JIDC | THE JOURNAL OF INFECTION IN DEVELOPING COUNTRIES

Coronavirus Pandemic

Comparative evaluation of a novel saliva collection strip and nasopharyngeal swab for SARS-CoV-2 validated by in-house RT-qPCR

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Abstract

Introduction: The most commonly used sample collection method for detecting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is nasopharyngeal swab; however, sample collection, especially from pediatric patients, is difficult. Therefore, the aim of this study was to design a saliva collection strip and to compare the effectiveness of this strip with the nasopharyngeal swab. Additionally, the performance of different isolation procedures before real time quantitative polymerase chain reaction (RT-qPCR) were investigated and an in-house RT-qPCR assay was developed.

Methodology: A total of 200 samples was collected from patients and 92 samples were confirmed as SARS-CoV-2 positive. In the first technique, nucleic acid from the samples were isolated using different isolation methods, and then analyzed by RT-qPCR. In the second technique, the samples were analyzed directly by RT-qPCR without any isolation process. Additionally, in-house RT-qPCR assay was performed and the results were compared with conventional RT-qPCR.

Results: The cycle threshold (Ct) values were compared between the techniques, and very similar results were obtained with all of the methods. This reveals that both sample collection methods, both isolation methods, and both RT-qPCR assays had comparable accuracy.

Conclusions: In this study, in-house optimization, validation, and integration of the SARS-CoV-2 assay with both isolation-based and extraction (direct lysis) workflows were compared. In addition, its compatibility with the newly designed saliva strip collection system was analyzed. Very similar results were obtained from all of the methods. Therefore, the sample collection strip and in-house assay can be useful tools for detecting SARS-CoV-2.

Key words: nasopharyngeal; swab; respiratory; saliva, sample collection strips; SARS-CoV-2.

J Infect Dev Ctries 2026; 20(8):1114-1121. doi:10.3855/jidc.22270

(Received 26 August 2025 – Accepted 18 January 2026)

Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was identified in December 2019 following an outbreak of acute respiratory tract infections in Wuhan, China; and rapidly spread worldwide, resulting in a global pandemic. SARS-CoV-2 is the causative agent of coronavirus disease 2019 (COVID-19), which may present with a broad clinical spectrum ranging from asymptomatic infection to severe pneumonia and respiratory failure [1]. Prior to the emergence of SARS-CoV-2, two zoonotic coronaviruses of animal origin—severe acute respiratory syndrome coronavirus (SARS-CoV), identified in 2002; and Middle East respiratory syndrome coronavirus (MERS-CoV), reported in 2012—were recognized as the first coronaviruses causing disease in humans, both being associated with high morbidity and mortality [2,3].

The primary route of SARS-CoV-2 transmission involves respiratory droplets and saliva-derived aerosols generated during coughing, sneezing, speaking, and normal breathing [4,5]. These particles may remain suspended in the air, particularly in enclosed and poorly ventilated environments, thereby facilitating person-to-person transmission [6]. Accordingly, saliva is considered both a key biological component in viral dissemination and a clinically relevant diagnostic specimen [7].

Clinical specimens used for the laboratory diagnosis of SARS-CoV-2 include nasopharyngeal swabs, saliva, sputum, bronchoalveolar lavage (BAL), and tracheal aspirates. Viral load distribution among these specimen types may vary depending on the stage of disease and clinical condition [8]. Although nasopharyngeal swabs are the most widely used specimen type in routine diagnostic algorithms, the diagnostic performance and feasibility of alternative specimen types have also been evaluated [9].

Nasopharyngeal swab sampling is an invasive procedure requiring accurate advancement of the swab

to the appropriate anatomical site. Reflex responses such as coughing and sneezing during sampling may increase the risk of viral exposure for the healthcare personnel. In addition, patient discomfort may compromise sample adequacy; particularly in pediatric patients, elderly individuals, and those with a history of nasal surgery; leading to false-negative results and the need for repeat sampling [10]. Furthermore, transportation of swab specimens in viral transport medium (VTM) carries inherent risks of leakage, contamination, and sample loss during handling and processing [11].

Real time quantitative polymerase chain reaction (RT-qPCR) is the reference method for the detection of SARS-CoV-2 infection [12]. RT-qPCR assays may be performed following RNA isolation or using extraction direct PCR approaches [13]. RNA isolation is commonly achieved using magnetic bead–based or spin column–based isolation methods. While RNA isolation enhances analytical sensitivity by removing inhibitory substances, it increases processing time and labor requirements [14]. In contrast, extraction direct RT-qPCR enables faster turnaround times and simplified workflows, making it particularly advantageous for high-throughput testing during pandemic conditions [13].

The aim of this study was to design and evaluate a novel saliva collection strip system for the detection of SARS-CoV-2 as a more practical and patient-friendly alternative to the routinely used nasopharyngeal swab sampling method, which presents several practical limitations, particularly in pediatric patients. In this study, the diagnostic performance of samples obtained using saliva collection strips was directly compared with that of nasopharyngeal swabs. To assess the applicability of the proposed system across different laboratory workflows, sample compatibility was evaluated using direct RT-qPCR following an extraction step limited to lysis only, as well as RT-qPCR following magnetic bead–based RNA isolation. Furthermore, an in-house RT-qPCR assay was used to enable an objective assessment of diagnostic performance independent of variability introduced by commercial assays.

Methodology

Patient selection

Clinical samples were collected from 200 patients with fever, musculoskeletal pain, respiratory distress, or upper respiratory tract symptoms. Ninety-two samples were confirmed as SARS-CoV-2 positive by routine diagnostic RT-qPCR testing. All collected samples were stored at – 20 °C until molecular analysis. This study was approved by the Samsun University Ethics Committee (OMU KAEK 2022/460–26.10.2022). Clinical samples were collected from children and adolescents aged between 2–18 years from October 2022 until January 2023.

Sample collection

The strips used in the sample collection system were prepared from nitrocellulose membranes. Three nitrocellulose strip types with pore diameters of 400 µm, 500 µm, and 600 µm were evaluated, and their water retention capacities were compared under standardized laboratory conditions. The membrane with 600 µm pore diameter was selected, as it demonstrated the highest absorption performance. This membrane had increased saliva absorption capacity, allowing the collection of a higher clinically relevant sample volume. Saliva samples were collected from the same patients using both nasopharyngeal swab and saliva collection strip methods.

The patients did not consume any food or liquid for at least 30 minutes prior to sample collection [15]. Standardized instructions regarding the correct use of the saliva collection strips were provided by healthcare personnel. During sampling, patients collected their saliva, after which the saliva collection strip was placed in the oral cavity and maintained for approximately 2 minutes. At the end of this period, the strips were transferred into sterile tubes and stored under appropriate conditions until molecular analysis.

The nasopharyngeal swab sampling, used as a reference method in clinical practice, was performed in accordance with the Centers for Disease Control and Prevention (CDC) guidelines for comparative purposes [16]. Following collection, nasopharyngeal swabs were placed in DiagnoVTM (Diagnotech, Istanbul, Türkiye). The VTM was formulated to preserve viral RNA integrity and to inhibit microbial growth during sample transport through the inclusion of buffered saline, stabilizing proteins, cryoprotectants, buffering agents, and antimicrobial components [12]. This formulation was used to stabilize clinical specimens for subsequent molecular analyses performed using extraction-based direct RT-qPCR, as well as RT-qPCR following magnetic bead-based RNA isolation.

Nucleic acid isolation and extraction

The clinical samples obtained from nasopharyngeal swabs and saliva collection strips were processed using two different viral nucleic acid isolation workflows. In the first workflow, the samples were analyzed using

RT-qPCR following extraction (lysis only). For the saliva collection strip samples, 500 µL of DiagnoVTM was added to each strip and vortexed for 10 seconds prior to analysis. Nasopharyngeal swab samples were transferred directly into DiagnoVTM at the time of collection and required no additional processing.

In the second workflow, magnetic bead–based RNA isolation was performed using the Diagnotech Viral Nucleic Acid Isolation Kit (Diagnotech, Istanbul, Türkiye). In accordance with the manufacturer's instructions, 200 µL of sample was used for both nasopharyngeal swab and saliva strip samples. The reagents included in the isolation kit were supplied pre-dispensed in deep-well plates. The procedure involved the sequential addition of 200 µL of sample to the lysis well, followed by addition of 15 µL of proteinase K and 350 µL of binding buffer. Nucleic acid isolation was completed using an automated magnetic bead–based system (GeneRotex 96 Nucleic Acid Extraction System, Xi'an Tianlong Science and Technology Co., Ltd., Shaanxi, China).

Accordingly, both nasopharyngeal swab and saliva strip samples were processed using RT-qPCR following extraction and RT-qPCR following magnetic bead–based RNA isolation, and the analytical performances of the two workflows were compared.

SARS-CoV-2 RT-qPCR analysis

Qualitative detection of SARS-CoV-2 was performed using an in-house developed RT-qPCR assay. The assay design was based on previously published primer–probe sequences reported in the literature [17]. In this study, three different primer–probe sets targeting the SARS-CoV-2 N1 genomic region together with an internal control targeting the human RNase P (RP) gene were selected and comparatively evaluated for performance.

Primer–probe performance was assessed under identical experimental conditions using a commercially available RT-qPCR kit. Evaluation criteria included amplification curve stability, cycle threshold (Ct) reproducibility, fluorescence signal intensity, and analytical specificity. Based on these comparative analyses, the primer–probe set recommended in the CDC 2019-nCoV Real-Time RT-qPCR protocol [17] demonstrated the most consistent and reliable performance, and was therefore used for all subsequent analytical and diagnostic evaluations in this study. The primer–probe sequences were listed in Table 1.

All primer–probe combinations, reaction components, and thermal cycling parameters were optimized during assay design. RT-qPCR reactions were prepared using the HiScript III One Step RT-qPCR Probe Kit (Vazyme, Nanjing, China) and were performed in a final reaction volume of 20 µL, consisting of One Step Mix, enzyme mix, primer–probe mix, and 5 µL of the processed sample.

Thermal cycling was carried out with a reverse transcription step at 55 °C for 15 minutes, followed by initial denaturation at 95 °C for 2 minutes, and 40 amplification cycles of 95 °C for 15 seconds and 60 °C for 30 seconds.

Analytical sensitivity, diagnostic sensitivity, and cross-reactivity

Analytical sensitivity, diagnostic sensitivity, and cross-reactivity assessments were conducted in accordance with in vitro diagnostic (IVD) performance evaluation principles. The reference materials were diluted at a 1:1 ratio in VTM for analytical and diagnostic sensitivity and cross-reactivity performance, to closely simulate clinical specimen conditions, including matrix effects, dilution dynamics, and potential transport-related inhibitory factors; and all experiments were performed using these VTM-diluted standards [18]. A human nasopharyngeal sample matrix was added to the reference materials to maintain diagnostic sensitivity and to allow evaluation of RNase P amplification signals under matrix-matched conditions.

Analytical sensitivity, expressed as the limit of detection (LoD), was determined using serial dilutions of the AccuPlex™ SARS-CoV-2 Reference Material Kit (Material No. 0505-0126; SeraCare Life Sciences, Milford, USA) [19], and the lowest detectable concentration was determined based on reproducible amplification across replicate measurements. Selected dilutions were additionally evaluated using the World Health Organization (WHO) First International SARS-CoV-2 RNA Standard (NIBSC code 20/146) spiked

Table 1. Primer–probe sequences used for SARS-CoV-2 RT-qPCR assay.

Primer-Probe	Sequence	Reference
2019-nCov_N1-Reverse	TCTGGTTACTGCCAGTTGAATCTG	
2019-nCov_N1-Forward	GACCCCAAAATCAGCGAAAT	[17]
2019-nCov_N1-Probe	**FAM**-ACCCCGCATTACGTTTGGTGGACC-**BHQ1**	
RP-Reverse	GAGCGGCTGTCTCCACAAGT	
RP-Forward	AGATTTGGACCTGCGAGCG	[17]
RP-Probe	**HEX**-TTCTGACCTGAAGGCTCTGCGCG-**BHQ1**	

into a human nasopharyngeal specimen matrix for comparison with an international reference [20]. All analytical experiments were performed using an extraction-based direct RT-qPCR workflow including only the lysis step. Diagnostic sensitivity was assessed using four serial dilutions of AccuPlex™ SARS-CoV-2 reference material (SeraCare Life Sciences, Milford, USA) spanning a range of viral loads in combination with 50 nasopharyngeal clinical samples previously confirmed as SARS-CoV-2 positive by a reference RT-qPCR assay, and no additional nucleic acid purification was performed during analysis. Cross-reactivity was evaluated to assess primer–probe specificity using a panel of non–SARS-CoV-2 respiratory viruses available in the laboratory, including human adenovirus (NIBSC 16/324), human parainfluenza virus type 1 (ATCC VR-94), human parainfluenza virus type 2 (ATCC VR-92), human parainfluenza virus type 3 (ATCC VR-93), human parainfluenza virus type 4 (ATCC VR-579), human metapneumovirus (ATCC VR-3250SD), enterovirus A71 (ATCC VR-1432), human betacoronavirus OC43 (ATCC VR-1558D), and Middle East respiratory syndrome coronavirus (MERS-CoV; ATCC VR-3248SD). The virus names and classifications were reported in accordance with the International Committee on Taxonomy of Viruses (ICTV) nomenclature standards.

Comparison of sample collection systems

All samples with measurable Ct values were analyzed using both magnetic bead–based nucleic acid isolation and direct extraction–based processing methods to compare the performance of the two processing strategies across nasopharyngeal swab and saliva collection strip specimens using commercial and in-house designed RT-qPCR assays.

Ct-based statistical analyses were performed exclusively on SARS-CoV-2–positive samples. Six comparisons were evaluated: (1) isolated swab-direct swab, (2) isolated strip-direct strip, (3) isolated swab-isolated strip, (4) direct swab-direct strip, (5) isolated swab-direct strip, and (6) mean swab-mean strip.

Statistical analysis

All statistical analyses were performed using the IBM SPSS Statistics software (version 25.0; IBM Corp., Armonk, NY, USA). Normality of data distributions was assessed using the Shapiro–Wilk test, and non-parametric statistical methods were applied when distributional assumptions were not met. Group comparisons were analyzed by the Mann–Whitney U test and Pearson correlation coefficient [21]. p value < 0.05 was considered as statistically significant.

Results

SARS-CoV-2 RT-qPCR analysis

The performance of the three evaluated primer–probe sets targeting the SARS-CoV-2 N1 genomic region and the RNase P internal control was assessed under identical experimental conditions. One primer–probe set demonstrated superior analytical performance compared with the others. This set showed low variability in mean Ct values across replicate measurements, with a coefficient of variation below 5%, as well as stable amplification curve profiles and higher fluorescence signal intensity.

Technical reproducibility was further supported by a high coefficient of determination across replicate reactions ($R^2 > 0.98$). Based on these performance metrics, the primer–probe set recommended in the CDC 2019-nCoV Real-Time RT-qPCR protocol was selected as the final assay configuration and used for all subsequent analytical sensitivity, diagnostic sensitivity, and workflow comparison analyses.

Analytical sensitivity, diagnostic sensitivity, and cross-reactivity

Analytical sensitivity was assessed using the AccuPlex™ SARS-CoV-2 Reference Material Kit (SeraCare Life Sciences, Milford, USA) containing defined viral copy numbers. Twenty-four technical replicates were analyzed across 3 dilution levels (1/1000, 1/100, and 1/50), selected to span concentrations below, near, and above the expected limit of detection in accordance with IVD performance evaluation principles. Mean Ct values obtained with the designed assay were highly comparable to those generated by the commercial RT-qPCR system. Minimal variability was observed among replicates, with a standard deviation < 0.5 and a coefficient of

Table 2. Limit of detection (LoD) determination and analytical comparison between the designed RT-qPCR assay and a commercial reference method.

Dilution level (IU/mL)	Replicates (n)	Designed kit mean Ct ± SD	%CV	Reference kit mean Ct ± SD	Mean Ct difference (designed − reference)	Mann-Whitney U *p* value	Pearson r value
1/1000 IU/mL	24	33.01 ± 0.46	1.39	33.28 ± 0.49	− 0.16 Ct	0.41	0.995
1/100 IU/mL	24	35.98 ± 0.45	1.25	35.94 ± 0.47	+ 0.08 Ct	0.53	0.992
1/50 IU/mL	24	37.85 ± 0.48	1.27	37.98 ± 0.46	− 0.07 Ct	0.47	0.989

variation (% CV) < 2 across all dilution levels [22]. Table 2 summarizes the LoD determination and analytical comparison between the designed RT-qPCR assay and a commercial reference method.

Diagnostic sensitivity was evaluated by direct comparison of Ct values obtained using the in-house RT-qPCR assay and the commercial reference kit for both AccuPlex™ serial dilutions and clinical samples. No statistically significant differences were observed between the two methods (Mann–Whitney U test, $p > 0.05$). Ct values obtained with the two assays were either identical or differed by no more than 0.1 Ct across all measurements. Pearson correlation analysis demonstrated a near-perfect linear correlation between Ct values obtained with the in-house RT-qPCR assay and the commercial reference system across all dilution levels and clinical samples ($r \approx 1.00$), indicating strong agreement between the two methods. The in-house RT-qPCR assay correctly identified all 50 previously confirmed SARS-CoV-2–positive clinical samples, corresponding to a diagnostic sensitivity of 100%.

Cross-reactivity was evaluated through three independent experiments using the respiratory pathogens available in the laboratory. Testing was performed in parallel using both the in-house developed RT-qPCR assay and the commercially available reference kit. No amplification signals were detected for any of the tested pathogens in any experiment, and Ct values were consistently recorded as N/A. The absence of detectable amplification across all replicates indicates that no non-specific amplification or primer–template cross-reactivity was observed for either assay. These findings demonstrate that the developed RT-qPCR assay exhibits analytical specificity for the tested respiratory pathogens.

Comparison of Ct values between sample processing methods and specimen types

Statistical analyses were performed for comparing: (1) isolated swab-direct swab, (2) isolated strip-direct strip, (3) isolated swab-isolated strip, (4) direct swab-direct strip, (5) isolated swab-direct strip, and (6) mean swab-mean strip. No statistically significant differences were found between the different sample collection types ($p > 0.05$), indicating that neither sample processing strategy nor specimen type significantly affected Ct values. Similarly high Pearson correlation coefficients were found ($r = 0.96–0.99$) showing strong correlations between all comparison groups. Table 3 summarizes the comparison of Ct values between different sample processing methods and specimen types using Mann–Whitney U test and Pearson correlation analysis.

Discussion

The minor Ct differences of approximately 1–2 cycles observed between direct extraction–based and magnetic bead–based isolation workflows for nasopharyngeal swab specimens are consistent with previously reported variability inherent to clinical respiratory samples [23]. Comparable Ct distributions were observed for saliva collection strip specimens processed using both methods, suggesting that nucleic acid processing strategy had no measurable impact on Ct values. Furthermore, the similar Ct values between nasopharyngeal swab and saliva strip specimens detected with both direct and isolation-based conditions suggests that specimen type did not substantially influence assay performance. The high similarity observed in the comparison of mean Ct values between swab and strip specimens further supports the comparable analytical performance of the two sampling approaches.

In many studies, saliva-based sampling has been investigated for detecting SARS-CoV-2. In these studies, similar results were obtained from both saliva and nasopharyngeal swab samples. Rao *et al*. reported high diagnostic similarity between nasopharyngeal

Table 3. Comparison of Ct values between different sample processing methods and specimen types using Mann-Whitney U test and Pearson correlation coefficients.

			(Mann-Whitney U) *p* value	Pearson r value
Isolated swab vs direct swab	Isolated swab mean Ct ± SD 26.04 ± 6.63	Direct swab mean Ct ± SD 27.14±6.66	0.281	0.969
Isolated strip vs direct strip	Isolated strip mean Ct ± SD 25.64 ± 6.30	Direct strip mean Ct ± SD 26.50 ± 6.35	0.325	0.966
Isolated swab vs ısolated strip	Isolated swab mean Ct ± SD 26.04 ± 6.63	Isolated strip mean Ct ± SD 25.64 ± 6.30	0.666	0.991
Direct swab vs direct strip	Direct swab mean Ct ± SD 27.14 ± 6.66	Direct strip mean Ct ± SD 26.50 ± 6.35	0.429	0.986
Isolated swab vs direct strip	Isolated swab mean Ct ± SD 26.04 ± 6.64	Direct strip mean Ct ± SD 26.5 ± 6.35	0.702	0.963
Average swab vs average strip	Average swab mean Ct ± SD 26.59 ± 5.59	Average strip mean Ct ± SD 26.07 ± 6.27	0.490	0.992

swabs and early morning saliva samples [24]. Similarly, Al Suwaidi *et al.* demonstrated the clinical applicability of saliva sampling in school-age children, supporting its use as a practical alternative specimen type. Similar results were obtained between both of the collection methods in the present study [25].

Pre-analytical characteristics of liquid saliva, including variable viscosity and heterogeneous matrix composition, have been reported to inhibit amplification, particularly in direct RT-qPCR workflows [26,27]. Therefore, in this study, an alternative collection method for nasopharyngeal swabs was designed that reduced the risk of infection for healthcare workers and also eliminated PCR inhibition in saliva samples.

Previous clinical studies have also indicated that small Ct differences between saliva and swab specimens are likely due to biological variability, such as sampling time or symptom onset, rather than true methodological differences [24]. In the present study, strip-based saliva sampling resulted in only minimal Ct deviations, suggesting that the strip format may reduce heterogeneity commonly associated with liquid saliva specimens. One possible explanation is that nitrocellulose membranes promote capillary-driven uptake and more uniform specimen distribution, thereby improving handling consistency and reducing localized inhibitor effects [28].

Another key finding of this study is that direct extraction RT-qPCR demonstrated analytical performance comparable to magnetic bead–based nucleic acid isolation. Extraction-based RT-qPCR approaches have been reported as practical alternatives during periods of high testing demand; however, their analytical performance may vary depending on specimen matrix characteristics and workflow configuration [13]. In this study, consistent Ct values were observed that indicate the saliva strip system provides a compatible matrix for reliable amplification under direct extraction conditions.

The cross-reactivity panel used in this study was limited to respiratory pathogens available in the laboratory and was intended as an initial assessment of analytical specificity. Consequently, not all clinically relevant respiratory viruses were included. Future studies incorporating broader pathogen panels will be required to further validate assay specificity under different clinical conditions.

The strip-based saliva collection offers practical advantages for clinical analysis, including non-invasive sampling, improved tolerability in pediatric populations, suitability for supervised self-collection, and reduced risks associated with liquid sample transport. These characteristics align with published evidence indicating that saliva is a suitable specimen type for large-scale community-based screening when appropriate pre-analytical controls are applied [9,29].

Conclusions

In this study, in-house optimization, validation, and integration of the assay with both extraction-based and direct lysis methods, as well as its compatibility with the newly designed saliva strip collection system were analyzed.

Comparable Ct values and consistent performance between strip-based and swab-based specimens were observed across both isolation and extraction methods, indicating no meaningful analytical differences (no statistically significant differences) between the sampling strategies. Therefore, this study also demonstrates that saliva collection strips represent a reliable alternative to nasopharyngeal swabs for SARS-CoV-2 RT-qPCR testing.

The non-invasive and extraction-compatible design of the saliva collection strip provides practical advantages, particularly for pediatric testing, large-scale screening, and use in resource-limited settings, where simplicity and reliability of pre-analytical workflows are essential.

In conclusion, the saliva strip represents a simple and clinically applicable sampling approach that can be readily integrated into routine molecular diagnostic workflows. Further multicenter and longitudinal studies could be valuable to evaluate its performance across broader respiratory pathogen panels and varied clinical settings.

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Conflict of interest

No conflict of interest is declared.

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