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Comparison of next generation diagnostic systems (NGDS) for the detection of SARS-CoV-2

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Abstract

Introduction: The World Health Organization (WHO) declared coronavirus disease 2019 (COVID-19) a pandemic in March 2020. Initially, supply chain disruptions and increased demand for testing led to shortages of critical laboratory reagents and inadequate testing capacity. Thus, alternative means of biosample collection and testing were essential to overcome these obstacles and reduce viral transmission. This study aimed to 1) compare the sensitivity and specificity of Cepheid GeneXpert® IV and BioFire® FilmArray® 2.0 next generation detection systems to detect SARS-CoV-2, 2) evaluate the performance of both platforms using different biospecimen types, and 3) assess saline as an alternative to viral transport media (VTM) for sample collection.

Methods: A total of 1,080 specimens consisting of nasopharyngeal (NP) swabs in VTM, NP swabs in saline, nasal swabs, oropharyngeal (OP) swabs, and saliva were collected from 216 enrollees. Limit of detection (LoD) assays, NP VTM and NP saline concordance, and saliva testing were performed on the BioFire® FilmArray® 2.0 Respiratory Panel 2.1 and Cepheid GeneXpert® Xpress SARS-CoV-2/Flu/RSV assays.

Results: LoD and comparative testing demonstrated increased sensitivity with the Cepheid compared with the BioFire® in detecting SARS-CoV-2 in NP VTM and saline, nasal, and OP swabs. Conversely, saliva testing on the Cepheid showed statistically significant lower sensitivity compared to the BioFire®. Finally, NP swabs in saline showed no significant difference compared with NP swabs in VTM on both platforms.

Conclusion: The Cepheid and BioFire® NGDS are viable options to address a variety of public health needs providing rapid and reliable, point-of-care testing using a variety of clinical matrices.

KEYWORDS
BioFire, biospecimen, Cepheid, COVID-19, next generation detection systems, SARS-CoV-2

1 | INTRODUCTION

In late 2019, a novel respiratory pathogen appeared in Wuhan city, Hubei province, China with symptoms resembling both influenza and pneumonia.[1,2] Initial sequencing determined that the etiological respiratory agent was a new virus of the genus *Betacoronavirus*, within the family *Coronaviridae*,[3] subsequently named Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). By March of 2020, the World Health Organization (WHO) declared COVID-19 a pandemic, and as of October 28, 2021, SARS-CoV-2 has infected 245 million people worldwide and claimed 4.97 million lives. As a result, world governments have implemented public health mitigation strategies (i.e., lockdowns, social distancing, and mask mandates) along with rapid diagnostic testing systems to accurately detect, isolate, and trace infected individuals to help slow the spread of COVID-19.

Initial diagnostic testing for SARS-CoV-2 relied on the use of real-time polymerase chain reaction (RT-PCR) as the gold standard; however, early on delayed testing times and availability of laboratory supplies were inadequate to meet testing demands. Specifically, typical RT-PCR requires 1–2 days from sample collection to results leading to long delays in public health interventions and increasing person-to-person viral spread.[4] Furthermore, global supply chain disruptions adversely impacted the availability of testing kits, viral transport media (VTM), nasopharyngeal (NP) collection swabs, and general laboratory supplies. Consequently, the U.S. Food and Drug Administration (FDA), through the Emergency Use Authorization (EUA) process, worked quickly to approve new diagnostic platforms and systems with faster turnaround times.[5,6] Various EUA requests included modifications of previously FDA-approved assays for respiratory infections, such as the addition of specific SARS-CoV-2 molecular targets. However, only a few of the EUA-approved systems addressed the critical supply shortages brought upon by the pandemic, including the significant reliance on NP sampling and VTM.

To overcome supply chain obstacles and improve turnaround times, many healthcare systems including the military began relying on the use of next generation diagnostic systems (NGDS) for infectious disease testing and surveillance. A significant benefit from the use of these systems is the reduced use of reagents and samples due to the integrated sample processing. Within the military health system (MHS), two NGDS have been previously used for the detection of upper respiratory pathogens and are currently used for SARS-CoV-2: the BioFire® FilmArray® 2.0 and Cepheid GeneXpert®. The BioFire® FilmArray® 2.0 system uses the FimArray® Respiratory Panel 2.1 (RP2.1), which can detect 22 respiratory pathogens including SARS-CoV-2 in as little as 45 min while the Cepheid GeneXpert® uses the Xpress SARS-CoV-2/Flu/RSV assay and detects SARS-CoV-2 in 25 min.

The purpose of the current study was to 1) determine whether the BioFire® FilmArray® RP 2.1 and Cepheid Xpert® SARS-CoV-2\Flu\RSV assays were comparable at detecting SARS-CoV-2 in clinical upper respiratory tract samples, 2) perform an independent validation of their limit of detection of these assays, and 3) assess
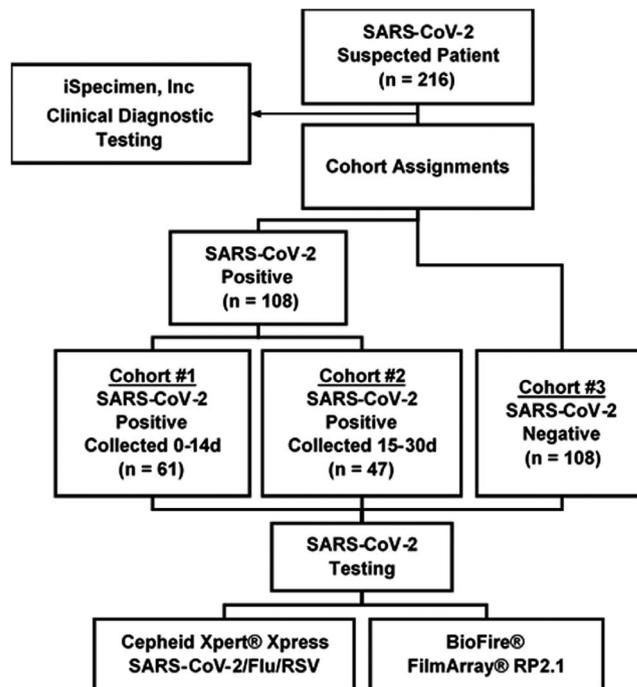
FIGURE 1 Overview of Study Design. Participants were assigned to each cohort according to the initial clinical RT-PCR test

clinical sample concordance as specified by their respective EUAs. Additionally, BioFire® RP2.1 and Cepheid SARS-CoV-2/Flu/RSV panels were used to compare four upper respiratory biospecimen collection sites as well as the use of saline as an alternative transport medium to the previously validated nasopharyngeal (NP) swab in VTM.

2 | MATERIALS AND METHODS

2.1 | Study design and sample processing

A total of 1080 specimens were collected from 216 enrollees, who were recruited by iSpecimen, Inc. under an Institutional Review Board (IRB) approved protocol; and consented to submit five separate specimens from four upper respiratory tract locations. This study was determined to be exempt from research regulation 32 CFR 219 regarding the protection of human subjects Category 4 [32 CFR 219.104(d)[4]] by the 59th MDW Institutional Review Board (IRB) Chairperson or designee via the exempt review/determination process. The overview of the study design is shown in Figure 1. The specimen types collected included a nasal swab, an oropharyngeal (OP) swab in VTM, a saliva sample, and two NP swabs, stored in either VTM or saline. After collection, samples were shipped overnight on dry ice and then stored at −80°C until time of testing. On the day of testing, all samples were thawed at 4°C and tested with BioFire® RP2.1 pouches. The following day, samples were tested using the GeneXpert system and Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV cartridges. Sample testing with both assays was

completed in accordance with each company's instructions for use (IFU).

2.2 | Limit of detection testing

Previously identified SARS-CoV-2 negative samples were pooled and tested by RT-PCR. After confirmation of negativity, samples were spiked with known concentrations of SARS-CoV-2 viral RNA. Concentrations ranged from 50 to 150 copies/ml for the Cepheid Xpert® SARS-CoV-2/Flu/RSV assay and 150–500 copies/ml for the RP2.1 testing.

2.3 | BioFire® FilmArray® RP2.1 and Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV (4-in-1) assays

The BioFire® FilmArray® System Respiratory Panel 2.1 (RP2.1; BioFire® Diagnostics, LLC) contains integrated lyophilized reagents which include primer sets for 22 upper respiratory tract pathogens. The closed pouch system has all the necessary reagents on-board for automated sample preparation and pathogen detection by RT-PCR. Specifically, RP2.1 targets the SARS-CoV-2 Spike (S) and membrane (M) proteins (Table 1). A sample is considered positive for SARS-CoV-2 when either one or both proteins are detected. According to the IFU provided by the manufacturer as part of the EUA approval, the RP2.1 positive percent agreement (PPA) was determined to be 98% and the negative percent agreement (NPA) was 100% in archived specimens.

Similarly, the Cepheid GeneXpert® Xpert® SARS-CoV-2/Flu/RSV assay (Cepheid) is fully automated and based on cartridge technology with all the reagents on-board for a completely hands-off workflow that integrates sample preparation, nucleic acid extraction, amplification, and detection of respiratory viruses in nasopharyngeal, mid-turbinate, and nasal swabs. Unlike the RP2.1, the Xpert® SARS-CoV-2/Flu/RSV assay can only simultaneously detect three common upper respiratory pathogens (influenza A, B, and respiratory syncytial virus) in addition to SARS-CoV-2. The specific integrated primers for SARS-CoV-2 proteins target the nucleocapsid (N) and the envelope protein (E) (Table 1). The EUA IFU for Xpert® SARS-CoV-2/Flu/RSV assay states a PPA of 97.9% and a NPA of 100.0% in archived samples.

2.4 | Concordance between nasopharyngeal (NP) swab transport media types

Differences in SARS-CoV-2 detection between the two transport media types (VTM and saline) used for NP swabs were determined. A regression analysis was conducted to compare the cycle threshold (C_t) values from NP swabs diluted in VTM to NP swabs diluted in saline. The comparative analysis was limited to SARS-CoV-2 positive samples detected by the Cepheid Xpert® SARS-CoV-2/Flu/RSV assay because SARS-CoV-2 negative samples and BioFire® FilmArray® system do not produce a C_t value.

2.5 | SARS-CoV-2 detection in saliva samples before and after centrifugation

Given that saliva had not been validated as a sample type for SARS-CoV-2 detection by either the Cepheid or BioFire® assays at the time of our testing and is known to contain cellular debris, we evaluated whether sample centrifugation to remove cellular debris reduced SARS-CoV-2 detection. C_t values from saliva samples evaluated before centrifugation were compared to those obtained from identical samples which were not centrifuged.

2.6 | Data analyses

Statistical analyses were performed using R version 4.0.3 and the R packages "epiR" and "fmsb." For comparative analyses between platforms and between sample types, we used Cohen's kappa statistics to estimate agreement and test the null hypothesis that agreement was random (i.e., kappa statistic equals zero).[7] McNemar's chi-square test was used to test the null hypothesis that the platforms are equivalent in terms of sensitivity and specificity.[8]

As a result of the recruitment plan for this study, there was a time lag between initial RT-PCR Clinical Laboratory Improvement Amendment (CLIA) testing and sample collection. For comparative analyses, a Welch two-sample t test was used to test the null hypothesis of no difference in the number of days between CLIA testing and sample collection (lag time) between concordant positive results and discordant results. A Welch two-sample t test was also used to test the null hypothesis of no difference between Cepheid C_t values between

TABLE 1 Comparison of two diagnostic tests for the detection of SARS-CoV-2

Brand name	EUA-validated Sample types	Assay run time (min)	Sample volume (µl)	Analytical sensitivity per IFU	SARS-CoV–2 Targets
Cepheid Xpert® Xpress	NP VTM, NW/A[a], NS[a]	25	300	131 copies/ml	E & N2
BioFire® FilmArray®	NP-VTM	45	300	500 copies/ml	S & M

Abbreviations: E, Envelope; Flu, influenza; IFU, instructions for use; M, membrane protein gene; N2, nucleocaspid; RP2.1, respiratory panel 2.1; RSV, respiratory syncytial virus; RT-PCR, reverse transcriptase polymerase chain reaction; S, Spike protein gene.

[a]Nasal wash/aspirate and nasal swab sample performance has not been assessed or established by company as per IFU.

concordant positive samples and discordant samples which were positive on the Cepheid, but negative on the BioFire®. We encoded "detected" and "not detected" as 1 and 0, respectively, and used locally weighted scatterplot smoothing implemented within the loss.

Smooth R function with an alpha of 0.1 to visually evaluate the relationship between the percentage of samples that tested positive and the length of time that passed between positive CLIA testing and sample collection.

Linear regression and visual interpretation of scatter plots were used to understand the relationship between C_t values before and after centrifugation of saliva samples. A paired t test was used to test the null hypothesis of no difference in the mean C_t values before and after centrifugation.

3 | RESULTS

3.1 | Cohort recruitment and assignment

iSpecimen, Inc. recruited and consented 216 study participants between November 6, 2020, and January 7, 2021, at three sites located in California, New Jersey, and New York. Each study participant provided nasal and OP swabs, two NP swabs, and a saliva sample. For the evaluation of the effects of transport media on SARS-CoV-2 detection, the two NP swabs were stored and transported in either VTM or saline, individually. The age and sex information for the study participants is shown in Table 2.

Based on the results of an initial CLIA SARS-CoV-2 RT-PCR test, study participants were placed into one of three cohorts. Cohort 1 consisted of SARS-CoV-2 positive enrollees, who were instructed to submit their samples between the day of RT-PCR testing and up to 14 days thereafter. Cohort 2 was also SARS-CoV-2 positive, but these enrollees were asked to submit samples from 15 to 30 days after initial RT-PCR testing. The final cohort group consisted of SARS-CoV-2 negative individuals, who donated samples up to 30 days after RT-PCR testing.

Figure 2 depicts the percent of samples from cohorts 1 and 2 that tested positive for SARS-CoV-2 on the BioFire® RP2.1 post-CLIA testing. As expected, 100% of all biological samples tested positive for SARS-CoV-2 when collection was done soon after CLIA testing. The percentage of SARS-CoV-2 positive samples began to decline as more time passed between the initial positive CLIA testing and the day of sample collection.

3.2 | Limit of detection testing

Table 3 depicts the range of known viral concentrations used to estimate the LoD for each diagnostic testing platform. The lowest viral concentration with a positivity rate of ≥99% was observed at 387.5 copies/ml for the BioFire® FilmArray® RP2.1 and 81 copies/ml for the Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV assay. In comparison, each company reported a LOD of 500 copies/ml and 131 copies/ml, respectively.

3.3 | NGDS comparative testing

BioFire® FilmArray® RP2.1 and Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV diagnostic platforms are not intended to be quantitative tests, results are reported qualitatively as either "detected" or "not detected" indicating SARS-CoV-2 presence. Table 4 summarizes the results of comparative testing of both platforms in different sample types. Kappa statistics indicate "nearly perfect correlation" for nasal swab, NP swabs in either VTM or saline, and OP swabs, and "substantial agreement" for saliva samples.

The Cepheid and BioFire® platforms were non-equivalent in sensitivity at detecting SARS-CoV-2 in nasal swabs ($p = 0.004$; McNemar test) and NP swabs in VTM ($p = 0.002$; McNemar test). Nine of 10 nasal swabs and 12 of 15 nasopharyngeal swabs in VTM with discordant results were from the CLIA positive group. Most discordant results were detected by the Cepheid compared with the BioFire®; all 10 discordant results from nasal swabs and 14 of 15 discordant results from NP swabs. Furthermore, the mean C_t values

TABLE 2 Participant demographics

	Sex		
	Male (n = 98)	Female (n = 118)	All (N = 216)
Age (Mean ±SD)	49 (19.2)	48 (15.5)	48 (15.6)
Range	21–80	20–75	20–80

Abbreviation: SD, standard deviation.
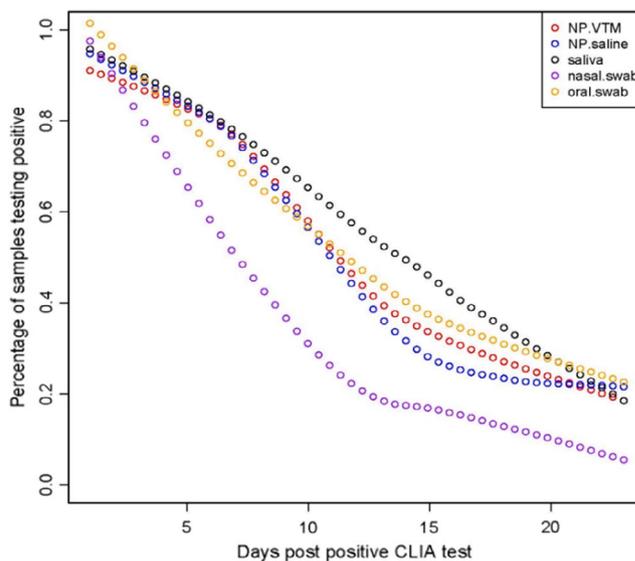
FIGURE 2 Analysis of the time-lag effect on positivity in respiratory samples. The graph shows the frequency of samples testing positive in relation to an interval of time following a previous positive COVID-19 PCR test. The study estimate is that the time gap caused a decline in the percentage of tests reported as positive by the RP2.1 test. Abbreviations: NP VTM, nasopharyngeal swab in VTM; NP saline, nasopharyngeal swab in saline; oral swab, oropharyngeal swab in VTM; CLIA, Clinical Laboratory Improvement Amendments

for the samples that were positive on the Cepheid and negative on the BioFire® were higher on average (mean nasal swab C_t =42.34; mean NP swab VTM C_t =40.32) than the samples that were concordant positive (mean nasal wash C_t =30.98; mean NP swab VTM C_t =30.68). These differences were statistically significant (nasal swab $p < 2.2 \times 10^{-16}$; NP swab VTM $p = 8.18 \times 10^{-11}$).

3.4 | Saliva comparative testing

Initial testing using saliva samples led to the qualitative observation that the Cepheid platform was detecting fewer SARS-CoV-2 positive samples compared with the BioFire®. It was hypothesized that cellular debris in saliva samples was interfering with the performance of this platform. To test this hypothesis, saliva samples used for the Cepheid were briefly centrifuged to sediment cellular debris and re-analyzed. As shown in Figure 3 C_t values of SARS-CoV-2 detection from Cepheid were strongly correlated before and after centrifugation. A paired t test indicated that the effect of centrifugation on C_t values (mean [95% CI] = −1.047 [−0.35, 2.44]) was not statistically significant ($p = 0.14$). Furthermore, five additional samples that tested negative before centrifugation tested positive after centrifugation. Kappa statistics indicated "substantial agreement" for saliva. However, the Cepheid and BioFire® platforms were non-equivalent for saliva (Table 4, $p = 3.0 \times 10^{-5}$; McNemar test). 19/23 saliva samples with discordant results were from the CLIA positive group, with 22 discordant results detected by the BioFire®, but not the Cepheid.

3.5 | Comparative analysis of transport matrices for SARS-CoV-2 detection

The initial shortages in VTM availability at the beginning of the pandemic highlighted the need to validate additional transport matrices. Thus, we compared SARS-CoV-2 detection in NP swabs stored and transported in either VTM or saline. On the Xpert® SARS-CoV-2/

Flu/RSV assay, Kappa statistic (k = 0.82) indicated "nearly perfect agreement" between nasopharyngeal samples stored and transported in saline and VTM (Table 5). The results using saline were non-inferior to VTM ($p = 0.10$; McNemar test). There was a relatively high PPA of 84% (95% CI, 74%–91%) and NPA of 96% (95% CI, 91%–99%) between NP swabs diluted in VTM and saline. On the BioFire® FilmArray® RP2.1, Kappa statistic (k = 0.75) indicated "substantial agreement" between nasopharyngeal samples stored and transported in saline and VTM. The results using saline were non-inferior to VTM ($p = 0.67$; McNemar test). Lastly, there was a relatively high PPA of 81% (95% CI, 70%–89%) and NPA of 93% (95% CI, 88%–97%) between NP swabs diluted in VTM and Saline (Table 5).

4 | DISCUSSION

The current study demonstrates the utility of using upper respiratory tract specimen types other than NP swabs in VTM, the gold standard, as well as NGDS to accurately and quickly detect SARS-CoV-2. Early on in the pandemic, testing procedures relied only on the use of NP swabs transported in VTM.[9] As NP collection is inherently uncomfortable it may be likely to deter some individuals from being tested.[9] Therefore, the validation of additional upper respiratory specimens could circumvent the need for healthcare workers to rely solely on NP swabs in VTM, not only overcoming patient hesitancy but also future supply shortages.

Results from both the BioFire® RP2.1 and Cepheid Xpert® SARS-CoV-2/Flu/RSV assays, using specimen types not currently validated for testing such as nasal swabs, OP swabs, and saliva yield estimates for PPA and PNA that ranged between 70% and 100%. These estimates provide evidence that alternative respiratory sample matrices can serve as acceptable candidate specimens for SARS-CoV-2 testing. Additionally, given that some VTM formulations have been reported to yield false negative results we addressed the practicality of using saline as an alternative medium to transport NP swabs.[10,11] We found no difference in SARS-CoV-2

TABLE 3 Analytical limits of detections for NGDS SARS-CoV-2 assays

Cepheid Xpert® Xpress SARS-CoV–2/Flu/RSV[a]			BioFire® FilmArray® RP2.1[b]		
Dilution	Copies/ml	No. of replicates detected/total replicates	Dilution	Copies/ml	No. of replicates detected/total replicates
3.0×10^{-2}	150	6/6	1.2×10^{-1}	500	6/6
2.0×10^{-2}	100	6/6	1.0×10^{-1}	425	6/6
1.8×10^{-2}	88	6/6	9.2×10^{-2}	387.5	6/6
1.6×10^{-2}	81	6/6	8.3×10^{-2}	350	5/6
1.5×10^{-2}	75	5/6	6.0×10^{-2}	250	4/6
1×10^{-2}	50	3/6	3.6×10^{-2}	150	4/6
NC	0	0/6	NC	0	0/6

Abbreviations: Flu, influenza; NC, negative control; No., number; RP2.1, respiratory panel 2.1; RSV, respiratory syncytial virus.
[a]SeraCare AccuPlex SARS-CoV-2 Reference Material Kit # 0505–0126.
[b]ATCC Heat-inactivated SARS-CoV-2 strain 2019-nCoV/USA-WA1/2020 # VR-1986HK.

TABLE 4 Comparison of two NGDS for detection of SARS-CoV-2 in different biospecimen types

Specimen Type	"Detected" RP2.1/4plex	"Detected" RP2.1 only	"Detected" 4plex only	"Not Detected" RP2.1/4plex	PPA [95% CI]	NPA [95% CI]	Cohen's κ [95% CI] (p-value)	McNemar test p-value
NS	52	10	0	154	1.00 [0.93, 1.00]	0.94 [0.89, 0.97]	0.881 [0.81, 0.95] (<2.2e-16)	0.004427
NP-S	62	3	11	136	0.95 [0.87, 0.99]	0.93 [0.87, 0.96]	0.852 [0.77, 0.93] (<2.2e-16)	0.06137
NP-V	67	1	14	134	0.99 [0.92, 1.00]	0.91 [0.85, 095]	0.847 [0.77, 0.92] (<2.2e-16)	0.001946
OP	65	3	8	140	0.96 [0.88, 0.99]	0.95 [0.90, 0.98]	0.884 [0.82, 0.95] (<2.2e-16)	0.2278
Saliva	53	22	1	119	0.71 [0.59, 0.81]	0.99 [0.95, 1.00]	0.737 [0.64, 0.84] (<2.2e-16)	3.04e-05

Abbreviations: 4plex, Cepheid Xpert Xpert SARS-CoV-2/Flu/RSV; NP, nasopharyngeal; NPA, negative percent agreement; NS, nasal swab; OP, oropharyngeal; PPA, positive percent agreement; RP2.1, BioFire® Respiratory panel 2.1.
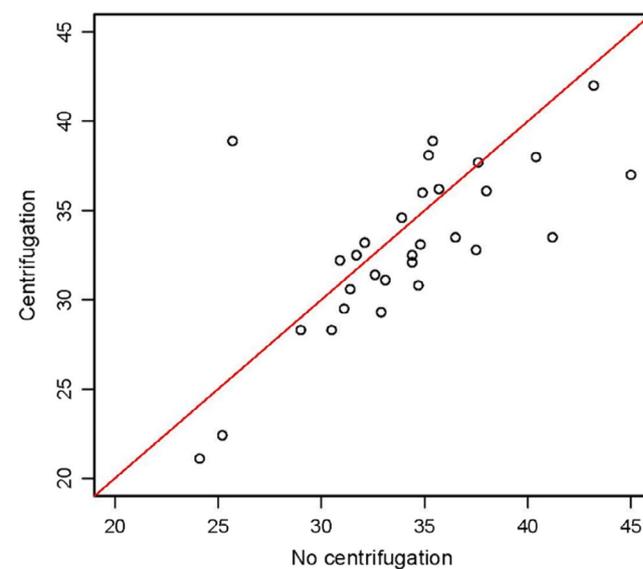
detection in NP swabs transported in either saline or VTM. We observed a high positive and negative concordance between the two transport matrices suggesting that both media types are equally viable options for collection of nasopharyngeal samples for SARS-CoV-2 testing.

We also evaluated the utility of using saliva as a suitable sample type for diagnostic testing of individuals experiencing symptoms of COVID-19. One impediment to the use of saliva for clinical testing is the additional centrifugation step may prove difficult or unsuitable in rural testing sites, at home, or in austere environments. Nagura-Ikeda et al suggested that results using saliva can be highly variable and that better processing techniques may improve testing sensitivity.[12] As such, we wanted to determine whether the centrifugation of cellular debris increased the detectability of SARS-CoV-2 in clinical samples as has been reported by others.[13] Interestingly, our data showed no significant difference when using saliva samples with and without a centrifugation step prior to testing. Our results support previous studies proposing saliva as a candidate clinical specimen for the detection of SARS-CoV-2.[14,15]

One limitation of this study is that biological samples were not collected at the time of CLIA laboratory testing. Indeed, we observed a sharp decline in SARS-CoV-2 positivity rates when there was more time between CLIA testing and that of sample collection suggesting that SARS-CoV-2 positive study participants mounted an innate and/or adaptive immune response to clear the virus from their system. As a result, the positive samples collected for this study may be enriched for SARS-CoV-2 viral loads near or below the limit of detection for the devices compared to clinical samples from studies in which samples are collected on the same day that

FIGURE 3 Effect of centrifugation on the detection of SARS-CoV-2 in saliva. The C_t values shown were produced on the Cepheid Xpert SARS-CoV-2/Flu/RSV test and characterized specimens before (x-axis) and after (y-axis) centrifugation. The effect of centrifugation on C_t value, was not statistically significant ($p = 0.14$)

TABLE 5 Comparison of two transport media for the detection of SARS-CoV-2

Test method	"Detected" VTM/Saline	"Detected" Saline only	"Detected" VTM only	"Not detected" VTM/Saline	PPA [95% CI]	NPA [95% CI]	Cohen's κ [95% CI] (p-value)	McNemar test p-value
BioFire® RP2.1	55	10	13	138	0.81 [0.70, 0.89]	0.93 [0.88, 0.97]	0.750 [0.65, 0.85] (<2.2e−16)	0.6767
Cepheid Xpert®	68	5	13	126	0.84 [0.74, 0.91]	0.96 [0.91, 0.99]	0.817 [0.74, 0.90] (<2.2e−16)	0.09896

Note: Transport media does not affect SARS-CoV-2 detection in nasopharyngeal swabs. Nasopharyngeal swabs were diluted in either VTM or saline and were tested on the BioFire® RP2.1 and Cepheid Xpert® SARS-CoV-2/Flu/RSV assays.

Abbreviations: NPA, negative percent agreement; PPA, positive percent agreement; RP2.1, respiratory panel 2.1; VTM, viral transport media.

participants present to the clinic. Thus, estimates of PPA in this study are conservative.

The high sensitivity of both the BioFire® FilmArray® RP2.1 and the Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV assays reported in this study correspond with results provided within the EUA from both manufacturers. These two multiplex PCR devices offer a rapid and easy-to-operate molecular diagnostic option for both point-of-care settings where frequent COVID-19 testing is desired. Our study suggests that efforts to reprocess existing FDA-approved assays for the purpose of mounting an immediate public health response to emerging pathogens can be an effective tool amidst an on-going pandemic.

5 | CONCLUSION

The COVID-19 pandemic altered how the world reacts to a highly transmissible RNA virus, including producing highly effective deployable, diagnostic tests to help curb spread of the novel virus. This study has shown that both the BioFire® FilmArray® RP2.1 and Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV assays serve as ideal candidates for rapid testing and reliable detection of SARS-CoV-2 in a variety of clinical matrices.

CONFLICT OF INTEREST

The authors have nothing to disclose.

AUTHOR CONTRIBUTION

T.T.Y. and S.N.A. designed the study. A.O.S., S.N.A., J.S.M., and A.N.B. wrote the first draft of the article. A.O.S. and S.N.A. validated the data. A.N.B. conducted the statistical analyses of the data. A.O.S., A.R.O., C.R.V., S.L.H., and R.E.M. performed testing of the clinical samples. All authors edited, reviewed, and approved the final version of the article.

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