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Research Article

Validation of a Lateral Flow Immunoassay for The Detection of Igg/Igm Antibodies to Sars Cov2 -Covid 19 Among Symptomatic and Asymptomatic High Risk Obgyn Patients in Selected Hospitals in Olongapo City and Zambales - A Multicenter Prospective Study

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Abstract

As the world face health system shocks from coronavirus disease 2019 (COVID-19), an emerging infectious disease caused yet by a novel pathogen (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]), Obstetrician-gynecologists became perplexed by the uncertainties it may bring to each pregnant women and the rest of the vulnerable gynecologic population. Despite the caveats of the CDC study, the susceptibility of a severe covid19 symptoms poses a "signal" to all pregnant women. On the other hand, high risk gynecologic patient such as cancer patients report high fatality rates due to Covid-19. The country's initial Capacity for acute diagnosis via RTPCR testing consist of only tiny aperture of the population, Case finding strategies through centralised specialist laboratories were mostly limited to patients admitted to hospital with moderate to severe symptoms. Indeed, a substantial proportion of asymptomatic pregnant women and gynecologic cancer patients often get de-prioritized due to limited testing kits. The case reporting in these cases, while important, becomes less of a priority. Missed opportunity occurs whenever we fail to test people who might be asymptomatic COVID-19 carriers. Hence, came the approval of rapid based antibody test kits by Department of Health to serve as an adjunct to the diagnosis Covid19 with a short turnaround time compared to the RTPCR.With the intent of coming up a less expensive fast point of care test kits, antibody-based lateral flow assays were developed to test for IgM and IgG antibodies. These tests to detect antibody responses to Covid19 may add to our understanding of the extent of infecion among people who are not identified through active case finding and surveillance efforts. This paper aims to determine the accuracy of antibody tests for presence of IgM and IgG antibodies as an adjunct to RT- PCR for diagnosis of COVID-19 among high risk OBGYN patients.

Key words: asymptomatic; covid19; pregnancy; rapid antibody test; rt-pcr

Introduction

The Coronavirus COVID 19 infection is making a life changing impact worldwide, because of its pervasiveness as an infectious agent combined with its deadly outcomes. It spreads primarily through respiratory droplets leading to severe acute respiratory syndrome (SARS-CoV-2). When the World Health Organization (WHO) declared an outbreak to the level of a pandemic, the global panic was palpable, as we watch cases continue to rise in epic proportions. We have not conquered the virus. And we live in fear of our safety, and are compelled to be always cautious and on guard at all times.

Much about the uncertainties about this infection lies in the difficulty about identifying a person who is infected. There is no single standardized test to detect the presence of the virus nor to accurately test for antibodies to determine if the person has been infected and has recovered. To complicate the matter, there are noted positive tests among asymptomatic individuals that add to making the diagnosis cumbersome.

At present, the diagnosis of COVID19 is by detecting the virus using real-time Polymerase chain reaction (RTPCR). This test involves a highly technical process that requires a machine which necessitates biosafety level 2 (BSL 2) laboratory. The processing of specimen takes 6 to 8 hours, with results taking as long as 3-7 days depending on the load of the laboratory where the specimen was taken. With the increasing cases of COVID19

worldwide, testing capacity has been limited in relation to the deman. This situation places a lot of COVID 19 suspects on queue, with diagnosis and isolation of positive cases delayed, and potential spread of the virus among asymptomatic individuals The brewing concern for asymptomatic transmission came from the findings of the Italian study (ECDC, 2020) [1], that pegged this mode of transmission to as high as 44% of confirmed cases. There is however still limited data as to the extent of this subgroup, as well as its transmission dynamics. The Harvard Global Health Institute (June 2020) [2] stated "All of the best evidence suggests that people without symptoms can readily spread SARSCoV2. In fact, some evidence suggests that people may be most infectious in the days before they become symptomatic". With the intent of providing a fast point of care test kits, that is less expensive, antibody-based lateral flow assays were developed to test for IgM and IgG antibodies. Unlike RT-PCR, rapid test kits use blood samples with a turnaround time of only 15 minutes. However, these tests measure antibodies and not the viral load. There is little peer reviewed data on the utility of lateral flow assays for COVID-19. A study by Li and Colleagues (February 2020) [3], reported a sensitivity of 88.66% and specificity of 90.63% with a caveat that the gold standard still was PCR. A study by Guo et al. (2020) [4], showed that pairing IgM and RT-PCR together resulted in an increase positive detection from 51.9% for PCR alone to 98.6% in the combined tests.

Therefore, WHO currently does not recommend the use of Rapid Antibody Test (RAT) alone for diagnosis but encourages the continuation of work to establish their usefulness in disease surveillance and epidemiologic research. Recently, the Food and Drug Administration (FDA) approved five rapid test antibody test kits for the detection of COVID-19 infection with high sensitivity and specificity. Consequently, Department of Health (DOH) issued guidelines last March 21, 2020 regarding the use of rapid antibody testing. The DOH last June 12, 2020 expanded its testing coverage guidelines to include vulnerable individuals at high risk of contracting COVID-19 [6], "Subgroup F" covers vulnerable individuals that include pregnant women who should be tested during the peripartum period, immunocompromised patients those undergoing dialysis, chemotherapy, or radiotherapy; those who will undergo high-risk elective surgical procedures; and those living in confined spaces such as persons deprived of liberty. [6]
The government's coronavirus interagency task force on the other hand, reiterated that rapid test kits must be used in conjunction with PCR-based test kits in its drive to augment the country's testing efforts. The goal of this study is to determine the accuracy of available RAT for presence of IgM and IgG antibodies as an adjunct to RT- PCR for diagnosis of COVID-19 among high risk OBGYN patients.

Significance of the Study

The validation of a relatively inexpensive RAT kits may find potential use in detecting for the presence of IgM and IgG antibodies among individuals suspected of being infected with COVID 19 and benefit in the low resource setting where the gold standard RT PCR is not available. and emergency situations in the clinical setting may find these kits provide useful information instead of none at all. These kits may also find usefulness in detecting potential asymptomatic infections as well as give a clue as to the magnitude of the spread of infection in an otherwise subset of population that will be ignored because they lacked the symptom of infection. Because mass testing using the RT PCR is expensive, these RAT kits may provide valuable information useful for detecting past infection and possible immunity and give us a glimpse of how close we are to achieving herd immunity and restoring future social functions. Test to detect antibody responses to COVID19 in a specific subset of population will add to our understanding of the extent of infection among people who are not identified through active case finding. Lastly, collecting demographic information allows the gathering of epidemiological data on SARS-CoV-2 including incidence, prevalence and information on asymptomatic high-risk carriers for public health purposes and possible identification of risk factors in the said subset of population.

Objectives

General Objectives:

To determine the diagnostic accuracy of the rapid test lateral flow immunoassay for the detection of SARS- CoV2 using RT PCR as gold standard among symptomatic and asymptomatic high risk ob-gyne population.

Specific Objectives:

1. To determine the extent of IgM and IgG positivity in the symptomatic and asymptomatic populations.

2. To determine the sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio and accuracy of the rapid test in:

2.1 symptomatic ob-gyne patients
2.2 asymptomatic high risk ob-gyne patients
2.3 combined sample of symptomatic and asymptomatic high risk ob-gyne patients

Materials And Methods

Research Design

A multi-center cross-sectional study was carried out from March 2020 - August 2020 in Olongapo and Zambales which included four Institutions.

Participants

Patients from the four participating hospitals who fulfilled the criteria for inclusion were accepted to the study. A local government hospital with residency training in Obstetrics and Gynecology Department had the bulk of patients (80%). While the other three institutions shared the remaining percentage of cases (20%).

A. Inclusion Criteria

This will include symptomatic and asymptomatic patients which will further be divided into 2 subgroups:

I. Symptomatic

1. Symptomatic COVID-19 suspect/probable patients

1.1 Under high-risk Pregnancy

Pregnancy alone in the setting of new flu like symptoms

i. Fever defined as an axillary temperature of 38°C and above
ii. Cough
iii. Sore Throat
iv. Difficulty of Breathing

II. ASYMPTOMATIC

1. Asymptomatic high risk OB GYN patients for elective/ seen at the OPD
2. Asymptomatic high risk patiets for emergency procedures

High risk pregnancy is defined as:

i. With Hypertension, Pre-eclampsia
ii. Diabetis Mellitus
iii. Immunocompromised state, HIV

A. Exclusion Criteria

Asymptomatic Low risk patients with no exposure to a covid19 patient.

B. Sample Size

The study population was based on the on the methodology on Journal of Biomedical Informatics by K. Hajian- Tilaki (2014) which assumes at 96% sensitivity and 97% specificity of the 2019 nCov Antibody test (Colloida Gold) that a sample size of 68 per subset of population will result to a LR positive of 6 [7]. The subjects were selected by nonprobability sampling specifically purposive quota sampling.

Data Collection Process

Patients were interviewed by the researcher using the Case Report Form **(refer to Appendix A).** Consent and approval of participation were secured from study participants. These consent forms underwent validation from the Cental Luzon Health Resourch Development Consortium Ethics Review Committe **(refer to Appendix B).**

RT-PCR tests together with the 2019 nCovAntibody test (Colloidal Gold) were done per Institution and were documented using a case tabulation form. **(Refer to Appendix C)** RT-PCR swabbing were facilitated by the Institution's respective Infection Control Committee personnel previously trained by DOH. While the RAT were done in the laboratory facility of each institution using the 2019 nCov Antibody test (Colloidal Gold) kit. All institutions followed DOH and CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. [8]

Asymptomatic patients were monitored for any development of symptoms via phone call or text. For patients who develop symptoms, repeat RT PCR and RAT were done on the 5th day until the 14th day from the onset of symptoms. Also, for all Covid-19 positive patients, repeat RTPCR and RAT were done on day 14 from the onset of symptoms. All patients included in the study were managed according to the DOH guidelines for COVID 19.

Statistical tests/ tools used

All test results were entered using a two-by-two table to compute for the sensitivity (Sn), specificity (Sp), positive and negative predictive value (PPV/NPV), likelihood ratios (LR) comparing RT-PCR with IgM/IgG using Medcalc statistical software. Subgroup analysis were also done using a two-by-two table to compare the Sp, Sn, PPV, NPV and LR between groups.

The said statistics are defined as follows and reported with their 95% Confidence Intervals:

Sensitivity: probability that a test result will be positive when the disease is present (true positive rate).

Specificity: probability that a test result will be negative when the disease is not present (true negative rate).

AUC: Area under the ROC curve.

Positive likelihood ratio: ratio between the probability of a positive test result given the *presence* of the disease and the probability of a positive test result given the *absence* of the disease, i.e.

= True positive rate / False positive rate = Sensitivity / (1 − Specificity)

Negative likelihood ratio: ratio between the probability of a negative test result given the *presence* of the disease and the probability of a negative test result given the *absence* of the disease, i.e.

= False negative rate / True negative rate = (1 − Sensitivity) / Specificity

Positive predictive value: probability that the disease is present when the test is positive.

$$PPV = \frac{sensitivity \times prevalence}{sensitivity \times prevalence + (1 - specificity) \times (1 - prevalence)}$$

Negative predictive value: probability that the disease is not present when the test is negative.

$$NPV = \frac{specificity \times (1 - prevalence)}{(1 - sensitivity) \times prevalence + specificity \times (1 - prevalence)}$$

Accuracy: overall probability that a patient is correctly classified.
= Sensitivity × Prevalence + Specificity × (1 − Prevalence)

Results and Discussion

	Symptomatic (n = 78)	Asymptomatic (n = 69)
Age	Mean + / - SD = 28.0 +/- 7.5 years	Mean + / - SD = 37.5 +/- 13.2 years
	Range = 17 to 58 years	Range = 19 to 76 years
Mode of Delivery / Management	Normal Delivery = 47 (60.3%) CS = 17 (21.8%) Medical / Surgical Mgmt = 11 (14.1%) Fractional Curettage = 3 (3.8%)	Normal Delivery = 15 (21.7%) CS = 20 (29.0%) Medical / Surgical Mgmt = 24 (34.8%) Fractional Curettage = 10(14.5%)
Symptoms	Fever = 16 (20.5%) Cough = 43 (55.1%) Nasal Congestion = 10 (12.8%) Dyspnea = 13 (16.7%) Myalgia/ Body Pains = 2 (2.6%) Chest Pain = 2 (2.6%) Malaise/ Fatigue = 4 (5.1%) Sore Throat = 7 (9.0%) Loss Taste = 1 (1.3%) Loss Smell/ Anosmia = 0 (0.0%) Diarrhea = 0 (0.0%)	
Co-morbids	Pre-eclampsia = 4 (5.1%) Anemia = 2 (2.6%) Bronchial Asthma = 2 (2.6%) Gestational hypertension = 2 (2.6%) Hypertension = 2 (2.6%) Pneumonia = 2 (2.6%) PTB = 2 (2.6%) Gravidocardiac = 1 (1.3%) Hyperthyroid = 1 (1.3%) Pulmonary edema = 1 (1.3%) Seizure disorder = 1 (1.3%)	Pre-eclampsia = 16 (23.2%) Chronic Hypertension = 10 (14.5%) Obese = 9 (13.0%) Endometrial CA = 9 (13.0%) Gestational Hypertension = 7 (10.1%) Cervical CA = 5 (7.2%) Elderly Primi / Gravid = 4 (5.8%) Chronic Kidney Disease = 3 (4.3%) Anemia = 3 (4.3%) Gestational Diabetes Mellitus = 2 (2.9%) Ovarian New Growth = 2 (2.9%)

	Transient Atony = 1 (1.3%) Valvular heart problem = 1 (1.3%)	Preterm = 2 (2.9%) Abnormal Uterine Bleeding = 1 (1.4%) Hypothyroid = 1 (1.4%) Cervical Incompetence = 1 (1.4%) Myoma = 1 (1.4%) Gestational Trophoblastic Neoplasia = 1 (1.4%) Mitral Valve Prolapse = 1 (1.4%) Placenta Previa Totalis = 1 (1.4%) Pneumonia = 1 (1.4%) UTI = 1 (1.4%) Asthma = 1 (1.4%)
RT-PCR Result	Positive = 4 (5.1%) Negative = 74 (94.9%)	Positive = 1 (5.1%) Negative = 68 (94.9%)

Table 1: Participant Characteristics

Symptomatic COVID Positive

age	gp ob score	Diagnosis on admission	Mode of delivery	fever	cough	Nasal congestion	dyspnea	Sore throat
28	G3|P2	28 y/o G3P2(2001) PU 31 weeks AOG, cephalic not in labor;	5	1	1	1	0	1
18	G1P0	Pregnancy uterine 37 weeks AOG, Cephalic in second stage of	1	0	0	0	0	0
31	G4P3	pu 40 5/7 weeks AOG, cephalic in early labor, covid suspect	3	0	1	0	0	0
26	g2p1	PU 12 4/7 weeks AOG Cephalic in treatened preterm labor	5	0	1	0	0	0

Patients' occupation	Travel history two weeks prior or less	Maternal comorbidities	AOG
freelancer	in manila 1 week ago	NONE	31.0
UNEMPLOYED	NONE	NONE	37.0
vendor	none	gestational hypertension	31.9
none	none		12.7

shows that a total of 78 symptomatic (mean age = 28.0 +/- 7.5 years) and 69 asymptomatic high risk ob-gyne patients (mean age = 37.5 +/- 13.2 years) participated in this study. For the symptomatic group, majority had mild symptoms wherein the most common symptoms noted were cough [55.1%] and fever [20.5%]. Their Mode of delivery were mostly normal spontaneous vaginal delivery with [60.3 %] followed by Cesarean Section [21.8%], Medical Mangement of [14.1%] and Curettage with only 3.8 %. Related co-morbidities include Pregnancy Induced Hypertension with 10.3%, followed by Pulmonary problems with 9.1% and Anemia with 3.9 %.

Among the asymptomatic participants, a 32-year-old with Gestational Hypertension who underwent an Emergency Cesarean Section was noted to have negative RAT but tested positive for RT-PCR. Of every 100 symptomatic OB-Gyne patients, about 23 test positive in the rapid test for IgM and / or IgG while for every 100 asymptomatic high-risk OB-Gyne patients roughly only 3 have a positive RAT result [Table 2].

Rapid Test Result	**Symptomatic n (%)**	**Asymptomatic n (%)**
IgM (-) IgG (-)	60 (76.92)	67 (97.10)
IgM (-) IgG (+)	4 (5.13)	1 (1.45)
IgM (+) IgG (-)	12 (15.38)	1 (1.45)
IgM (+) IgG (+)	2 (2.56)	0 (0.00)

Table 2: Rapid Antibody Test Results among Symptomatic and Asymptomatic High-Risk OB-Gyne Patients

The following findings on the rapid test for IgM can be inferred from Table 3:

Group	Rapid Test Result	Positive by RT PCR	Negative by RT PCR	Total	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio	Accuracy
Symptomatic	Positive	0	14	14	0.00 %	81.08 %	0.00%	93.75 %	0	1.233	76.92 %
	Negative	4	60	64							
	Total	4	74	78							
Asymptomatic	Positive	0	1	1	0.00 %	98.53 %	0.00%	98.53 %	0	1.015	97.10 %
	Negative	1	67	68							
	Total	1	68	69							
Total	Positive	0	15	15	0.00 %	89.44 %	0.00%	96.21 %	0	1.118	86.40 %
	Negative	5	127	132							
	Total	5	142	147							

Table 3: Summary of the Sensitivity, Specificity, PPV, NPV of the Rapid Test for IgM Compared to RT PCR

The RAT for IgM was not found to be sensitive in both symptomatic and asymptomatic high-risk ob-gyne patient groups. It was not able to identify any one of the five patients who had COVID-19 based on RT-PCR. These five patients all tested negative in RAT for IgM. This implies that the RAT for IgM is not useful for ruling out COVID-19 even if a person has a negative result. Moreover, the (PPV) was found to be zero because the 15 persons who tested positive in the RAT for IgM were all negative in the RT-PCR. This means there is a very high probability that both symptomatic and asymptomatic high-risk ob-gyne patients can have a "positive" rapid test for IgM result but actually do not have COVID-19. Given that the RAT for IgM had zero true positive rate, positive (LR) were also zero for both groups.On the other hand, specificity of the RAT for IgM is high for both symptomatic and asymptomatic high-risk ob-gyne patient groups although it is higher for the latter wherein 67 out of 68 patients who did not have COVID-19 tested negative. This means the RAT for IgM does well in identifying patients who truly do not have COVID-19. The (NPV) of the rapid test for IgM is also high for both groups meaning there is high probability that symptomatic and asymptomatic high-risk ob-gyne patients who get a negative test result in the RAT for IgM truly do not have the disease. However, since all the five patients who had COVID-19 based on RT-PCR were negative based on the rapid test for IgM, negative (LR) were found to be greater than 1 implying greater probability of a negative test result given the presence of the disease as compared to the probability of a negative test result given the absence of the disease.Overall, the probability that a symptomatic ob-gyne patient is correctly classified based on RAT for IgM is only 76.92% while the probability that an asymptomatic high-risk ob-gyne patient is correctly classified based on RAT for IgM is 97.10%. The combined probability of correct classification for the ob-gyne patients based on RAT for IgM is 86.40%. The following findings on the rapid test for IgG can be inferred from Table 4:

Group	Rapid Test Result	Positive by RT PCR	Negative by RT PCR	Total	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio	Accuracy
Symptomatic	Positive	1	5	6	25.00%	93.24 %	16.67 %	95.83 %	3.7	0.804	89.74 %
	Negative	3	69	72							
	Total	4	74	78							
Asymptomatic	Positive	0	1	1	0.00 %	98.53 %	0.00%	98.53 %	0	1.015	97.10 %
	Negative	1	67	68							
	Total	1	68	69							
Total	Positive	1	6	7	20.00%	95.78 %	14.29 %	97.14 %	4.733	0.835	93.20 %
	Negative	4	136	140							
	Total	5	142	147							

Table 4: Summary of the Sensitivity, Specificity, PPV, NPV of the Rapid Test for IgG Compared to RT PCR

The RAT for IgG was also not found to be sensitive in both symptomatic and asymptomatic high-risk ob-gyne patient groups. It was able to identify only one of the five patients who had COVID-19 based on RT-PCR. This patient who tested positive in both the rapid test for IgG and RT-PCR was symptomatic. The positive (LR) for the symptomatic group was 3.7 meaning there is almost 4 times greater probability of a true positive as compared to a false positive RAT for IgG result in the symptomatic group. The positive (LR) for the asymptomatic group was 0 since no true positive rapid test for

IgG result was recorded in the asymptomatic group. Moreover, the (PPV) was found to be only 14.29% with only 1 of 7 persons who tested positive in the RAT for IgG testing positive in the RT-PCR. This means there is a very low probability that a patient with positive RAT for IgG result truly has COVID-19. On the other hand, specificity of the RAT for IgG is high for both symptomatic and asymptomatic high-risk ob-gyne patient groups although it is higher for the latter wherein 67 out of 68 patients who did not have COVID-19 tested negative. This means the RAT for IgG does well in identifying patients who truly do not have COVID-19. The (NPV) of the rapid test for IgG is also high for both groups meaning there is high probability that symptomatic and asymptomatic high-risk ob-gyne patients who get a negative test result in the RAT for IgG truly do not have the disease. In terms of negative (LR), a ratio of less than one was noted in the symptomatic group and overall implying greater probability of a negative test result given the absence of the disease as compared to the probability of a negative test result given the presence of the disease.

Overall, the probability that a symptomatic ob-gyne patient is correctly classified based on RAT for IgG is only 89.74% while the probability that an asymptomatic high-risk ob-gyne patient is correctly classified based on RAT for IgG is 97.10%. The combined probability of correct classification for the ob-gyne patients based on rapid test for IgG is 93.20%

Conclusion

With a very low sensitivity (5% in our study) and low ability to accurately detect infected patients who do have the condition, the RAT for COVID-19 is not recommended for screening purposes. However, it could be helpful in disease surveillance. The specificity and sensitivity of the RAT varies largely depending upon the method and the manufacturer. WHO mentioned the sensitivity of RATs might be expected to vary from 34-80%. Thus, WHO suggests that it shouldn't be used for clinical decision making and patient care. The diagnostic utility of RAT is encouraged for epidemiologic research settings, to confirm past COVID-19 patients, and determine (herd) immunity of the country. Our results suggest that detection of IgG antibodies can be very useful if performed at least 14 days after onset of symptoms or at the end of the outbreak for the asymptomatic patients. There is currently no clear evidence that measuring IgM is useful as the infectivity of the virus may not be determined. Our results even suggest that it might be better not to measure IgM since this could result in a significant number of false-positive results without a significant gain in diagnostic performance. Testing a subset of population like for pregnant patients wherein positive cases are high but are Asymptomatic, using the rapid antibody test too early in the covid care pathway may deter the capability of a facility to mitigate the infection and expose employees to higher work-related risks Gabriela Baron (2020) had conducted a similar study at PGH and concluded that effective measures be implemented to prevent COVID-19 spread and not rely on RAT with merely 20% sensitivity. Among the personnel tested in June, only 2% tested positive and among the frontliners 1.4% was reported to have positive rapid test. Even for screening, the RAT missed 80% of cases which is significantly high.Important questions remain regarding the use of RAT for epidemiological purposes. Until now it is still not clear whether IgG antibodies are protective against reinfection and if patients colonized with SARS cov 2 may develop any antibody over time.

Limitation of the Study

There are numerous factors that can affect the accuracy of the test, including time from onset of illness, concentration of antibody in the specimen, processing, quality of the collected specimen and the precise formulation of the reagents in the test kits.Based on the RAT for other respiratory diseases such as influenza, the sensitivity of these tests might be expected to vary from 34% to 80%.

Recommendations

The Researcher would like to recommend the use of Laboratory based immunoassays such as chemiluminescence assay (CLIA) and enzyme-linked immunosorbent assay (ELISA) as other preferred tests for the antibody determination. Since ELISA-based has specificity of greater than 99% and sensitivity of 96% with less cross reactivity from viruses causing cold. However, these may not be used as basis for screening compared to RTPCR as the gold standard.

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Authors would like to declare that there is no conflct of interest in the choice of 2019 nCov Antibody test (Colloidal Gold) as primary RAT kit for the study.

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