Advanced Biological Laboratories Receives CE-IVD Registration for its UltraGene Combo2Screen SARS-CoV-2 Assay

Thursday 21 May, 2020

Luxembourg (Luxembourg), Metz (France) — May 21— Advanced Biological Laboratories (ABL) announced today the CE-IVD registration of its UltraGene® Combo2Screen SARS-CoV-2 assay, now available for in-vitro diagnostics use.

This test is intended to be used for the qualitative detection of nucleic acids from severe acute respiratory syndrome-associated coronavirus 2 (SARS-CoV-2) in a clinical specimen. The real-time RT-PCR test aids the diagnosis of coronavirus disease (Covid-19) infection.

Targeting the N gene + E gene regions of the SARS-CoV-2 genome (in full compliance with the WHO Guidelines) in a multiplex format with internal control for the reverse transcription and PCR steps, the UltraGene® Combo2Screen CE-IVD assay is a fast and easy-to-use diagnostic solution with the highest TCID50 sensitivity ($1*10^{-6}$ $TCID_{50}$/mL). The specimen is intended to be collected from nasopharyngeal swab. It is compatible with most automatic or manual RNA extraction methods, as well as with most qPCR instruments equipped with at least three channels.

The test developed by Advanced Biological Laboratories, will complement a large menu of molecular biology assays dedicated to the management of infectious diseases, including DeepChek®-8-plex CoV-2 Genotyping Assay; a target-specific PCR kit with downstream next generation sequencing (NGS) analysis software. This application is for Research Use Only (RUO). It shall help in the research field (genotyping, surveillance studies) about the SARS-CoV-2 virus.

“Receiving the CE-IVD mark for our UltraGene® Combo2Screen assay is a major milestone for ABL. It will help additional virology labs perform SARS CoV-2 detection and improve the overall management of patients suffering from COVID-19 disease worldwide,” said Dimitri Gonzalez, Head of the Diagnostics division of ABL. “Our company is committed to delivering the highest quality products.”

“The ABL regulatory team has been rigorous in the verification and validation of our molecular diagnostics application, including the QCMD external quality assessment panel and the external performance validation by the french Covid-19 national reference centre (CNR Lyon)” added Mr. Ronan Boulmé, Governance, Risk and Compliance Manager of the ABL Group. “This diligence increases the quality of our product solutions overall.”

To learn more about UltraGene® Combo2Screen SARS-CoV-2 assays, already authorized by FDA to be commercialized in the USA, please visit
https://www.ablsa.com/laboratory-applications/ultragene-combo2screen/

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About Advanced Biological Laboratories (ABL SA)

Improving Disease Management

Advanced Biological Laboratories (ABL), S.A., is a diagnostic and medical software company founded in 2000 as a spin-off from CRP-Santé (https://www.lih.lu/) Luxembourg.

ABL's products offer to infectious disease clinicians, virology and microbiology laboratories

- Assays and standalone software systems for accredited laboratories (i.e. ISO 15189), mainly for microbiology applications (related to HIV, Coronavirus, Tuberculosis, HCV, HBV, HPV, CMV, HPV, Flu, 16s RNA…) for clinical genotyping through sequencing (DeepChek®), DNA and RNA detection and quantification (UltraGene®), including powerful downstream analysis software applications fully integrated with knowledge databases and analysis systems for capillary and high-throughput Next Generation Sequencing data.
- Clinical software applications for infectious diseases units
- IT dashboards and clinical database aggregation applications for research and clinical management

Related Sectors:

Coronavirus (COVID-19) :: Medical & Pharmaceutical ::

Related Keywords:

Covid :: Diagnostics :: Pcr :: Detection :: Coronavirus :: Genotyping :: Infectious Diseases ::

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ABL took in 2013 the rights to all viral hepatitis B & C related assets from EVIVAR MEDICAL as well as a personalized medicine electronic medical record system (EMR) in infectious disease from GlaxoSmithKline in 2016. In July 2018, acquired CDL Pharma to develop CRO related services and assays manufacturing capacity. In June 2019, ABL created its affiliate in the USA (AdvancedDx Biological Laboratories) covering the entire North American territory.

ABL has a comprehensive suite of healthcare management products, including Nadis®, TherapyEdge®, ViroScore®, SeqHepB, DeepChek®, UltraGene®, VisibleChek®, HepatiC®, BacterioChek, MicrobioChek and the DPM used for data and patient management, monitoring and personalized reporting applications. Since 2012, some of ABL's products are CE-IVD marked. In 2020, ABL got CE-IVD marking for its DeepChek®-HIV assays as well as for its UltraGene Combo2ScreenSARS-CoV-2 assay. The other products are currently available for Research Use Only.

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