First in-field evaluation of STANDARD M10 RT-PCR for the rapid detection of SARS-CoV-2: Preliminary results

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Background: Rapid diagnosis of SARS-CoV-2 is crucial to tackle the ongoing pandemic. Although RT-PCR is currently the gold standard method, most available assays have suboptimal turnaround times and requires sophisticated equipment and trained personnel. The objective of this project is to perform an independent evaluation of the novel STANDARD M10 assay for the rapid diagnosis of SARS-CoV-2 in different types of clinical specimens and collection kits.

Methods: For the main study, we plan to test 500 (200 positive and 300 negative) routinely collected naso- and/or oropharyngeal samples eluted in universal transport medium (UTM™, Copan Diagnostics Inc., US). Samples were tested using three different methods: (i) extraction-based RT-PCR (ebRT-PCR); (ii) extraction-free RT-PCR (efRT-PCR); and (iii) STANDARD M10 (SD Biosensor, Republic of Korea). Their duration per run is approximately 270, 150 and 60 min, respectively. For the ebRT-PCR, RNA was extracted using a STARMag Universal Cartridge Kit (Seegene Inc., South Korea) on an automated Nimbus IVD (Seegene Inc., South Korea) platform. The amplification step for both ebRT-PCR and efRT-PCR was performed on a CFX96™ instrument (Bio-Rad Laboratories, USA) using an Allplex™ 2019-nCoV assay (Seegene Inc., South Korea). Allplex™ 2019-nCoV assay detects three gene targets, namely nucleocapsid (N), RNA-dependent RNA-polymerase (RdRp) and envelope (E), while STANDARD M10 targets the open reading frame 1ab (ORF1ab) and E regions. Additionally, approximately 60 (50% positive) naso- and/or oropharyngeal swabs eluted in detergent- and guanidine thiocyanate-based collection tubes (eNat®, Copan Diagnostics Inc., US) and as many lower respiratory tract (LRT) specimens will be evaluated.

Results: So far, a total of 100 (50 positive and 50 negative) samples were tested in the three assays. There was a perfect agreement (kappa=1, 95% CI: 0.80–1) between ebRT-PCR and STANDARD-M with a sensitivity and specificity of 100% (95% CI: 92.9–100%) for both. By contrast, efRT-PCR did not detect one sample positive in both ebRT-PCR and STANDARD-M. Cycle threshold values showed by STANDARD M (ORF1ab: 21.1±6.0; E: 20.3±6.3) were significantly (P<0.001) lower than those found in either ebRT-PCR (N: 24.4±6.1; RdRp: 25.5±6.4; E: 23.5±6.2) or efRT-PCR (N: 26.6±6.2; RdRp: 28.7±6.2; E: 26.8±6.4). Analogously, eNat® (N=9) and LRT (N=8) samples tested so far showed a perfect agreement between ebRT-PCR and STANDARD-M.

Conclusions: Our preliminary findings suggest that STANDARD M10 is a reliable RT-PCR assay for detecting SARS-CoV-2 in different types of specimens and collection kits and may be used in the point-of-care setting.