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Introduction

Many studies have noted false negative SARS-CoV-2 RT-PCR tests, as high as 29%-41% [1-3]. Such inconsistency could result from variability in the duration of symptoms [4-6], type of sample e.g. NP, throat, deep endotracheal [5] as well as suboptimal collection or use of a less sensitive molecular test. We developed a 3D printed swab to cope with anticipated and subsequent actual shortages of commercial NP swabs. Two of the authors (KC and ML) collected both conventional and 3D swabs from 24 previously documented Coronavirus Disease 2019 (COVID-19) positive patients at the same time, eliminating many of the variables that might contribute to discordant results.

Methods

Patient population

Twenty-four patients admitted to the UF Health Shands hospital Gainesville, FL in March- April, 2020 known to have been positive for SARS-CoV-2 were tested by both conventional and 3D printed swabs. Four of these tested negative with both swab types, leaving a nal group of 20 who had at least one positive viral gene.

show the swabs during di erent stages of production.

Collection procedure

Collection personnel had extensive collection experience and collected both types at the same time using 1 nostril for each swab type. All were tested at the same time upon receipt in the laboratory without freezing. e 3D swabs were placed in Quest VCM (Diagnostic Hybrids, Athens, OH). e standard swab was the Copan FLOQSwabs® Copan Diagnostics, Murrieta, CA.

Laboratory testing

has a limit of detection of 500 copies/ml and detects RdRp, E and N genes, along with the human RNAse P gene as an Internal Control (IC). Cycling parameters and test methods were performed as described by EliTech a er onsite training.

Statistics

To test for overall statistical di erences between swab types, we used Fisher's Exact Test and for the paired net di erence in Cts both the Mann-Whitney U test and t-test. Standard Deviations (SDs) were

8QLYHUVLW\ RI)ORULGD *DLQHVYLOOH 86$ (PDLO

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each of the viral genes for each swab type was signi cantly larger than those for the comparable internal control genes, p<0.00001.

For each swab pair that detected a viral gene and the internal control gene, paired net di erences in Ct between the 2 swab types was calculated and is shown graphically in (Figures 2A-2C). ere is clearly a great deal more variability in the absolute value of the viral genes paired di erences than for the IC: RdRp gene vs. IC gene, p=0.01598 by t test, E gene p=0.01133 and N gene p=0.01827 (Figures 2A-2C). In addition for the viral genes that were detected Ct values di ered by >10 fold for the N gene between the swab types for 10/20 (50%) vs. 1/20 (5%) for the human RNAse P internal control gene (p=0.0033, Fisher's Exact Test); comparable values for the RdRp gene vs. IC gene, p=0.0039 and for the E gene, p=0.0119.

Figures 3A and 3B show scatter gram plots for the correlation of all viral gene vs internal control gene Cts within each swab type compared with the same plot between swab types, Figure 3C. e correlation