Advanced Biological Laboratories (ABL) Releases the First & Unique Commercial CE-IVD Registered COVID-19 rRT-PCR Assay Validated also for Human Saliva Specimens

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Advanced Biological Laboratories (ABL)
announced today the CE-IVD marking of its UltraGene® Combo2Screen SARS-CoV-2 qPCR assay. It is the first qPCR detection kit now validated with SARS-CoV-2 RNA extracted from nasopharyngeal swabs and saliva. The collection of saliva samples is not invasive and allows easier and broader population testing and 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 workflow, costs and convenience of the test together with the comfort of the patients. It allows to target asymptomatic patients, increase patients' acceptance for testing and reduces workload and risk of infection for healthcare professionals performing nasopharyngeal or oropharyngeal collections. Patients collect saliva samples under healthcare professionals' supervision under a simpler and painless collection protocol.

The UltraGene® Combo2Screen CE-IVD assay is targeting two highly conserved regions of the SARS-CoV-2 genome (Nucleocapsid (N) and Envelop (E) genes) in a multiplex format which includes an internal control. The test remains one of the most sensitive and easy to use assays from the market (~200 cp/mL) either with naso-oropharyngeal or saliva samples. It is compatible with most of the automated or manual RNA extraction methods, as well as with most of the qPCR instruments.

The instructions for use of the assay describes a saliva collection process which shall be adapted and validated by the laboratory according to its own accredited procedures (patient eligibility, patient's skill, supervision or self-collection …).

"We are proud to enhance our COVID-19 line of solutions. Converting the assay into a non-invasive fluid saliva collection workflow should significantly help increasing the number of people being tested and ease the access to diagnostics to fragile population such as children or elderly patients and to asymptomatic patients" said Dr. Chalom Sayada, CEO of ABL. "Proactive saliva collection strategy at schools and business places shall be foreseen to monitor prospectively SARS-CoV-2 infection"

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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