Advanced Biological Laboratories Receives CE-IVD Registration for its DeepChek® Whole Genome SARS-CoV-2 Genotyping Assay, the First CE-IVD Marked Kit for SARS-CoV-2 genotyping clinical applications

Tuesday 25 May, 2021

Advanced Biological Laboratories (ABL) announced today the **CE-IVD** registration of its **DeepChek® Whole Genome SARS-CoV-2 Genotyping Assay**, the first in-vitro diagnostics kit to aid clinical applications and intended for use on previously diagnosed COVID-19 patients.

This innovative and unique assay, suited to small, medium and high throughput laboratories is intended to be used for amplifying >99% of severe acute respiratory syndrome-associated coronavirus 2 (SARS-CoV-2) genome, in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, and oropharyngeal swab specimens, and nasopharyngeal wash/aspirate or nasal aspirate specimens) from individuals already tested positive to SARS-CoV-2.

The assay, available in a kit format, provides multiplexed amplicons that can easily be prepared into distinct libraries or pooled with other types of samples and applications (Ex.: HIV, 16s RNA, Tuberculosis…) for subsequent Next Generation Sequencing on many platforms and lab configurations.

It can be bundled with a downstream analysis software to perform a comprehensive list of clinically relevant analyses like SARS-CoV-2 variants identification (including UK, Indian, South African, Brazilian variants of concern databases like Pangolin and Nextclade) for cluster management. It is also used for nucleotide and amino-acid mutations calling and coupled with a constantly up-to-date knowledge database correlating genomic variations with clinical interpretations like virus infectivity or vaccine efficacy. All information is centralized into a PDF report. The analysis and listing of genomic variations by the analysis software, either through a Cloud access or local appliances, is for Research Use Only (RUO). Virologists and physicians use the related genotyping data in conjunction with other patients' information.

The DeepChek® Whole Genome SARS-CoV-2 Genotyping Assay can be part of a laboratory validated environment for an end-to-end solution including automation (liquid handling robot) and integration with the laboratory information system (LIS).

“After completing CE-IVD registration of our HIV Assays in 2020, we are delighted to offer to virologists another genotyping application for SARS-CoV-2 using the DeepChek® technology which brings lots of efficiency and flexibility to microbiology.” said Dimitri Gonzalez, Head of Diagnostics at ABL.

“ABL actively keeps offering high-quality assays and software to microbiology labs covering qPCR et sequencing tests for a growing portfolio of applications which all aim to optimize disease management, our Company’s philosophy since 2000” explained Dr. Chalom Sayada, the CEO of the ABL Group.

To learn more about DeepChek® Whole Genome SARS-CoV-2 Genotyping Assay, please visit

https://www.ablsa.com/laboratory-applications/deepchek_whole_genome_sars-cov-2_genotyping/

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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, SARS-CoV-2, 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

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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

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 and for its UltraGene SARS-CoV-2 Multi Variants Deletions V1 assay and Triplex assay. The other products are currently available for Research Use Only. Please consult ABL team for further information about registration status of the ABl’s products in your territory.

For more information, visit www.ablsa.com.

Media Contact:

Advanced Biological Laboratories

contact@ablsa.com

+352 263896761

Company Contact:

ABL Diagnostics SA

T. +33 7 83 64 68 50
E. contact@abldiagnostics.com
W. https://www.abldiagnostics.com/

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