral Meningitis, a multiplex real-time PCR assay intended for the qualitative detection and differentiation of the major viral pathogens associated with meningitis and other central nervous system (CNS) infections.

The assay simultaneously detects Herpes simplex virus 1 (HSV-1), Herpes simplex virus 2 (HSV-2), Varicella-zoster virus (VZV), Mumps virus (MuV), Enterovirus (EV), and Human parechovirus (HPeV) from cerebrospinal fluid (CSF) specimens. As with the other assays in the UltraGene portfolio, the complete workflow of UltraGene Viral Meningitis can be automated on ABL Diagnostics' OpenChek platform, enabling laboratories to streamline sample processing, reduce hands-on time, and improve workflow standardization.

The product has obtained CE-IVD registration under Council Directive 98/79/EC (IVDD) through ABL SA Luxembourg, acting as the legal manufacturer. The device is commercialized in accordance with the applicable transitional provisions established by Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), subject to continued compliance with the regulatory requirements applicable to legacy devices.
ABL Diagnostics SA will be responsible for the worldwide commercialization, distribution and customer support activities associated with the product.

Continuity of a Well-Established Fast Track Diagnostics Assay:
UltraGene Viral Meningitis originates from the former Fast Track Diagnostics (FTD) molecular diagnostic portfolio transferred to the ABL group following the know-how and technology transfer agreement concluded with Siemens Healthineers in 2025.
Following the transfer of manufacturing activities, technical documentation and quality processes, the assay is now manufactured and released under the quality management system of ABL SA Luxembourg.
The intended purpose, technological principles and core performance characteristics of the assay remain consistent with those of the previously marketed FTD product, supporting continuity of supply for laboratories that have historically relied on this established testing solution.

ABL Diagnostics has successfully re-established industrial production and global commercialization of the portfolio under the UltraGene brand. The company has expanded distribution across Europe, the Middle East, Africa, Asia, and Latin America, with strong adoption by clinical microbiology laboratories seeking reliable and cost-effective syndromic PCR solutions.

CE-IVD Registration Under the Applicable Transitional Framework:
UltraGene Viral Meningitis forms part of a broader program through which ABL SA Luxembourg is maintaining and commercializing selected legacy assays originating from the former Fast Track Diagnostics portfolio.
These products are CE-IVD registered under the IVDD framework and are intended to remain available in accordance with the transitional provisions established by Regulation (EU) 2017/746 (IVDR), provided that all applicable regulatory conditions continue to be fulfilled, including the requirements relating to legacy devices and the absence of significant changes affecting their intended purpose or design.
This approach allows clinical laboratories to continue accessing established molecular diagnostic assays while supporting a structured transition toward compliance with the European IVDR regulatory framework.

Progressive Integration into the IVDR Regulatory Strategy:
ABL SA Luxembourg has established a long-term regulatory strategy for the transferred FTD portfolio.
As part of this strategy, former FTD products maintained under the applicable IVDD and IVDR transitional provisions are being incorporated into the company's IVDR transition program.
The portfolio is intended to be progressively reviewed and assessed within the framework of ABL SA Luxembourg’s regulatory activities conducted with its notified body, BSI, as part of the company's broader IVDR conformity assessment roadmap.
This strategy is designed to support both regulatory continuity and the long-term availability of these molecular diagnostic solutions for clinical laboratories worldwide.

Supporting Laboratories Worldwide:
UltraGene Viral Meningitis expands ABL Diagnostics' syndromic portfolio dedicated to central nervous system infections and complements the group's broader molecular diagnostics offering.
Through the combined activities of ABL SA Luxembourg as legal manufacturer and ABL Diagnostics SA as commercial organization, the ABL group aims to ensure continued access to reliable molecular diagnostic solutions derived from the former Fast Track Diagnostics portfolio while advancing its transition toward the European IVDR framework.
"UltraGene Viral Meningitis strengthens our commitment to providing laboratories with rapid and reliable syndromic solutions for high-impact infectious diseases. Meningitis remains a medical emergency where timely molecular diagnosis can directly influence patient management and therapeutic decisions. Through ABL SA Luxembourg, we are ensuring regulatory continuity for this well-established assay while supporting laboratories with a robust,

CE-IVD registered solution that integrates seamlessly into existing molecular workflows and our long-term IVDR strategy," said Mr Ronan Boulmé, GRC Director at ABL Diagnostics and PRRC (Person Responsible for Regulatory Compliance) for ABL SA Luxembourg.

A Growing Global Market for CNS Syndromic Testing:
The demand for rapid molecular diagnosis of central nervous system infections continues to increase as hospitals and reference laboratories adopt multiplex PCR assays to improve the management of patients presenting with suspected meningitis or encephalitis.
International clinical guidelines increasingly recommend molecular testing of cerebrospinal fluid for herpes simplex viruses, varicella-zoster virus, enteroviruses and parechoviruses because these pathogens frequently present with similar clinical symptoms while requiring very different therapeutic approaches. Rapid identification can contribute to earlier targeted treatment, improved antimicrobial stewardship, shorter hospital stays and optimized use of healthcare resources.

According to industry analyses, the global multiplex molecular diagnostics market is expected to continue growing at a double-digit annual rate over the coming years, driven by the increasing adoption of syndromic testing beyond respiratory infections into areas such as central nervous system, gastrointestinal and bloodstream infections.
With its combination of clinically relevant pathogen coverage, validated analytical performance, open-platform compatibility and OpenChek automation capability, UltraGene Viral Meningitis is well positioned to support laboratories seeking scalable and cost-effective molecular diagnostics for CNS infections worldwide.

About ABL Diagnostics (ABLD)
ABL Diagnostics (ABLD) is an international company that specializes in innovative molecular biology tests and global solutions for its customers:
- Molecular polymerase chain reaction (PCR) detection – UltraGene, and
- Genotyping by DNA sequencing – DeepChek®.

Following the acquisition of TEXCELL's operations, ABL Diagnostics is expanding its activities in the life sciences sector by integrating expertise and services dedicated to virology, biosafety testing and biopharmaceutical development support.

Dr Sayada
ABL Diagnostics SA
+33 7 83 64 68 50
email us here

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