

DIAGNOSTIC ACCURACY OF RAPID ANTIGEN TEST IN DETECTING SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) INFECTION.

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ABSTRACT

BACKGROUND: Improving the means to detect SARS-COV-2 infection is important in the ongoing battle against the COVID-19 pandemic. STANDARD™ Q COVID-19 Ag Test offers an easy to use, cheap and rapid way of testing that must be evaluated first to optimize its utility.

OBJECTIVES: This study aims to evaluate the diagnostic accuracy of this test kit compared with Reverse Transcription Polymerase Chain Reaction (RT-PCR) for SARS-COV-2 diagnosis.

METHODS: Using retrospective cross-sectional study, seventy seven (77) nasopharyngeal swabs in viral transport media were used to determine the sensitivity, specificity, positive predictive value and negative predictive value of STANDARD™ Q COVID-19 Ag Test compared with the reference method, RT-PCR.

RESULTS: Among all participants, the rapid antigen test has a sensitivity of 9.86%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 8.57%. The sensitivity increases among symptomatic participants and when Ct value is less than 20 to 25.00% and 31.58%, respectively.

CONCLUSION: Despite the low sensitivity, STANDARD™ Q COVID-19 Ag Test has a high specificity and positive predictive value and could be a cheap and efficient test in the proper clinical context. Its use in conjunction with RT-PCR for those who tested negative initially should be emphasized in the implementation of the existing policies.

Keywords: *SARS-COV-2, COVID-19, Antigen Testing, diagnostic accuracy*

INTRODUCTION

Statement of the Problem

Following its emergence in Wuhan, China in November 2019, the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2) has infected millions around the globe. The disease it causes known as Coronavirus Disease 2019 (COVID-19) has been declared as a pandemic by the World Health Organization (WHO) in March 2020. Consequently, various methods of testing for the detection of SARS-COV-2 Infection have been developed. The currently accepted gold standard for testing is the Reverse Transcriptase – Polymerase Chain Reaction (RT-PCR)¹. However, this test requires special equipment, specific and unique infrastructure requirements, and skilled laboratory personnel. Furthermore, this test can be costly, time-consuming and may not be readily available.

Improving the testing capacities of nations is crucial in battling the effects of this pandemic. However, the accuracy in detection of SARS-COV-2 is important in choosing the test as the results do not only support patient care clinically but are also critical for public health management. SARS-COV-2 Antigen Testing was developed for

the qualitative determination of the presence of the viral antigen in nasopharyngeal secretions.² Theoretically, this test offers the advantage of ease of use, fast turnaround time (TAT) and low-cost. For these reasons, this test may be utilized at point of care (POC).

STANDARD Q COVID-19 Ag Test is a rapid antigen test made by SD Biosensor Inc, a global manufacturer of in vitro diagnostics in South Korea.³ It is available in the Philippines through its representative importer and distributor, Worldwidelink Trading Corporation. For the purpose of the diagnostic evaluation of the product, Worldwidelink requested for a clinical assessment from the Philippine Children's Medical Center and donated a total of 125 kits to be utilized in this trial.

This rapid antigen test was granted special certification for COVID-19 Diagnostic Test by the Department of Health – Food and Drug Administration in May 27, 2020.⁴ The test kit offers results within 30 minutes, ease of use and provision of all the necessary reagents and device needed in one kit. Considering these advantages, the kit must be validated for its diagnostic accuracy to be useful in our setting.

The Philippine Children's Medical Center had setup a molecular laboratory which offers diagnosis of SARS-COV-2 infection via RT-PCR. With the current increase in the number of daily positive SARS-COV-2 cases, an additional way of testing will help the nation's fight in this pandemic.

SIGNIFICANCE OF THE STUDY

With the urgent need to increase the testing capacity to detect SARS-COV-2 infection, this study will help in ensuring that the relatively easy-to-use and available test kits have optimal performance. This study will also add knowledge to the usability of these tests in our setting. Likewise, the results of the study may be used as guidance in the development of clinical protocols in the diagnosis and management of COVID-19.

REVIEW OF RELATED LITERATURE

The diagnostic tests for SARS-COV-2 infection is rapidly evolving as newer methods become readily available and controversially, replace the currently accepted gold standard. As with diagnostic methods for other diseases, there are various issues that must be understood in choosing the right method for SARS-COV-2 infection.

Tang et al discussed the various preanalytical, analytical and postanalytical issues regarding laboratory diagnosis of SARS-COV-2 infection². In this paper, nasopharyngeal swab is superior to oropharyngeal swab in the detection of viral particles especially within 5 to 6 days of onset of symptoms when the patient demonstrated high viral loads. This paper also recognized the potential for use of rapid antigen tests, however they warned of poor sensitivity based on the experience with this method for Influenza viruses. This finding is echoed in a review by Loeffelholz⁵.

Diagnostic Evaluation of Antigen Tests

Mak et al evaluated the diagnostic performance of commercially available rapid antigen test (BIOCREDIT COVID-19 Ag test) compared with viral culture and RT-PCR⁶. It was found out that the rapid antigen test was 10³ fold less sensitive than viral culture while the rapid antigen test was 10⁵ fold less sensitive than RT-PCR. In this study, a modified procedure was used in utilizing samples already in viral transport media.

Schoy et al did a similar evaluation of rapid antigen test using Coris COVID-19 Ag

Respi-Strip⁷. They found out that amongst the 106 positive RT-qPCR samples, 32 were detected by the rapid antigen test, given an overall sensitivity of 30.2%. Both studies concluded that rapid antigen tests should only be used as an adjunct to RT-PCR because of the potential for false negative results.

Van Honacker et al compared the performance of five (5) SARS-CoV-2 rapid antigen tests in the hospital setting and found out that the sensitivity ranged from 88.9% to 100% for samples with Ct <26, and specificity from 46.2% to 100%⁸. In their evaluation, they adapted the protocol used and tested samples already in viral transport media to avoid additional sampling from the patients. In the implementation phase, about 157 patients were transferred to the COVID-19 ward directly instead of the regular ward due to the rapid turn-around time of the tests.

STANDARD Q COVID-19 Ag Test

STANDARD Q COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx³. The principle behind this assay is the lateral flow of the analyte on a porous material from a sample loading zone,

to the labeling zone, and ultimately to the detection zone⁹. In general, the proximal end contains labeled antibodies or antigen that mixes with analyte when an aliquot is loaded. Through capillary action, the analyte flow through the membrane and forms a complex with a conjugate in the detection zone resulting to immobilization of the antibody to form a positive-colored line which is interpreted by the reader.

In the clinical evaluation for the STANDARD Q COVID-19 Ag Test conducted at Yeungnam University Medical Center in Korea using 125 specimens, the test kit showed 89.23% sensitivity and 96.67% specificity¹⁰. A similar study done in Brazil using 21 samples yielded 100% sensitivity and 100% specificity¹¹.

In the evaluation made by the Foundation for Innovative New Diagnostics (FIND) across Germany and Brazil, the sensitivity of the STANDARD Q COVID-19 Ag Test compared with RT-PCR is 76.6% and 88.7%, respectively, while the specificity is 99.3% and 97.6%, respectively. Factors that increase the sensitivity of the test are symptoms occurring less than or equal to

seven days and low Ct values¹². Further, the ease of usability was rated 86 out of 100.

Since these rapid test kits are designed to be performed without the need for biosafety cabinets, the virus inactivation performance of the extraction kit was evaluated by Jung-Ho et al. In this study, the virus was incubated in one setup with the extraction buffer and with a cell culture media. These are then subsequently inoculated to Vero cells. Cytopathic effects was not seen in the culture mixed with the STANDARD Q COVID-19 Extraction buffer, whereas, all other cell culture media demonstrated cytopathic effects¹³.

OBJECTIVES OF THE STUDY

This study aims to evaluate the diagnostic performance of the STANDARD™ Q COVID-19 Ag Test compared with RT-PCR in detecting SARS-COV-2 infection. Specifically, it attempts to answer the following research objectives:

5.1 Determine the sensitivity of STANDARD™ Q COVID-19 Ag Test compared with RT-PCR in detecting SARS-COV-2 infection.

5.2 Determine the specificity of STANDARD™ Q COVID-19 Ag Test

compared with RT-PCR in detecting SARS-COV-2 infection.

5.3 Determine the positive predictive value of STANDARD™ Q COVID-19 Ag Test compared with RT-PCR in detecting SARS-COV-2 infection.

5.4 Determine the negative predictive value of STANDARD™ Q COVID-19 Ag Test compared with RT-PCR in detecting SARS-COV-2 infection.

5.5 Determine the overall diagnostic accuracy of STANDARD™ Q COVID-19 Ag Test compared with RT-PCR in detecting SARS-COV-2 infection.

OPERATIONAL DEFINITION OF TERMS AND VARIABLES

- Rapid Antigen Test – a point of care diagnostic test (STANDARD™ Q COVID-19 Ag Test) that detects SARS-COV-2 antigen from the nasopharyngeal swab of a patient.
- RT-PCR – the gold standard for detecting SARS-COV-2 infection in which the rapid antigen test will be compared.
- Confirmed SARS-COV-2 case – a person with detected SARS-COV-2 ribonucleic acid (RNA) based on RT-PCR.

- Negative for SARS-COV-2 – a person who has not detectable SARS-COV-2 RNA based on RT-PCR.
- Sensitivity – the ability of the Rapid Antigen Test to correctly detect a true positive or a confirmed SARS-COV-2 case.¹⁴
- Specificity – the ability of the Rapid Antigen Test to correctly detect a true negative SARS-COV-2 case.¹⁴
- Positive Predictive Value – a measure to establish whether the positives in Rapid Antigen Test are actually confirmed SARS-COV-2 cases using RT-PCR.¹⁴
- Negative Predictive Value – a measure to establish whether the negatives in Rapid Antigen Test are actually negative for SARS-COV-2 using RT-PCR.¹⁴
- Diagnostic Accuracy - proportion of correctly classified SARS-COV-2 positives and SARS-COV-2 negatives (TP+TN) among all cases (TP+TN+FP+FN).¹⁵

METHODOLOGY

Research Design

A retrospective cross-sectional study is used to determine the sensitivity, specificity, positive predictive value and negative predictive value of STANDARD™ Q COVID-19 Ag Test compared with the reference method, RT-PCR.

Target Population, Subject Sampling, Sample Size Calculation

The sample population for this study included 81 nasopharyngeal and oropharyngeal swabs confirmed by RT-PCR in the Philippine Children’s Medical Center COVID-19 Laboratory, regardless of the exposure, symptom onset, or disease severity. These swabs are collected in the viral transport media routinely used in our laboratory (Kangjian Virus Collection and Preservation system, Jiangsu Kangjian Medical Apparatus CO.,Ltd). Only specimen from patients aged 1 year old and above were included, since only oropharyngeal swab was obtained for patients less than 1 year old. The specimens were selected using non-probability (convenience) sampling from the database of the COVID-19 laboratory based on the Ct values of the RT-PCR and are grouped as Not Detected, $Ct < 20$, $20 \leq Ct < 26$,

$26 \leq Ct < 30$, $30 \leq Ct < 36$. Exclusion criteria for this study were the following: unclear specimen information, contaminated samples, and oropharyngeal swabs only.

The sample size for study was estimated using single population proportion formula with the following assumptions: 95% confidence interval, 10% margin of error, and 10.2% prevalence based on the Philippine SARS-COV-2 positivity rate¹⁶. The sample size was calculated using Epi Info version 7.2.2.6 and has yielded a minimum sample size of 36.

OUTCOME/S ASSESSMENT, DATA COLLECTION METHOD, INSTRUMENT/S TO BE USED

The Case Investigation Forms (CIF) were retrieved to obtain the demographic profile and presence of symptoms of the patients. These were tabulated in Microsoft Excel.

SARS-COV-2 Testing

The NPS/OPS in viral transport media of the selected participants were retrieved from the storage of the PCMC COVID-19 laboratory. The Case Investigation Forms (CIF) were retrieved to

obtain the demographic profile and presence of symptoms of the patients.

As per manufacturer's instruction, direct performance on the nasopharyngeal swab using the Standard Q COVID-19 Ag test kit is recommended. However, the protocol was adapted to validate the antigen test on the swabs already in the transport media to avoid additional direct sampling from the patient. 200µl of the specimen was mixed with 200µl of the extraction buffer included in the kit making a one is to one dilution. Three (3) drops of the extracted specimen was put to the specimen well of the test device. The test was interpreted within 15-30 minutes after specimen collection in a Biosafety Cabinet and using the following guide from the manufacturer³:

- | |
|---|
| <ol style="list-style-type: none">1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C).2. A colored band will appear in the lower section of the result window. This band is test line of SARS-CoV-2 antigen (T).3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and |
|---|

the test result should be interpreted as a positive result.

* The presence of any line no matter how faint the result is considered positive.

* Positive results should be considered in conjunction with the clinical history and other data available.

Confirmation of SARS-COV-2 infection is done using Maccura SARS-CoV-2 Fluorescent PCR Kit performed according to manufacturer's instructions.

ETHICAL CONSIDERATIONS

The research is developed in compliance to the Data Privacy Act (2012) and National Ethical Guidelines for Health and Health-Related Research.

To ensure the protection of the study participants, each data is treated with utmost confidentiality. No personal identifiable information is included and each data set is coded with a control number. Only the investigators is allowed to retrieve and have access to the data. The hard copy and excel files used in this research is kept for 5 years from the time the last medical records is retrieved and disposed by shredding the physical copy and deleting the electronic

records. Approval is also obtained from the Institutional Review Board prior to the commencement of the study.

The Rapid Antigen Test kits are donated by SD Biosensor for the purpose of diagnostic evaluation. All parts of the study are properties of the PCMC and the authors.

DATA PROCESSING AND ANALYSIS

The data is collated and analyzed using Microsoft Excel. Mean age, percentage of male and female participants, presence of symptoms, percentage of confirmed cases, percentage of invalid PCR results and the Ct value are tabulated to illustrate the characteristics of all patients included and those who tested positive or negative with the Rapid Antigen Test. Table 1 shows an example of the dummy table on the characteristics of the participants.

The individual specimens are grouped per Ct values as follows: Not Detected, $Ct < 20$, $20 \leq Ct < 26$, $26 \leq Ct < 30$, $30 \leq Ct < 36$. Diagnostic test evaluation will be done using a 2x2 table (see Table 2) per group and for total number of specimens. The formula for the calculation of sensitivity, specificity, PPV and NPV will be as follows:

$$\text{Sensitivity} = \text{TP}/(\text{TP} + \text{FN})$$

$$\text{Specificity} = \text{TN}/(\text{TN} + \text{FP})$$

$$\text{Positive Predictive Value (PPV)} = \text{TP}/(\text{TP} + \text{FP})$$

$$\text{Negative Predictive Value (NPV)} = \text{TN}/(\text{TN} + \text{FN})$$

$$\text{Diagnostic Accuracy} = (\text{TP} + \text{TN})/(\text{TP} + \text{FP} + \text{FN} + \text{TN})$$

Excluded in the computation for sensitivity, specificity, PPV, NPV and diagnostic accuracy are specimens with invalid RT-PCR results.

RESULTS

Eighty-one (81) specimen in viral transport media were obtained for the study; however, four (4) were excluded in the final study sample for containing oropharyngeal swab only. The characteristics of the study sample is illustrated in Table 1. The mean age for the total participants is 34 years old, while those who tested positive in rapid antigen test is 35 years old. 35% of all participants are female. 42% presented with symptoms. 71 out of 77 of the samples in viral transport media had SARS-COV-2 viral RNA detected

via RT-PCR, 19 of which have ORF Ct value less than 20, 18 have ORF Ct value greater than or equal to 20 but less than 26, 17 have ORF Ct value greater than or equal to 26 but less than 30, 17 have Ct greater than or equal to 30 but less than 36. Six (6) specimen were not detected to have SARS-COV-2 viral RNA.

Seven (7) out of 77 specimen tested positive using the rapid antigen test device. All of these presented with symptoms. 86% of which have ORF Ct value less than 20, while the remaining 14% have ORF Ct value greater than or equal to 20 but less than 26. All specimen without detected SARS-COV-2 viral RNA via RT-PCR also tested negative using the rapid antigen test device.

Among all participants, the rapid antigen test has a sensitivity of 9.86%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 8.57%. The overall diagnostic accuracy is 16.88%. Table 2 shows the comparison of the rapid antigen test and the gold standard, RT-PCR among all participants.

Table 1. Characteristics of Participants

	Rapid Antigen Test Positive (7)	Rapid Antigen Test Negative (70)	Total Participants (77)
Mean Age (years)	35	34	34
% Female participants	42% (3)	34% (24)	35% (27)
% Male participants	48% (4)	66% (46)	65% (50)
% Symptomatic participants	100% (7)	36% (25)	42% (32)
% Confirmed SARS-COV-2 infection by RT-PCR	100% (7)	91% (64)	92% (71)
Samples with Ct<20	86% (6)	19% (13)	25% (19)
Samples with 20≤Ct<26	14% (1)	24% (17)	23% (18)
Samples with 26≤Ct<30	0	24% (17)	22% (17)
Samples with 30≤Ct<36.	0	24% (17)	22% (17)
Samples that are Not Detected on RT-PCR	0	9% (6)	8% (6)

Table 2. Diagnostic accuracy of Rapid Antigen Test compared with RT-PCR among all participants.

Rapid Antigen test	Gold Standard: RT- PCR		Total
	Positive	Negative	
Positive	7	0	7
Negative	64	6	70
Total	71	6	77

Sensitivity: 9.86% (95% CI 2, 17)
 Specificity: 100%
 Positive Predictive Value: 100%
 Negative Predictive Value: 8.57% (95% CI 2, 15)
 Diagnostic Accuracy: 16.88%

Among symptomatic participants, the rapid antigen test has a sensitivity of 25.00%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 16.00%. The diagnostic accuracy is 34.37% for symptomatic patients. Table 3 shows the

comparison of the rapid antigen test and the gold standard, RT-PCR among symptomatic participants.

Table 3. Diagnostic accuracy of Rapid Antigen Test compared with RT-PCR among participants who presented with symptoms.

Rapid Antigen test	Gold Standard: RT- PCR		Total
	Positive	Negative	
Positive	7	0	7
Negative	21	4	25
Total	28	4	32

Sensitivity: 25.00% (95% CI 9, 41)
 Specificity: 100%
 Positive Predictive Value: 100%
 Negative Predictive Value: 16.00% (1, 30)
 Diagnostic Accuracy: 34.37%

When stratified per ORF Ct value, the rapid antigen test has a sensitivity of 31.58%,

specificity of 100%, positive predictive value of 100%, and negative predictive value of 31.58% among participants with ORF Ct value less than 20. The diagnostic accuracy is 48.00%. Table 4 shows the comparison of the rapid antigen test and the gold standard, RT-PCR among participants with Ct value less than 20. Specimen with no detected SARS-COV-2 viral RNA were used as true negative for comparison.

Table 4. Diagnostic accuracy of Rapid Antigen Test compared with RT-PCR among participants with ORF Ct value < 20, using specimen with no detected SARS-COV-2 viral RNA as comparison.

Rapid Antigen test	Gold Standard: RT- PCR		Total
	Positive	Negative	
Positive	6	0	6
Negative	13	6	19
Total	19	6	25

Sensitivity: 31.58% (95% CI 11, 53)
 Specificity: 100%
 Positive Predictive Value: 100%
 Negative Predictive Value: 31.58% (95% CI 11, 52)
 Diagnostic Accuracy: 48.00%

The rapid antigen test has a sensitivity of 5.55%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 26.09% among participants with ORF Ct value greater than 20 but less than 26. The diagnostic accuracy is 29.17%. Table 5 shows the comparison of the rapid antigen test and the gold standard, RT-PCR among participants with Ct value greater than 20 but less than 26. Specimen

with no detected SARS-COV-2 viral RNA were used as true negative for comparison.

Table 5. Diagnostic accuracy of Rapid Antigen Test compared with RT-PCR among participants with ORF Ct value >= 20 but < 26, using specimen with no detected SARS-COV-2 viral RNA as comparison.

Rapid Antigen test	Gold Standard: RT- PCR		Total
	Positive	Negative	
Positive	1	0	1
Negative	17	6	23
Total	18	6	24

Sensitivity: 5.55% (95% CI -5, 16)
 Specificity: 100%
 Positive Predictive Value: 100%
 Negative Predictive Value: 26.09% (95% CI 8, 44)
 Diagnostic Accuracy: 29.17%

DISCUSSION

On October 26, 2020, the DOH Department Memorandum 2020-0468 *Supplemental Guidance on the Use of Rapid Antigen Test* allowed the use of Rapid Antigen Test Kits for diagnostic testing of closed contacts in communities and closed or semi-closed institutions with confirmed outbreaks and in remote settings where RT-PCR is not accessible, provided that the antigen testing can be used as a confirmatory for symptomatic close contacts, and that a confirmation with RT-PCR or a repeat antigen testing within 48 hours after the first negative result should be done for asymptomatic close contacts¹⁷. The same memorandum also recommends that only

rapid antigen tests with a minimum sensitivity of 80% and specificity of 97% be used. After the increase in cases in March 2021 in the National Capital region Plus Bubble, the use of rapid antigen tests as a confirmatory test was operationalized in the DOH Department Memorandum 2021-0169 *Interim Guidelines on Rapid Antigen Test Reporting for the NCR Plus Bubble*, wherein a suspect or a probable COVID-19 case who tested positive with rapid antigen test shall be interpreted as a confirmed COVID-19 case and shall be traced, tested, quarantined/isolated, and managed as per existing DOH guidelines¹⁸.

This decision to use a positive rapid antigen test was backed by the recommendations from the rapid review done by Health Technology Assessment Unit Policy Planning and Evaluation Team and Bayona et al released on September 24, 2020. Based on a meta-analysis conducted for nine studies, the pooled sensitivity of rapid antigen test kits was found to be 49% (95%CI: 28,70; I²=97.33, 95%CI: 96.54, 98.12) while the pooled specificity was found to be 99% (95%CI: 98, 100; I²=0, 95%CI: 0, 87.51)¹⁹. The same study found out that the

sensitivity increases to 50.3% (95%CI: 20, 80.7; I²=99.8) in the presence of symptoms. The evaluation done by the Research Institute for Tropical Medicine (RITM) showed a clinical sensitivity of 71.43% (55.42 to 84.28) and clinical specificity of 100% (91.96 to 100) among symptomatic patients for Standard Q COVID-19 Ag Test between the period of August 11-September 9, 2020²⁰.

The results of this study show low sensitivity of Standard Q COVID-19 Ag Test compared with the HTAC and RITM findings. Although we use nasopharyngeal swabs as the source of specimen, the dilution with viral transport media which is a deviation from the manufacturer's instruction on the use of Standard Q COVID-19 Ag Test might have affected the overall sensitivity of the assay. The long storage of the specimen, some lasting up to 3 days, from collection to performance of the rapid antigen test might have contributed to the deterioration of the viral particles. However, the study done by Van Honacker et al was able to obtain a sensitivity ranging from 88.9% to 100% for samples with Ct <26, and specificity from 46.2% to 100% using samples already in viral

transport media and five (5) different rapid antigen kits.⁸

This study replicates the increase in sensitivity when restricted to symptomatic participants or when the Ct value is less than 20, a potential marker for increased viral load. This, combined with a low-test accuracy in asymptomatic participants poses a question on the utility of a negative rapid antigen test as a single screening method and supports the DOH guidelines of proceeding with an RT-PCR for patients who have negative rapid antigen test result.

While a negative test result should not be used to decrease standard protective measures, the high specificity and high positive predictive value of Standard Q COVID-19 Ag Test implies that there is no cross-reactivity with other antigen that might result to a false positive result. Hence, this helps greatly in clinical decision making in patients who has positive antigen test result and supports the tagging of confirmed COVID-19 case in such instances.

CONCLUSION

The Standard Q COVID-19 Ag Test is less sensitive in detecting SARS-COV-2

infection compared with the current gold standard which is RT-PCR and should not be used as a single screening method. However, rapid antigen test could be a cheap and efficient test in the proper clinical context and in conjunction with RT-PCR for those who tested negative initially, which should be emphasized in the implementation of the existing policies.

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APPENDICES

Appendix 1. Data Collection Form

Number	Age	Sex	Symptom	Rapid Antigen Test Result	RT-PCR			
					Ct ORF	Ct E gene	Ct N gene	Result
Ct<20								
1	34	M	Asymptomatic	NEG	14.16	12.39	12.53	Detected
2	81	F	Asymptomatic	NEG	16.08	15.66	16.06	Detected
3	26	M	Asymptomatic	NEG	15.18	13.58	13.18	Detected
4	23	M	Asymptomatic	NEG	18.42	16.42	16.17	Detected
5	29	F	Cough, Fatigue	NEG	13.96	13.21	12.47	Detected
6	30	M	Cough, Fatigue	POS	17.97	15.96	18.71	Detected
7	31	M	Fever	NEG	17.97	17.64	19.92	Detected
8	25	M	Asymptomatic	NEG	18.11	17.78	18.36	Detected
9	22	F	Cough	NEG	18.25	16.5	16.08	Detected
10	60	M	Cough, Fatigue, Sore Throat	NEG	16.07	15.83	15.34	Detected
11	27	M	Cough	POS	19.23	19.36	20.97	Detected
12	29	M	Cough	POS	18.69	19.52	22.74	Detected
13	54	M	Cough, Fatigue, Sore Throat	POS	16.74	16.67	16.95	Detected
14	24	F	Cough, Fatigue	POS	16.19	16.23	17.86	Detected
15	36	F	Fever	POS	13.38	13.38	14.91	Detected
16	15	F	Asymptomatic	NEG	18.27	16.85	17.83	Detected
17	30	M	Fever, Fatigue, Sore throat	NEG	13.62	11.98	11.35	Detected
18	48	M	Fever, Headache	NEG	17.07	17.25	19.24	Detected
19	50	F	Asymptomatic	NEG	18.03	17.88	19.95	Detected
20≤Ct<26								
20	36	F	Asymptomatic	NEG	23.1	21.68	20.75	Detected
21	45	F	Asymptomatic	NEG	20.51	18.39	17.23	Detected
22	45	F	Asymptomatic	NEG	22.27	20.85	19.49	Detected
23	34	F	Asymptomatic	NEG	23	21.16	19.78	Detected
24	38	F	Cough	NEG	22.06	20.76	20.18	Detected
25	31	F	Asymptomatic	NEG	25.45	25.75	27.57	Detected
26	44	M	Asymptomatic	NEG	21.88	22	22.48	Detected
27	29	M	Fever, Headache, Anosmia, Ageusia	NEG	23.37	21.75	22.03	Detected
28	25	M	Asymptomatic	NEG	25.24	24.61	24.14	Detected
29	28	F	Asymptomatic	NEG	24.65	25.14	27.04	Detected
30	32	F	Asymptomatic	NEG	22.48	22.67	24.28	Detected
31	31	F	Asymptomatic	NEG	21.3	22.18	23.05	Detected
32	27	M	Asymptomatic	NEG	20.98	19.12	18.58	Detected
33	41	M	Asymptomatic	NEG	21.06	18.92	18.13	Detected
34	28	M	Asymptomatic	NEG	24.6	22.43	22.04	Detected
35	45	F	Cough	POS	22.8	20.77	20.93	Detected
36	66	M	Fever, Fatigue	NEG	23.39	22.52	24.02	Detected
37	43	M	Asymptomatic	NEG	21.26	20.19	19.59	Detected
26≤Ct<30								
38	32	F	Asymptomatic	NEG	27.47	26.25	26.61	Detected
39	53	F	Asymptomatic	NEG	27.22	26.03	26.74	Detected
40	28	F	Asymptomatic	NEG	27.52	26.51	27.3	Detected
41	21	M	Asymptomatic	NEG	29.94	30.92	31.18	Detected
42	32	M	Asymptomatic	NEG	29.91	28.57	29.11	Detected
43	37	M	Asymptomatic	NEG	29.06	28.93	29.39	Detected
44	24	F	Asymptomatic	NEG	26.2	26.41	27.99	Detected
45	37	M	Asymptomatic	NEG	27.5	27.97	29.14	Detected
46	44	F	Asymptomatic	NEG	29.77	28.95	29.97	Detected
47	36	F	Fever, Anosmia, Ageusia	NEG	28.81	27.25	28.36	Detected

48	45	M	Sore throat	NEG	29.91	29.66	29.09	Detected
49	42	F	Asymptomatic	NEG	28.3	28.16	27.9	Detected
50	41	M	Cough, Sore throat	NEG	29.19	29.4	30.52	Detected
51	27	M	Headache	NEG	29.02	28.95	29.96	Detected
52	23	F	Cough, Headache	NEG	29.13	28.87	29.41	Detected
53	32	F	Asymptomatic	NEG	29.55	28.57	27.98	Detected
54	50	M	Asymptomatic	NEG	29.32	29.46	30.56	Detected
30≤Ct<38								
55	18	F	Asymptomatic	NEG	33.75	32.42	32.97	Detected
56	30	M	Asymptomatic	NEG	35.41	32.76	33.62	Detected
57	43	F	Asymptomatic	NEG	33.18	36.56	31.87	Detected
58	57	F	Asymptomatic	NEG	30.03	29.44	29.9	Detected
59	28	F	Asymptomatic	NEG	33.2	32.61	33.36	Detected
60	27	F	Fever, Cough	NEG	35.14	-	35.8	Detected
61	28	F	Fever, Headache	NEG	33.54	32.43	31.64	Detected
62	24	M	Cough	NEG	37.35	38.81	37.08	Detected
63	14	M	Asymptomatic	NEG	36.04	-	34.86	Detected
64	42	M	Asymptomatic	NEG	33.11	31.52	32.72	Detected
65	28	M	Asymptomatic	NEG	34.1	31.66	30.61	Detected
66	26	F	Fever, Sore throat	NEG	34.52	33.01	33.8	Detected
67	33	F	Cough	NEG	33.71	35	33.88	Detected
68	46	F	Asymptomatic	NEG	33.79	30.8	31.94	Detected
69	63	F	Fever, Headache, Sore throat	NEG	35.98	35.53	36.99	Detected
70	49	F	Asymptomatic	NEG	35.29	33.54	34.16	Detected
71	28	F	Fever, Cough	NEG	32.47	34.05	33.51	Detected
Not Detected								
72	8	M	Fever, Cough	NEG				Not Detected
73	16	F	Vomiting	NEG				Not Detected
74	7	M	Fever	NEG				Not Detected
75	15	M	Fever, Headache	NEG				Not Detected
76	22	F	Asymptomatic	NEG				Not Detected
77	18	M	Asymptomatic	NEG				Not Detected