Comparison of Saliva vs Nasopharyngeal Swab in Detection of SARS-CoV-2 on the Roche cobas® Liat® Point-of-Care System

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Background

- COVID-19 testing plays a critical role in the fight against the virus (1).
- IDSA recommends RT-PCR testing for SARS-CoV-2 with nasopharyngeal (NP) swabs referenced as the standard (2).
- NP specimen collection causes discomfort and generation of droplets which are hazardous to the healthcare workers collecting these specimens (3).
- Saliva is as an attractive alternative for the detection of SARS-CoV-2 with a reported sensitivity of 83% compared with 84.8% for NP samples, respectively (4).

Objectives

- The objective of this study is to evaluate the performance of a saliva sample compared to nasopharyngeal swab in the detection of SARS-CoV-2 on the Roche cobas® Liat® platform, at a research site in a rural area of Guatemala.

Methods

- Adults in an existing cohort study with influenza-like illness (ILI) provided clinical data and underwent NP swab (Copan) collection by trained nurses.
- Swabs were immediately placed into universal transport media (UTM), stored at 2-8 °C for less than 30 minutes and then tested on the Cobas Liat platform for SARS-CoV-2.
- Consenting subjects who had not eaten or drank in the last 2 hours were asked to provide a 5mL saliva sample directly into an RNAse free container.
- The saliva sample remained at 2-8°C for 24 hours, then diluted 1:2 with 0.85% saline (to reduce viscosity) and run on the same assay.
- We used descriptive statistics to compare the performance of saliva to NP swabs.

Liat System / Use Instructions

- **Saliva showed similar performance to NP swab in detecting SARS-CoV-2 on the Roche cobas® Liat® System.**
- **Combining NP/saliva tests would improve overall sensitivity in the detection of SARS-CoV-2.**
- **The saliva sample for the detection of SARS-CoV-2 could be a more acceptable and non-invasive alternative for patients and a safe procedure for health personnel.**

Table 1: Subject Characteristics — **N = 55**

Worker Demographics	
Age in years (mean, SD)	29.99 (8.28)
Male sex, n (%)	43 (78.2%)
Ethnicity: Ladino	30 (54.6%)
Indigenous	4 (7.3%)
Don't know	21 (38.2%)
Comorbidities	
Obesity (measured BMI> 30) (n=42 with weight and height data)	6 (14.3%)
Kidney disease	1 (1.8%)
Anemia or blood disorder	1 (1.8%)
Cardiovascular disease (heart failure, CAD)	1 (1.8%)
Diabetes	2 (3.6%)
Liver disease	1 (1.8%)
Any comorbidity	10 (18.2%)
Screening for other potential health issues	
CKD (eGFR<80 x 2) (of 44 subjects with data for 2020 and 2021)	3 (6.4%)
BMI < 20, (n= 42 with weight and height data)	4 (9.5%)
Household Conditions	
Concern about food insecurity in last year, n (%)	27 (49.1%)
Symptoms	**N = 60**
Fever	1.4 (1.9)
Cough	2.8 (2.3)
Difficulty breathing	0.3 (0.7)
Flu-iiQ severity Score (wellbeing score: n=48 sick visits with data)	0.10 (0.14)
Maximum duration of symptoms (fever, cough, and/or difficulty breathing)	3.4 (0.1)

Abbreviations: SD=standard deviation, BMI=body mass index, CAD=coronary artery disease, IQR=interquartile range, USD=US dollars.

Cobas Liat Test	NP Positive	NP Negative
Saliva Positive	17	3
Saliva Negative	2	38

* During this processing, 2 tests were invalid, and thus not included in the cells above

Table 2: Performance of Saliva Compared to NP Swab for Detection of SARS-CoV-2

Agreement:	91.7%
Sensitivity:	89.5%
Specificity:	92.7%
Positive predictive value (PPV):	85%
Negative predictive value (NPV):	95%

Table 3: SARS-CoV-2 Sequencing Data at the Trifinio site and the National Lab Jan-Aug 2022

Month	Trifinio Lab	National Lab
Jan	BA.1.1	BA.1, BA.1.1
Feb	BA.1 , BA.1.1, BA.1.15 BA.1.1.368	BA.1, BA.1.1
Mar	NA	BA.1, BA.1.1, BA.1.15
Apr	NA	BA.1, BA.1.1, BA.2 , BA.2.3
May-Jun	NA	BA.1.1, BA.2 , BA.2.12.1, BA.2.3, BA.2.9
Jun-Jul	NA	BA.2 , BA.2.12.1, BA.2.3, BA.2.9, BA.4.1, BA.5.1, BA-5.2, BA.5.2.1, BA-5.5
Aug	NA	BA.5.1, BA.5.2,BA.5.5 , BE.1 B4.1, BA4.2, BA4.3

Conclusions

- Our results show good agreement between NP and saliva samples in detection of SARS-CoV-2 on the Roche Cobas® Liat® PCR platform.
- Our findings support the collection of saliva samples in the detection of SARS-CoV-2, which is more acceptable for the patient and safer for the sample collector.

Table 4: Characteristics of Individuals with Discordant Saliva: NP SARS-CoV-2 Test Results

NP (-) / Saliva (+)	Age (years)	Sex	Ethnicity	Any Comorbidity	CT value	Fever (days)	Cough (days)	Difficulty Breathing (days)	Flu-iiQ Score (+/-)	Maximum duration of fever, cough, and/or difficulty breathing (days)
Subject 1	18.3	male	ladino	no	29.87	4	5	0	0.019	5
Subject 2	32	male	unknown	no	33.70	0	6	0	0	6
Subject 3	25.4	male	ladino	no	36.99	0	4	0	0.019	4
NP (+) / Saliva (-)										
Subject 1	18.9	male	unknown	no	36.17	1	0	0	-	1
Subject 2	32.6	female	ladino	no	33.75	0	0	2	0	2

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