ABL Diagnostics Announces UltraGene Respiratory Pathogens 21 After CE-IVD Registration by ABL SA Luxembourg

WOIPPY, FRANCE, July 27, 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 Respiratory Pathogens 21, a multiplex real-time PCR assay intended for the qualitative detection and differentiation of 21 viral and bacterial respiratory pathogens. As with the other assays in the UltraGene portfolio, the complete workflow of UltraGene Respiratory pathogens 21 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 Respiratory Pathogens 21 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 Respiratory Pathogens 21 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 Respiratory Pathogens 21 contributes to ABL's respiratory syndromic testing portfolio 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.

"The availability of UltraGene Respiratory Pathogens 21 as a CE-IVD product, in plus of the research (RUO) model, reflects an important milestone in the integration of the former Fast Track Diagnostics portfolio within the ABL Diagnostics' commercial offer. Through ABL SA Luxembourg, we are ensuring regulatory continuity under the applicable IVDD and IVDR transitional provisions while executing our long-term IVDR strategy. This approach supports uninterrupted access for laboratories currently using these established diagnostic assays and provides a foundation for future portfolio development", said Mr Ronan Boulmé, GRC Director at ABL Diagnostics and PRRC (Person Responsible for Regulatory Compliance) for ABL SA Luxembourg."
ABL Diagnostics confirmed that several new syndromic qPCR assays are currently under development, with expanded coverage for respiratory, central nervous system, gastrointestinal,

and tropical infectious diseases.

A Growing Global Market for Respiratory Syndromic Testing:
The global market for syndromic qPCR respiratory testing continues to expand, driven by the need for rapid differential diagnosis, antimicrobial stewardship, infection control, and preparedness for seasonal and emerging respiratory outbreaks.
According to MarketsandMarkets, the global syndromic multiplex diagnostics market is projected to grow from approximately USD 2.6 billion in 2024 to more than USD 5.0 billion by 2029, representing a compound annual growth rate (CAGR) of around 14%. Respiratory panels account for the largest segment of this market due to the high burden of influenza, RSV, rhinovirus, and other respiratory pathogens in both pediatric and adult populations. Grand View Research also projects sustained double-digit growth for multiplex molecular diagnostics, supported by increasing adoption in hospital laboratories and decentralized testing networks.

With its combination of broad pathogen coverage, validated performance, flexible open-platform workflow, and competitive cost profile, UltraGene Respiratory pathogens 21 is well positioned to address the growing demand for accessible and scalable respiratory syndromic testing 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.
ABL Diagnostics markets its entire product range globally through its own sales team and a network of exclusive distributors active on all continents.

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