

Advanced Biological Laboratories Receives CE-IVD Registration for its UltraGene Assay SARS-CoV-2 452R & 484K & 484Q Mutations

Tuesday 31 August, 2021

Related Sectors:

Coronavirus (COVID-19) ::

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Advanced Biological Laboratories (ABL) announced today the CE-IVD registration of its **UltraGene Assay SARS-CoV-2 452R & 484K & 484Q**

Mutations. Targeting key mutations on the virus, the test helps in this identification of the main variants of concern including lineages Delta and soon Lambda, synonymous of higher transmissibility and probably associated to a decrease of vaccines efficacy, and therefore impacting human health and health systems overall.

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, E484Q, and soon the 452Q 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.

"We are pleased to offer to virologists, another CE marked SARS-CoV-2 qPCR assay able to detect SARS-CoV-2 key mutations helping to quickly identify the newest variants of concern like Delta and soon Lambda which are spreading in many countries" said Dr Sayada, CEO of ABL.

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

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

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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 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.

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