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

Monday 26 April, 2021

Advanced Biological Laboratories (ABL) announced today the CE-IVD registration of its UltraGene® SARS-CoV-2 Triplex Assay, now available for in-vitro diagnostics use.

This innovative test is a real-time RT-PCR test intended for the qualitative detection of RNA from the SARS-CoV-2and genomic variations on the Spike (S) gene and on the ORF1ab gene in upper respiratory specimens from individuals suspected of COVID-19 by their healthcare provider.

Assay results are for the identification of SARS-CoV-2 RNA, the detection of a SARS-CoV-2 variant from a wild-type strain and for the distinction of main circulating SARS-CoV-2 variants (SARS-CoV-2 lineage B.1.1.7 (i.e. United Kingdom VOC 202012/01, VOC 202102/02; “UK”), SARS-CoV-2 lineage B.1.351 (i.e. South Africa VOC 202012/02; “SA”) and SARS-CoV-2 lineage P.1 (i.e. Brazil VOC 202101/02; “BR”).

Available in a two-wells format per sample, the test includes in the first well, primer and probe sets designed to detect RNA from the SARS-CoV-2 nucleocapsid (N) gene and envelope (E) gene in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, oropharyngeal swab specimens and nasopharyngeal wash/aspirate or nasal aspirate and bronchoalveolar lavage (BAL) fluid specimens) from individuals suspected of COVID-19 by their healthcare provider. It also includes an extraction, reverse transcription, and PCR amplification positive control

The second well includes primer and probe sets designed to detect RNA from the SARS-CoV-2 nucleocapsid (N), Spike (S) and ORF1ab allowing precise identification of lineages B.1.1.7, B.1.351 and P.1.

Validated on the UltraGene qPCR 48 or Applied Biosystems QuantStudio 5 instruments, the tests works on plaforms equipped with FAM, HEX, Cy 5, and ROX and flurorescent channels and is available in two models for two distinct workflows. The «Simultaneous» workflow is for sites willing to perform a single RNA isolation followed by a direct rRT-PCR of the two wells simultaneously within the same run. The «Sequential» workflow is for sites willing to perform a first RNA isolation followed by a rRT-PCR run for the SARS-CoV-2 Screening (Well #1), and then performing, sequentially, a second RNA isolation from upper respiratory specimen from positive SARS-CoV-2 patients followed by a rRT-PCR run for the SARS-CoV-2 Variant detection and typing (Well #2).

“Completing the CE-IVD marking of our UltraGene® SARS-CoV-2 Triplex assay is a real achievement which shall bring lots of efficiency to healthcare professionals fighting COVID-19 and to labs constantly requiring new innovative diagnostics products” said Dr. Sofiane Mohamed, Technical & Scientific Director of ABL.

“For more than one year and since the beginning of the pandemic, ABL is committed to develop and provide to microbiology labs, robust solutions including genotyping & RT-PCR tests which aid optimizing overall patients management.” explained Dr. Chalom Sayada, CEO of the ABL Group.

To learn more about UltraGene® Assay SARS-CoV-2 Triplex, Screening, Multi-Variants and Typing V1, please visit https://www.ablsa.com/laboratory-applications/ultragene-triplex/

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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

Related Sectors:

Coronavirus (COVID-19) ::

Related Keywords:

SARS-CoV-2 :: COVID-19 :: Screening :: Variant :: Lineages :: PCR :: ABL ::

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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. The other products are currently available for Research Use Only.

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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