Clinical Validation of SARS-Cov-2 RNA by Multiplex rRT-PCR Detection for Molecular Diagnosis of COVID-19 using CE-IVD Assay for Nasopharyngeal swab and Saliva Samples.

Ronan Boulmé[1], Lou Naldi[1], Francis Foguim[1], Alexandra Le Maire[2], Anh Thu Vu[1], Caroline Blanc[2], Audrey Chausson[2], Dimitri Gonzalez[1], Chalom Sayada[3], and Sofiane Mohamed[1]

[1]ABL France, Marseille, [2]CDL Pharma, Marseille [3]ABL SA, Luxembourg

Introduction:

The detection of SARS-CoV-2 RNA by real-time reverse transcription–polymerase chain reaction (rRT-PCR) is used to confirm the clinical diagnosis of COVID-19 by molecular diagnostic laboratories. Sample collection using nasopharyngeal (NP) swabs requires healthcare workers wearing personal protective equipment to collect samples, the swabs can be uncomfortable for the patients during collection. Saliva specimen can be an alternative to the NP. In this study we evaluated the multiplex UltraGene Assays for the detection of SARS-CoV-2 RNA for NP and saliva specimens.

Methods:

Clinical samples from nasopharyngeal swab and saliva were prepared, extracted (Roche MagNa Pure 24, Roche), amplified (Gentier48E, qPCR instrument, TianLong) using the CE-IVD UltraGene Assay SARS-CoV-2 (E/N) Sceen (ABL, France). Cross-reactivity was performed using a reference panel with high titer (ZeptoMetrix NATtrol™ Pneumonia Panel – Atypical Bacteria & Viruses). Coronavirus Outbreak Preparedness (CVOP) EQA Pilot Study from the Quality control for Molecular Diagnostics (QCMD, Ref# QAV204214_1) was tested.

Results:

The limit of detection was 0,000001 TCID50/mL or 1*10-6 TCID50/mL for SARS-CoV-2 for both NP swab and saliva specimens. No cross-reactivity was observed. The results interpretation agreement for saliva specimen between nasopharyngeal swab was perfect (Cohen's Kappa score=1). We obtained 100% clinical reproducibility for the international QCMD panel including the sample with the lowest viral load (2.30 Log10 Copies/ml) was detected.

Conclusions:

The CE-IVD (FDA EuA submission) UltraGene Combo2screen SARS-CoV-2 (E/N) multiplex rRT-PCR Assay shall enable highly sensitive detection of SARS-CoV-2 RNA, reducing reagent use, cost and time required by clinical laboratory technicians. Large scale SARS-CoV-2 saliva testing shall be a powerful solution in preventing spread of this virus and helping to control the COVID-19 pandemic including in asymptomatic patients.