

Clinical Validation of Fresh Drooled Whole Saliva and GeneFiX™ for SARS-CoV-2 Diagnosis



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Introduction

WHO reference standard for SARS-CoV-2 diagnosis is RT-PCR using DNA extracted from nasopharyngeal swab (NPS) or oropharyngeal swab (OPS)¹.

There is limited vigorous evidence for the use of saliva in SARS-CoV-2 diagnosis²⁻⁴.

Aim: To validate the diagnostic accuracy of whole saliva-derived DNA for PCR-based methods in the detection of SARS-CoV-2.

Methodology

12 adults comprising of 7 RT-PCR confirmed COVID-19 subjects and 5 Person Under Investigation (PUI) as negative controls were recruited.

Early morning fresh drooled saliva was collected into:

- Sterile plastic container (2mls)
- GeneFiX™ saliva container (2mls)

NPS taken from each subject in the same setting for diagnostic comparison (**Figure 1**). Samples were triple packaged and processed for viral titres within 6 hours at an accredited laboratory.



Figure 1 (L to R): Sterile plastic container, GeneFiX™ saliva collection kit and NPS collection kit

Results

The mean age was 31.83 ± 10.37 years. Half were asymptomatic and almost all (91.7%) had significant travelling history. Median days of illness was 0.5 days (IQR=5) and all were recruited within a median of 3 days (IQR=11) of admission (**Table 1**).

Margin of difference in Ct. values between the two saliva collection methods was small (**Table 2**).

There was good concordance among the 3 types of samples when taken during the early course of illness (**Table 3**). However, NPS gave a lower Ct. value between the three collection methods in both E and N2 genes.

References

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Table 1: Characteristics and Presentations of Subjects (N=12)

Characteristics/ Presentations	n(%)	Mean (SD)	Median (IQR)
Age (year)		31.83 (10.37) ^a	-
Days of Recruitment (days)			3.00 (11.00) ^b
Days of Illness (days)*		-	0.50 (5.00) ^b
Presenting Symptoms			
Fever	2 (16.7)		
Cough	1 (8.3)		
Shortness of breath	0		
GI symptoms	0		
Others**	3 (24.9)		
Asymptomatic	6 (50.0)		
COVID-19 Classification			
Category 1	11 (91.7)		
Category 2	1 (8.3)		
Category 3™	0		
Category 4	0		
Category 5	0		
Risk Factors			
Positive contact	0		
Traveling	11 (91.7)		
Others	0		
Unknown	1 (8.3)		

SD= Standard Deviation

IQR= Interquartile range

^aThe distribution is reasonably normally distributed

^bThe distribution is skewed to the right

*Days of illness for asymptomatic patients is counted from the day of swab is positive

**Two patients had fever with cough and fever with GI symptoms respectively, the other had sore throat only

Table 2: Comparison of Mean Ct. Values for N2 and E Genes Between RT-PCR for NPS and Saliva Specimens

	RT-PCR for NPS	GeneFiX™ Saliva	Whole Saliva
Mean Ct. Value for N2 gene	30.50	33.59	32.69
Mean Ct. Value for E gene	28.36	29.86	28.59

Table 3: Contingency Tables for Whole Saliva Testing Against GeneFiX™ Saliva and RT-PCR for NPS

GeneFiX™ Saliva	RESULTS	Whole Saliva	
		Positive	Negative
	Positive	7	0
Negative	0	5	

RT-PCR for NPS	RESULTS	Whole Saliva	
		Positive	Negative
	Positive	7	0
Negative	0	5	

Discussion/Conclusion

RT-PCR diagnostic test for SARS-CoV-2 using fresh drooled saliva is both sensitive and specific as the virus is also shed in saliva. Saliva can serve as an alternative specimen for detecting SARS-CoV-2.

Further validation using larger samples of COVID-19 subjects is necessary to support fresh saliva as a preferred non-invasive standard for COVID-19.

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