Performance Evaluation of Standard™ Q Covid-19 Ag Saliva Test in Detection of Covid-19 Among Patients in Tertiary Hospital*

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ABSTRACT

Newer diagnostic tests for COVID-19 such as antigen tests are being used for rapid identification of cases. Compared to reverse transcriptase polymerase chain reaction (RT-PCR), these tests offer simpler collection and processing. This study aims to determine the accuracy of a SARS-CoV-2 antigen-detecting rapid diagnostic test (Ag-RDT) using saliva compared to nasopharyngeal and oropharyngeal swab (NPS/OPS) RT- PCR among patients tested in the Emergency Room at Makati Medical Center. Patients who underwent NPS/OPS RT-PCR and who consented to participate in the study were asked to submit salivary sample to be analyzed using the Standard™ Q Covid-19 Ag Saliva Test kit. A total of 366 samples were collected. The overall accuracy was 81.69% with a sensitivity of 63.58% and a specificity of 97.93%. Subgroup analyses as to processing time, number of days from symptom onset, and presence or absence of symptoms had no effect the overall accuracy. The Standard™ Q Covid-19 Ag Saliva Test kit was able to satisfy the ≥97% specificity recommended by the WHO for SARS-CoV-2 Ag-RDTs but did not meet the minimum performance requirements of ≥80% sensitivity. A positive test results can help in the initiation of early treatment and isolation of cases, but a negative test should still be confirmed by NPS/OPS RT-PCR test.

Keywords: *Saliva Test for COVID-19, SARS-CoV-2 Ag-RDTs, COVID-19 Antigen Test*

BACKGROUND

Coronavirus disease 2019 (COVID-19), is a respiratory disease that has overwhelmed the world since the first quarter of 2020. Among the most important strategies to slow down and decrease the spread of the disease is early detection and isolation. There are several diagnostic tests that identifies SARS-CoV-2 virus. Some are specimens from the nasopharyngeal, oropharyngeal cavity, nasal mid-turbinate, anterior nares, nasopharyngeal or nasal wash or aspirate, and recently, on saliva.[1]

The gold standard for detecting and diagnosing SARS-CoV-2 is the reverse transcriptase polymerase chain reaction (RT-PCR).[2] Respiratory samples collected through nasopharyngeal swab (NPS) and oropharyngeal swab (OPS) are recommended specimens for SARS-CoV-2 RT-PCR testing.[3] Newer diagnostic tests offer alternative methods to collect respiratory samples such as saliva antigen tests. These tests offer simpler collection procedures for both patient and laboratory staff. Initial reports show that the accuracy of saliva RT-PCR tests in detecting SARS-CoV-2 is comparable to NPS/OPS RT-PCR.

OBJECTIVE

The aim of this study to determine the sensitivity and specificity of COVID-19 antigen saliva test compared to NPS/OPS RT-PCR. Furthermore, it aims to determine the accuracy of these tests among patients tested for SARS-CoV-2

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RESEARCH QUESTION

Is the COVID-19 antigen saliva test an accurate test to detect SARS-CoV-2 as compared with the gold standard NPS/OPS RT-PCR test?

SIGNIFICANCE

Evaluating the performance of a certain diagnostic test is needed prior to the use of any new diagnostic tests. The COVID-19 saliva antigen test offer advantages compared to the NPS/OPS RT-PCR including faster turn-around-time, ease of procedure, and cost-effectiveness. This test can also be deployed in outbreak settings during contact investigation without the need for trained staff to do NPS/OPS.

Published studies on the saliva antigen tests for COVID-19 have shown that saliva specimen is comparable to nasopharyngeal specimens and sometimes even yield more positive results.[4,5] Performing a validation study in the local setting is important to determine the performance of the tests in our own population. The results of this study will guide the hospital and doctors in crafting guidelines on the use of these tests in the diagnosis of COVID-19.

LITERATURE REVIEW

DIAGNOSTIC TESTS FOR COVID-19

Reverse Transcriptase Polymerase Chain Reaction

Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) is a simple approach that uses a DNA template to amplify unique in vitro DNA fragments. The estimated sensitivity is approximately 70% while the specificity is about 95%. Results from RT-PCR test can be affected by the method of collection and viral load sample.[6,7] There is a relatively high false negative result for RT-PCR when used during the early course of illness. Viral evolution and timing of collection may affect the results.[8]

RT-PCR is the gold standard for diagnosing SARS-CoV-2 infection by recognizing viral genomes in different samples and detecting the viral RNA.[7,9] It is highly sensitive and specific and may be used to detect COVID-19 early.[10] It may yield to a false negative result depending on the environment, handling, technique and expertise of handler. Furthermore, viral load and stage of illness may also affect the results.[9] A combination of clinical, molecular and serological tests may be adjunct in identifying sensitivity and specificity for SARS CoV-2.[9]

The most widely used method for detecting SARS CoV-2 infections is the RT-PCR but this may be costly due to the laboratory equipment, the need for highly skilled personnel and the test can take days to generate results.[11]

Antigen Test

Antigen tests are immunoassays that detect specific viral proteins or antigens. Once detected, it may signify current viral infection. These antigen tests are relatively inexpensive, can be done at point-of-care setting, and have faster turnaround-time.[2]

Antigen tests detect the viral protein present in the specimen and can provide rapid results.[13] These tests have lower sensitivity than most nucleic acid-based assays and recognize the existence of virus at the time of testing thus, it can be used as a screening test. [3,13]

Standard™ Q COVID-19 Ag Saliva Test

Intended Use[15]

The Standard™ Q COVID-19 Ag Saliva Test qualitatively detects the specific antigens of SARS-CoV-2 that exist in the human saliva specimen by using a rapid chromatographic immunoassay. The test is facilitated by healthcare professionals as an aid to early detection of SARS-CoV-2 among patients with signs and symptoms of COVID-19. The product is designed for medical professional use only.

Trained healthcare professionals are exclusively allowed to facilitate the test and interpret results. Confirmatory testing by RT-PCR is still required and the results of the saliva antigen test should not be the only basis for the diagnosis.

Test Principle[15]

STANDARD Q COVID-19 Ag Saliva Test consist of two pre-coated lines, "C" (Control) line, "T" (Test) line on the nitrocellulose membrane surface. The lines are invisible on the window before the specimen application. Coated with mouse monoclonal anti-SARS-CoV-2 antibody is the test line region while coated with anti-Chicken IgY antibody is the control region. The detection of SARS-COV-2 antigen depends on the mouse monoclonal anti-SARS-CoV-2 antibody bound with color particles.

SARS-CoV-2 antigen interacts with the monoclonal antibody SARS-CoV-2 antibody bound with the color particles producing a colored antigen-antibody particle complex which transfers on the membrane and attached to the mouse monoclonal anti-SARS-CoV-2 antibody. If SARS-CoV-2 antigen is existent, a colored test line will appear on the result window and if none is detected, no color appears in the test line. The control line is for procedural purposes and is present if the test is properly performed and the reagents for testing are working accordingly.

A study conducted in Bangkok Thailand compared real time RT-PCR assay test (Allplex 2019-nCoV Assay) using respiratory samples versus SARS-CoV-2 antigen detection test (Standard Q COVID-19 Ag test) using saliva specimen. Comparable results were noted with SARS-CoV-2 antigen test having sensitivity of 98.33% (95% CI, 91.06-99.96%) and specificity of 98.73% (95% CI, 97.06-99.59%) for real-time RT-PCR.[14]

RESEARCH DESIGN AND DATA ANALYSIS

The research was a prospective study. The researchers enrolled patients continuously from February 2021 until the projected sample size was reached by May 2021. The results of the saliva test were not divulged to the attending physicians or the patients because it was a validation study. Results were analyzed and the following parameters were reported: sensitivity, specificity, positive predictive and negative predictive values, and likelihood ratio, and accuracy. Data were statistically treated using McNemar's Test.

INCLUSION AND EXCLUSION CRITERIA

All patients who underwent SARS-CoV-2 oropharyngeal and nasopharyngeal swab RT-PCR were recruited to participate in the study. Participants below 18 years provided assent and also informed consent from parents or legal guardian. Those who did not sign consent or assent for the Saliva Antigen test were not included in the study. Subjects who were not able to submit saliva (i.e., intubated, unconscious, children who cannot be instructed to collect saliva) were also excluded.

WITHDRAWAL FROM THE STUDY

The participants were given the option to withdraw anytime during the study. If he/she wishes

to withdraw from the study, notification to the principal investigator or any members of the research team must be given either verbally or in writing. Withdrawing from the study requires a form to be filled out to document the process.

If the specimen was already processed (with results) prior to withdrawal, it cannot be undone, furthermore, the data collected prior to withdrawal were included in the study. Further collection of additional personal health information was discontinued. Since this is a validation study, results were unofficial and were not included in the patient's medical record nor relayed to the participant and attending physician until the end of the study (when requested).

The data gathered from a patient who withdrew from the study were included in the data analysis. This was explained to the participant. Data management (security of forms and patient data) were the same for all participants.

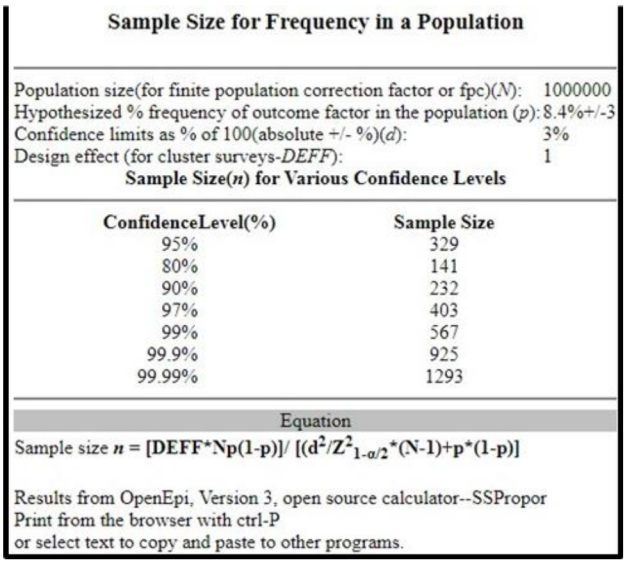
METHODOLOGY

SAMPLE SIZE

The OpenEpi, Version 3 was used to compute for the sample size. Based on the current report of WHO (as of January 5, 2021), the positivity rate in the Philippines is 8.4%. The margin of error used is 3%. At 95% confidence interval, result showed that the sample size is 329.

To account for the missing data, there should be additional 10%. The computation is as follows:

N_{final} = 329 + .10N_{final}
0.90N_{final} = 329
N_{final} = 365.56
The final sample size is 366.



Sample Size for Frequency in a Population

Population size(for finite population correction factor or fpc)(*N*): 1000000
Hypothesized % frequency of outcome factor in the population (*p*): 8.4%+/-3
Confidence limits as % of 100(absolute +/- %)(*d*): 3%
Design effect (for cluster surveys-*DEFF*): 1

Sample Size(*n*) for Various Confidence Levels

ConfidenceLevel(%)	Sample Size
95%	329
80%	141
90%	232
97%	403
99%	567
99.9%	925
99.99%	1293

Equation

Sample size $n = [DEFF*Np(1-p)]/ [(d^2/Z^2_{1-\alpha/2}*(N-1)+p*(1-p)]$

Results from OpenEpi, Version 3, open source calculator--SSPropor
Print from the browser with ctrl-P
or select text to copy and paste to other programs.

Procedure for Enrollment

Patients who underwent NPS/OPS RT-PCR testing at the Emergency Department were recruited to the study. Those who were willing to participate were oriented on the study and asked to sign the consent form. Participants were informed during consenting that the demographic, clinical and laboratory information that they indicated on the Department of Health Case Report Form (DOH CRF) will also be used for the study. This minimized the use of paper for questionnaires and also the time spent by the patient answering forms. The investigators validated the content of the DOH CRF to ensure completeness of information. Picture Archiving and Communication System (PACS) database of the hospital was used to obtain radiologic data. Results of RT-PCR were retrieved from the Electronic Medical Record. The patient's medical record number (MRN) were recorded on the data collection tool to cross-reference RT-PCR results and Saliva test result.

Procedure for collection of specimens

1. After collection of nasopharyngeal and oropharyngeal swab for RT-PCR, the patient was asked to submit a saliva specimen for the Covid-19 Ag Saliva test.

2. The patient was instructed not to eat, smoke, or chew gum 30 minutes before submitting saliva specimen.
3. The patient was provided with a labeled saliva container containing the initials of the patients and unique study number.
4. The patient was instructed to clear out mucus from the back of the nose and throat at least three times.
5. The patient was asked to lift the specimen collection cup close to his/her mouth and avoid touching the lid of the container with lips or hands.
6. The patient was asked to breath in and cough hard directly into the specimen cup.
7. The patient was asked to spit out the saliva with snorted nasal mucus into the specimen collection cup.
8. The specimen collector will stir the saliva and mucus specimen more than 10 times using a sterile swab.
9. The specimen was handled and processed according to the manufacturer's recommendation.
    - Test device and collected specimen were in room temperature prior to testing.
    - Instructions for using the kit were carefully read.
    - The back of the foil pouch was checked for expiration date. Expired kits were discarded.
    - Examined the test device and the foil pouch containing the desiccant.
    - Inserted the swab into the extraction buffer tube and stirred the swab more than 5 times.
    - Swab was removed to extract the liquid by squeezing the sides of the tube.
    - Nozzle cap was secured tightly onto the tube.
    - Three (3) drops of extracted specimen were instilled on the test device.
    - Read the test result in 15-30 minutes.
10. Results were photographed, recorded and interpreted by a licensed trained health care professional.
11. Results from the RT-PCR test for SARS-CoV-2 were recorded by the researcher.

ETHICAL CONSIDERATIONS

Ethical considerations and ethical principles set out in relevant guidelines (Declaration of Helsinki, WHO Guidelines, ICH-GCP, National Ethics Guidelines for Health Research) were strictly followed.

The participants were asked if he/she preferred the Filipino or English consent form. Consent forms were carefully read and reviewed by participants. The investigators discussed the study thoroughly with the patient and/or legal guardians. It was well emphasized that the participants have the right to withdraw from the study at any given time. Enough time was given for the participant to ask questions.

Vulnerability of subjects was considered. Coercion in any level was not tolerated. The primary investigator, together with a person of no interest in the study, who acted as witness, obtained from the participants their informed consents. They were provided with the contact numbers of the investigators for any questions regarding the study. The number of the IRB chair was included on the consent forms and the participant was informed that he/she can report any irregularities, such as but not limited to coercion, in the obtaining of consent to the IRB.

The participant affixed his/her signature to the informed consent form including the date of signing of the consent form.

For participants below 18 years old, an assent form was accomplished. Informed consent was obtained first from the parent/s or legal

guardian, then an assent form was presented to the participant. It was emphasized to the participant that he/she may decline to join the study and may withdraw anytime during the study. A minor without assent was not included in the study.

Privacy and confidentiality of participants were maintained. In order to ensure confidentiality, participants were assigned a unique study ID number. The numbers were only known to the investigators. The laboratory staff who processed the specimen were blinded and was given access only to the unique patient ID. Only the investigators had the list containing the patient's name and the corresponding ID number. Once all patients were enrolled, the results of RT-PCR tests were retrieved using the list with the patient's name and corresponding ID number.

The name of the patient did not appear on any other form to be used in the study. The name of the patients on the copy of the DOH CRF and all lab results were covered with either a sticker or a black marker. Forms were kept in a drawer with a lock. The database for data entry only included the patient ID.

The risk for harm was minimal. Only patients who consented to participate were included in the study. Since this was a validation study, the results of the tests were not used in the management of the patient. The results of the saliva test can be provided to the patient after completion of the study. The participants did not instantaneously directly benefit from the study because the official RT-PCR results were needed and the one relayed to the patient, since the diagnostic test is still undergoing a validation study. Participants will not be given tokens for participating in the study. The risk for injury is minimal because patients will just need to spit out saliva. No sputum induction or invasive procedure was performed. Should there be study-related injuries (injuries related to spitting of saliva), medical management were properly accorded.

No conflict of interest from the authors was declared in this research. The diagnostic test kits were provided for by the manufacturer/distributor for free but for the sole purpose of the research. Results were not altered in any way based on these circumstances.

All research data were managed only by the research trial team. All files were kept in secure areas and only accessible by the research trial team.

RESULTS AND DISCUSSIONS

DEMOGRAPHICS

The study has enrolled a total of 366 patients. Informed consents were signed by patients who willingly volunteered to be part of the study. Two (2) patients were included in the pediatric age group. The age group and gender of patients are presented in the Table 1. Most patients sought consult within 7 days of the illness (86%). The most common symptoms are respiratory in presentation - i.e. cough, fever and colds. Sixty-five (17.81%) were asymptomatic.

Table 1. Patient Characteristics

	N = 366 (%)	
Age Group (years)	**No**	**Percentage**
14-17	2	(0.55)
18-29	84	(22.95)
30-39	94	(25.68)
40-49	58	(15.85)
50-59	54	(14.75)
60-69	38	(10.38)
70-79	23	(6.28)
80-89	13	(3.56)
Gender	**No**	**Percentage**
Male	186	(50.81)
Female	180	(49.19)
Days of Illness	**No.**	**Percentage**
0-7	315	(86.06)
8-14	34	(9.29)
More than 14	17	(4.64)

Presenting Symptoms	No.	Percentage
Cough	153	
Fever	152	
Colds	72	
Throat Discomfort	62	
Body Malaise	45	
Disturbance in Breathing	44	
Diarrhea	39	
Headache	30	
Loss of taste or smell	14	
Other symptoms	79	
Asymptomatic	65	

There were four patients who were positive for Saliva Antigen test but were negative for RT-PCR. Two of them had normal chest radiographs, one had a pleural effusion with pulmonary mass, and another one had pneumonia on chest xray.

Among the 63 patients who tested positive for Saliva Antigen but were negative for RT-PCR, 11 did not have radiographs, 18 had normal chest xray results, and 34 had infiltrates on chest radiographs.

SENSITIVITY AND SPECIFICITY

Evaluation of the sensitivity and specificity of the antigen saliva test was done. Table 2 shows the sensitivity and specificity analysis of the data.

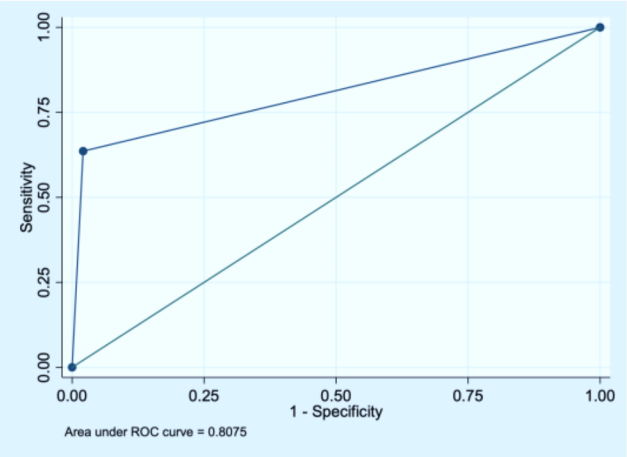
Table 2. Two-by-two table comparing the RT-PCR and Saliva Antigen Test

Saliva Antigen Test	RT-PCR		Total	P-value
	Positive	Negative		
Positive	110	4	114	<0.0001
Negative	63	189	252	
Total	173	193	366	

Using McNemar's Test, results showed that there is significant difference between the proportion of patients diagnosed with COVID-19 using Saliva Test and PCR Test.

Table 3 shows the different measures of validity of the saliva antigen test. The probability of Saliva antigen test in correctly identifying patients with COVID-19 was 63.58% (Sensitivity). The probability of Saliva Test in correctly identifying patient without COVID-19 was 97.93% (Specificity). Among those who have COVID-19 based on Saliva Test findings, the probability of having COVID-19 was 96.49% (PPV). On the other hand, among those without infection based on Saliva Test findings, the probability of not having the disease is 75% (NPV). The positive likelihood ratio of 30.68 indicates that there is a high increase in probability of having COVID-19, given a positive Saliva test. The negative likelihood ratio of 0.37 indicates that there is around 25% decrease in probability of having COVID-19, given a negative Saliva Test. The overall accuracy indicates that out of 366 patients tested for COVID-19, 81.69% of them have the same result for Saliva Test and PCR Test.

	Saliva Antigen Test
Sensitivity	63.58%
Specificity	97.93%
Positive predictive value	96.49%
Negative predictive value	75.00%
Likelihood ratio (+)	30.68
Likelihood ratio (-)	0.37
Overall accuracy	81.69%



Further analyses of the saliva antigen test as to processing time, day of illness on presentation, and presence or absence of symptoms were done.

The time from saliva collection to actual start of the processing of the samples were taken into account. There was a total of 251 (68.57%) samples which were processed within an hour from collection and 115 (31.43%) were processed beyond one hour. Table 4 shows the analysis of data based on the processing time. Result showed that there is no sufficient evidence to conclude that the diagnostic accuracy of Saliva Test is different according to processing time.

Table 4. Validity of Saliva Antigen Test Based on Processing Time

Saliva Test	PCR		Total
	Positive	Negative	
≤60 mins			
Positive	74	3	77
Negative	42	132	174
Total	116	135	251
>60 mins			
Positive	36	1	37
Negative	21	57	78
Total	57	58	115

Processing Time	≤60 mins	>60mins
Sensitivity	63.79%	63.16%
Specificity	97.78%	98.28%
Positive predictive value	96.10%	97.30%
Negative predictive value	75.86%	73.08%
Likelihood ratio (+)	28.71%	36.63%
Likelihood ratio (-)	0.37	0.37
Overall accuracy	82.07%	80.87%
P-value	0.99	

It is recommended that patients be tested for SARS CoV-2 antigen between 5-7 days of symptom onset. However, some patients seek consultation and treatment beyond 7 days of symptom onset. Majority of the patients (n = 315; 86.06%) had their saliva antigen tests done within 7 days of symptom onset. The researchers analyzed these group of patients and is presented on Table 5. Result showed that there is no sufficient evidence to conclude that the diagnostic accuracy of Saliva Test is different according to days of illness.

Table 5. Validity of Saliva Antigen Test Based on Number of Days from Symptom Onset

Saliva Test	PCR		Total
	Positive	Negative	
≤7 mins			
Positive	93	4	97
Negative	48	170	218
Total	141	174	315
>7 mins			
Positive	17	0	17
Negative	15	19	34
Total	32	19	51

Day of Onset	≤7 mins	>7mins
Sensitivity	65.96%	53.13%
Specificity	97.70%	100.00%
Positive predictive value	95.88%	100.00%
Negative predictive value	77.98%	55.88%
Likelihood ratio (+)	28.69	-
Likelihood ratio (-)	0.35	0.47
Overall accuracy	83.49%	70.59%
P-value	0.29	

Lastly, the researchers further grouped the data for the patients with symptoms and those who were asymptomatic at the time of testing. At the time of testing, those who were asymptomatic were 65 patients (17.81%). Table 6 shows the distribution of symptomatic and asymptomatic patients at the time of saliva collection. Result showed that there is no sufficient evidence to conclude that the diagnostic accuracy of Saliva Test is different according to presence of symptoms.

Table 6. Validity of Saliva Antigen Test Based on Presence of Symptoms

Saliva Test	PCR		Total
	Positive	Negative	
Without symptoms			
Positive	4	1	5
Negative	6	54	60
Total	10	55	65
With symptoms			
Positive	106	3	109
Negative	57	135	192
Total	163	138	301

Presence of Symptoms	Without	With
Sensitivity	40.00%	65.03%
Specificity	98.18%	97.83%
Positive predictive value	80.0%	97.25%
Negative predictive value	90.0%	70.31%
Likelihood ratio (+)	22.0	29.91
Likelihood ratio (-)	0.611	0.36
Overall accuracy	89.23%	80.07%
P-value	0.14	

ANALYSIS

The Saliva Antigen test exhibits a high specificity (96.10% - 100%) in detecting SARS CoV-2 among patients suspected to have Covid-19. The diagnostic test shows modest sensitivity (40% - 65.96%) in detecting SARS CoV-2 among Covid-19 suspects. Several subgroup analyses that were done (i.e. processing time, day of onset of symptoms, and presence of symptoms at the time of collection), did not have sufficient evidence that the diagnostic accuracy of the Saliva antigen differ among several factors considered.

The diagnostic test may be used as an alternative method in detecting SARS CoV-2 among patients, however, a negative result needs to be correlated with clinical condition of the patient and confirmed using RT-PCR.

In a study by Mioljub Ristić, et al, the same diagnostic test kit (Standard Q Covid-19 Antigen Test) was used in 120 symptomatic patients. The overall sensitivity was 58.1% (95% CI, 42.1-73.0) but was higher in the first five days of the symptom onset, with its sensitivity ranging from 66.7% to 100%.[17] This was consistent in our study, wherein the sensitivity is higher in those patients whose

symptoms are within 7 days, but statistical analysis did not show sufficient evidence to conclude that the diagnostic accuracy of Saliva Test is different according to days of illness.

There were a number of similar studies regarding Standard Q Covid-19 Ag Test. All studies showed high specificity and modest sensitivity in detecting SARS-CoV-2 infection among patients.

A prospective study was done in Brazil and Germany and published in the product brochure of Standard Q Covid-19 Ag Test for Nasopharyngeal Swab. A total of 1659 patients were enrolled, the pooled sensitivity in Germany was 76.6% (95% CI, 61.97-87.70) and pooled specificity was 99.3% (95% CI, 98.6 - 99.6%). The pooled sensitivity and specificity in Brazil were 88.68% (95% CI, 81.06-94.01%), and 97.6% (95% CI, 95.2-98.8%), respectively.[18]

In the study of Nalumansi, nasopharyngeal swab of 262 patients were analyzed and showed a sensitivity of 70.0% (95% CI, 60-79) and a specificity of 92% (95% CI, 87-96).

There is an emphasis on importance of early diagnostic testing when suspecting an infection most especially when molecular testing is not accessible. RT-PCR is still required to confirm the diagnosis.[19]

CONCLUSION AND RECOMMENDATIONS

The overall accuracy of the Standard Q Covid-19 Ag Test using saliva samples was 81.69%, with a sensitivity of 63.58% and a specificity of 97.93%. Among those who have COVID-19 based on Saliva Test findings, the probability of having COVID-19 was 96.49% (PPV). On the other hand, among those without COVID-19 based on Saliva Test findings, the probability of not having COVID-19 is 75% (NPV). The positive likelihood ratio of 30.68 indicates that there is a high increase in probability of having COVID-19, given a positive Saliva test. The negative likelihood ratio of 0.37 indicates that there is around 25% decrease in probability of having COVID-19, given a negative Saliva Test. The overall accuracy indicates that out of 366 patients tested for COVID-19, 81.69% of them have the same result for Saliva Test and PCR Test.

Several factors were considered and analyzed using McNemar's test. All subgroup analyses, as to processing time, presentation from day of onset of symptoms, and presence or absence of symptoms, did not show sufficient evidence to conclude that the results of the saliva antigen test is different according to the parameters mentioned.

Saliva antigen test may be used as an alternative method in detecting SARS CoV-2 among patients, especially in situations where a more sensitive test is unavailable. The high specificity of the diagnostic test may be used to detect disease and start early treatment and isolation. A negative result needs to be correlated with the clinical condition of the patient and confirmed further using a more sensitive test, like RT-PCR.

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