SARS-CoV-2 PCR Assay Now Approved for Human Saliva Specimens

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Advanced Biological Laboratories (ABL)
announced today the validation of its CE-IVD UltraGene® Combo2Screen SARS-CoV-2 qPCR assay to be used straight from non-invasive fluid saliva samples and allowing for broad population screening.

This optimization consisting in using saliva specimen as an input material for the SARS CoV-2 RNA extraction and qPCR detection, rather than traditional nasopharyngeal swabs, helps in improving the convenience and comfort of the test overall, target asymptomatic patients and reduce risk for nosocomial infection by healthcare professional performing nasopharyngeal or oropharyngeal collections.

Targeting two highly conserved regions of the SARS-CoV-2 genome (N gene + E Gene) in a multiplex format and an internal control, the sensitivity of the UltraGene® Combo2Screen CE-IVD assay from saliva samples remains very high and is still compatible with most automatic or manual RNA extraction methods, as well as with most qPCR instruments.

“We are proud to enhance our COVID-19 line of solutions. Converting the assay into a non-invasive fluid saliva test will significantly help increasing the number of people tested and will ease the diagnostics access to fragile people like children or asymptomatic patients” said Dr. Chalom Sayada, CEO of ABL.

To learn more about UltraGene® Combo2Screen SARS-CoV-2 assay, please visit https://www.ablsa.com/laboratory-applications/ultragene-combo2screen/

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

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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