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Sample collection and transport strategies to enhance yield, accessibility, and biosafety of COVID-19 RT-PCR testing

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ABSTRACT

Introduction: Non-invasive sample collection and viral sterilizing buffers have independently enabled workflows for more widespread COVID-19 testing by reverse-transcriptase polymerase chain reaction (RT-PCR).

Gap statement: The combined use of sterilizing buffers across non-invasive sample types to optimize sensitive, accessible, and biosafe sampling methods has not been directly and systematically compared.

Aim: We aimed to evaluate diagnostic yield across different non-invasive samples with standard viral transport media (VTM) versus a sterilizing buffer eNAT™- (Copan diagnostics Murrieta, CA) in a point-of-care diagnostic assay system.

Methods: We prospectively collected 84 sets of nasal swabs, oral swabs, and saliva, from 52 COVID-19 RT-PCR-confirmed patients, and nasopharyngeal (NP) swabs from 37 patients. Nasal swabs, oral swabs, and saliva were placed in either VTM or eNAT™, prior to testing with the Xpert Xpress SARS-CoV-2 (Xpert). The sensitivity of each sampling strategy was compared using a composite positive standard.

Results: Swab specimens collected in eNAT™ showed an overall superior sensitivity compared to swabs in VTM (70% vs 57%, P=0.0022). Direct saliva 90.5%, (95% CI: 82%, 95%), followed by NP swabs in VTM and saliva in eNAT™, was significantly more sensitive than nasal swabs in VTM (50%, P<0.001) or eNAT™ (67.8%, P=0.0012) and oral swabs in VTM (50%, P<0.0001) or eNAT™ (58%, P<0.0001). Saliva and use of eNAT™ buffer each increased detection of SARS-CoV-2 with the Xpert; however, no single sample matrix identified all positive cases.

Conclusion: Saliva and eNAT™ sterilizing buffer can enhance safe and sensitive detection of COVID using point-of-care GeneXpert instruments.

Running Head: Enhanced sampling for COVID-19 RT-PCR

Key words: Saliva, Nasal, Oral, eNAT™, Inactivation

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Abbreviations. Xpert, Xpert Xpress SARS-CoV-2 test; CLIA, Clinical Laboratory improvement Amendment; CT, cycle threshold; FDA, United States Food and Drug Administration; EUA, Emergency use authorization; RT-PCR, real-time polymerase chain reaction; VTM, universal viral transport medium; eNAT, eNAT™ commercial transport medium; NP, Nasopharyngeal; CI, confidence interval; SD, standard deviation.