Advanced Biological Laboratories Obtained a Derogatory Authorization from the French National Agency for Medicines and Health Products Safety (ANSM) for its UltraGene Assay SARS-CoV-2 452R & 484K & 484Q Mutations

Related Sectors:

Coronavirus (COVID-19) ::

Scan Me:

Tuesday 22 June, 2021

Advanced Biological Laboratories (ABL) announced today the obtention of a derogatory authorization from the French National Agency for Medicines and Health Products Safety (ANSM) for commercializing the **UltraGene Assay SARS-CoV-2 452R & 484K & 484Q Mutations** which meets sufficient performance to comply with safety requirements related to in-vitro diagnostics medical devices. This procedure helps proposing to the pathology laboratories a solution in the interest in the protection of public health to detect specific mutations identified for variants currently circulating.

The assay is a real-time (rt) reverse transcriptase (RT) polymerase chain reaction (PCR) test (nucleic acid technique (NAT)) intended to screen the emergence of SARS-CoV-2 genome harboring the mutations L452R, E484K and E484Q on the Spike (S) gene. The test is targeting the S region of SARS-CoV-2 patients' extracted RNA. This test is intended for use only on diagnosed PCR positive to SARS-CoV-2 with a test CE-marked and authorized by competent authorities for SARS-Cov-2 screening.

"This derogatory authorization will help laboratories to get immediate access to a simple and accurate test able to detect SARS-CoV-2 452R, 484K and 484Q key mutations, until CE marking is completed" said Dr Sayada, CEO of ABL.

To learn more about our SARS-CoV-2 Assays, please visit

https://www.ablsa.com/applications/coronavirus/

# # #

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 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 ABI'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/

View Online

Newsroom: Visit our Newsroom for all the latest stories:
https://www.ablsa.pressat.co.uk