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Saliva as an Alternate Specimen Source for Detection of SARS-CoV-2 in Symptomatic Patients Using Cepheid Xpert Xpress SARS-CoV-2

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Among the many facets of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic is the unprecedented pressure it has placed on different points of the supply chain for hospital systems worldwide, such as collection devices for the diagnosis of COVID-19. The emergency use authorization of most of the commonly used platforms for SARS-CoV-2 testing is approved for nasopharyngeal swab (NPS) specimens. However, with the increasing need for alternative sources due to the NPS shortage, our institution sought to validate saliva specimens for the diagnosis of COVID-19 using the Cepheid Xpert Xpress SARS-CoV-2 (Sunnyvale, CA) PCR test. The Xpert SARS-CoV-2 assay is a sample-to-answer real-time reverse transcriptase PCR (RT-PCR) test with a run time of approximately 30 to 51 minutes (1). There are two targets, E and N2; the detection of both targets or N2 alone is considered positive, and the detection of E alone is considered presumptive positive.

We compared our test samples with NPS specimens using 3 ml universal transport media (UTM) (Becton, Dickinson and Company, Franklin Lakes, NJ) with unpreserved saliva collected in the emergency department (ED) and from patients in a COVID-positive hospital unit. The specimens were collected prospectively in the ED, when a patient with suspected COVID-19 was being investigated, following institutional and national guidelines for testing (2) or randomly in the hospital COVID unit from patients not requiring mechanical ventilation. Education to the ED nursing staff and the nurses on the COVID unit was disseminated to encourage saliva, not sputum, collection. Also, it was highly recommended that patients did not have any food, drink, tobacco, or gum for 30 minutes prior to collection. Saliva was collected in sterile urine cups or sterile 50-ml conical tubes. Five milliliters of saliva was requested; however, specimens were considered acceptable if approximately 1 ml of saliva was submitted. Once specimens were collected, they were labeled with demographic information, double-bagged, and submitted to the laboratory through the pneumatic tube system. The liquid, nonviscous components of each specimen were drawn into the disposable pipettes (300 μl) issued with Xpert SARS-CoV-2 cartridges and directly inoculated and run according to the manufacturer's instructions (1). The NPS specimens were collected in the standard fashion, and similarly, testing was performed according to the manufacturer's instructions. All NPS samples were tested on demand. The saliva samples were held at 2°C to 8°C for up to 12 h prior to testing (validation of saliva was performed on first shift only).

A total of 156 paired NPS and saliva specimens were tested. The overall positivity was 50/156 (32.1%); the average age was 47.8 years old with a male/female (M/F) ratio of 90/66. The community rate of positivity during the week of collection was 11.1% (3). A total of 153/156 (98%; 95% confidence interval [CI], 94.48% to 99.60%) samples were

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TABLE 1 Xpert Xpress SARS-CoV-2 PCR assay results of nasopharyngeal and saliva specimens[a]

	Results (C_T) by target			
	E		N2	
Specimen type	Avg ± SD[b]	Range	Avg ± SD[c]	Range
Nasopharyngeal	23.83 ± 7.78	0–37.5	26.70 ± 7.61	0–42.2
Saliva	26.10 ± 11.20	0–41.1	30.40 ± 9.67	0–41.4

[a]$n = 50$.
[b]Comparison of specimen type, $P = 0.21$.
[c]Comparison of specimen type, $P = 0.73$.

in overall agreement. Also, 47/49 samples were positive in saliva compared with the NPS, resulting in a positive percent agreement of 96% (95% CI, 86.02% to 99.5%). A total of 105/106 samples had a negative saliva and NPS result. A single sample demonstrated detectable levels of SARS-CoV-2 nucleic acid in the saliva, but the NPS was negative (1/106), resulting in a negative percent agreement of 99% (95% CI, 94.86% to 99.98%). The average cycle threshold values are summarized and compared in Table 1.

We conclude that saliva is an acceptable alternative source for detecting SARS-CoV-2 nucleic acids. Another advantage to saliva versus NPS is that the process to collect saliva is noninvasive, and a patient, with education and coaching, could self-collect the specimen. These differences could reduce the risk to health care workers, decrease personal protective equipment usage, and provide less discomfort to patients during collection. Furthermore, an important preanalytical variable for SARS-CoV-2 testing is proper nasopharyngeal collection which may have been a contributing factor for the discrepant saliva positive/nasopharyngeal swab negative sample. Because saliva has excellent agreement with NPS in UTM, saliva could potentially be used for the diagnosis of COVID-19 in symptomatic patients using the Cepheid Xpert Xpress SARS-CoV-2 PCR test.

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