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Validation of a lateral flow immunoassay for the detection of immunoglobulin G/immunoglobulin M antibodies to severe acute respiratory syndrome coronavirus 2-COVID-19 among symptomatic and asymptomatic high-risk OBGYN patients in selected hospitals in Olongapo city and Zambales – A multicenter prospective study

Tosca Camille S. Guiao, Corazon R. Valdez, Louella P. Aquino, Daisy Grace Z. Rivera, Madonna M. Valenzuela

Abstract:

BACKGROUND/INTRODUCTION: As the world face health-system shocks from COVID-19, Obstetrician-Gynecologists become perplexed by the uncertainties these bring to the vulnerable pregnant and gynecologic population. The country's capacity for diagnosis via RTPCR consists of only a tiny proportion of the population. With the intent of coming up with a less expensive fast point of care test kits, antibody-based lateral flow assays were developed.

AIMS AND OBJECTIVES: Determine the diagnostic accuracy of a lateral flow immunoassay for the detection IgM/IgG antibodies to SARS-CoV2 using RT-PCR as gold standard among symptomatic and asymptomatic high risk OBGYN population.

MATERIALS AND METHODS: This is a multicenter cross-sectional prospective study performed on 147 asymptomatic and symptomatic high risk OBGYN patients who underwent both RTPCR and RAT. 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.

RESULTS: The RAT for IgG/IgM was not found to be sensitive in both groups. It was able to identify only one of the five patients who had COVID-19 based on RT-PCR. Moreover, the (PPV) was found to be only 20% since only one patient tested positive in the RAT for IgM/IgG that was also positive in the RT-PCR. The (LR+ and LR-) for the symptomatic group was close to 1 implying a slightly higher probability of a true positive compared to that of a false positive test and a negative test result given the absence of the disease respectively. (Sp) and (NPV) of the RAT for IgM/IgG is high for both groups. This means that RAT for IgM/IgG does well in identifying patients who truly do not have COVID-19.

CONCLUSION: With a very low sensitivity of 5% in this study, RAT for COVID-19 cannot be used for screening purposes.

Keywords:

Asymptomatic, COVID-19, pregnancy, rapid antibody test, real-time polymerase chain reaction

Department of Obstetrics and Gynecology, James L. Gordon Memorial Hospital, Olongapo City, Zambales, Philippines

Address for correspondence:
Madonna M. Valenzuela, No. 1 Perimeter St, New Asinan, Brgy Pag-asa, 2200 Olongapo City.
E-mail: totosh_26@yahoo.com

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Introduction and Review of Related Literature

The coronavirus disease 2019 (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. Moreover, 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 neither 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 COVID-19 is by detecting the virus using real-time polymerase chain reaction (RT-PCR). This test involves a highly technical process that requires a machine which necessitates biosafety level 2 laboratory. The processing of the specimen takes 6–8 h, 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 COVID-19 worldwide, testing capacity has been limited in relation to the demand. This situation places a lot of COVID 19 suspects on queue, with the 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 fast point of care test kits, that are less expensive, antibody-based lateral flow assays were developed to test for immunoglobulin M (IgM) and IgG antibodies. Unlike RT-PCR, rapid test kits use blood samples with a turnaround time of only 15 min. However, these tests measure antibodies and not the viral load. There are little peer-reviewed data on the utility of lateral flow assays for COVID-19. A study by Li *et al.* (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*.,[4] showed that pairing IgM and RT-PCR together resulted in an increase in positive detection from 51.9% for PCR alone to 98.6% in the combined tests.

The DOH released a revised interim Guideline last April 16, 2020 on Expanded testing which only covers 4 subgroups of population. 1. Subgroup A that involves patients or health care workers with severe/critical symptoms, relevant history of travel or contact. 2. Subgroup B are patients or health care workers with mild symptoms, relevant travel /contact and considered vulnerable 3. Subgroup C are patients or health care workers with mild symptoms, relevant history of travel/contact 4. Subgroup D. Patients or health workers with no symptoms but relevant history or travel /contact.[5]

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 approved five rapid test antibody test kits for the detection of COVID-19 infection with high sensitivity and specificity. Consequently, the 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 the presence of IgM and IgG antibodies

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as an adjunct to RT-PCR for the diagnosis of COVID-19 among high-risk OBGYN patients.

Significance of the study

The validation of 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 emergencies 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 the population that will be ignored because they lacked the symptom of infection.

Since 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 COVID-19 in a specific subset of the population will add to our understanding of the extent of infection among people who are not identified through active case finding.

Finally, 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 the 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 the gold standard among the 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 (PPV), negative predictive value (NPV), positive likelihood ratio (LR), negative LR, and accuracy of the rapid test in:
   a. Symptomatic ob-gyne patients
   b. Asymptomatic high-risk ob-gyne patients
   c. 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%).

Inclusion criteria

This will include symptomatic and asymptomatic patients which will further be divided into two subgroups.

Symptomatic

1 Symptomatic COVID-19 suspect/probable patients
   a. 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.

Asymptomatic

1. Asymptomatic high-risk OB-GYN patients for elective/seen at the outpatient department
2. Asymptomatic high-risk patients for emergency procedures.

High-risk pregnancy is defined as:
i. With hypertension, preeclampsia
ii. Diabetes mellitus
iii. Immunocompromised state, HIV.

Exclusion criteria

Asymptomatic low-risk patients with no exposure to a COVID-19 patient.

Sample size

The study population was based 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 the population will result to an 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. Consent and approval of participation

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were secured from study participants. These consent forms underwent validation from the Central Luzon Health Research Development Consortium Ethics Review Committee.

RT-PCR tests together with the 2019 nCovAntibody test (Colloidal Gold) were done per Institution and were documented using a case tabulation form. 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. Furthermore, for all COVID-19 positive patients, repeat RT-PCR 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), PPV/NPV, LR comparing RT-PCR with IgM/IgG using Medcalc statistical software. Subgroup analyses 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).

Area under the curve: Area under the ROC curve.

Positive LR: 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 LR: 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.

$$PPV = \frac{Specificity \times (1 - Prevalence)}{(1 - Specificity) \times Prevalence + Specificity \times (1 - Prevalence)}$$

Accuracy: Overall probability that a patient is correctly classified.

= Sensitivity × Prevalence + Specificity × (1 – Prevalence)

Results and Discussion

Table 1 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, the majority had mild symptoms wherein the most common symptoms noted were cough (55.1%) and fever (20.5%). Their mode of delivery was mostly normal spontaneous vaginal delivery with (60.3%) followed by cesarean section (21.8%), medical management of (14.1%), and curettage with only 3.8%. Related comorbidities 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].

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Table 1: Participant characteristics

	Symptomatic (*n*=78), *n* (%)	Asymptomatic (*n*=69), *n* (%)
Age, mean±SD (range)	28.0±7.5 (17-58)	37.5±13.2 (19-76)
Mode of delivery/management	Normal delivery=47 (60.3)	Normal delivery=15 (21.7)
	CS=17 (21.8)	CS=20 (29.0)
	Medical/surgical management=11 (14.1)	Medical/surgical Management=24 (34.8)
	Fractional curettage=3 (3.8)	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	
	Diarrhea=0	
Co-morbids	Preeclampsia=4 (5.1)	Preeclampsia=16 (23.2)
	Anemia=2 (2.6)	Chronic hypertension=10 (14.5)
	Bronchial asthma=2 (2.6)	Obese=9 (13.0)
	Gestational hypertension=2 (2.6)	Endometrial CA=9 (13.0)
	Hypertension=2 (2.6)	Gestational hypertension=7 (10.1)
	Pneumonia=2 (2.6)	Cervical CA=5 (7.2)
	PTB=2 (2.6)	Elderly primi/gravid=4 (5.8)
	Gravidocardiac=1 (1.3)	Chronic kidney disease=3 (4.3)
	Hyperthyroid=1 (1.3)	Anemia=3 (4.3)
	Pulmonary edema=1 (1.3)	Gestational diabetes mellitus=2 (2.9)
	Seizure disorder=1 (1.3)	Ovarian new growth=2 (2.9)
	Transient atony=1 (1.3)	Preterm=2 (2.9)
	Valvular heart problem=1 (1.3)	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)	Positive=1 (5.1)
	Negative=74 (94.9)	Negative=68 (94.9)

CS: Cesarean section, PTB: Preterm birth, CA: Cancer, UTI: Urinary tract infection, SD: Standard deviation, RT-PCR: Real-time polymerase chain reaction

Table 2: Rapid antibody test results among symptomatic and asymptomatic high-risk obstetrics-gynecologic patients

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

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

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 results but actually do not have COVID-19. Given that the RAT for IgM had zero true positive rates, positive (LR) were also zero for both groups.

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On the other hand, the 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 >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:

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.

Table 3: Summary of the sensitivity, specificity, positive predictive value, negative predictive value of the rapid test for IgM compared to real-time polymerase chain reaction

Group	Rapid test result	Positive by RT-PCR	Negative by RT-PCR	Total	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Positive likelihood ratio	Negative likelihood ratio	Accuracy (%)
Symptomatic	Positive	0	14	14	0	81.08	0	93.75	0	1.233	76.92
	Negative	4	60	64							
	Total	4	74	78							
Asymptomatic	Positive	0	1	1	0	98.53	0	98.53	0	1.015	97.10
	Negative	1	67	68							
	Total	1	68	69							
Total	Positive	0	15	15	0	89.44	0	96.21	0	1.118	86.40
	Negative	5	127	132							
	Total	5	142	147							

PPV: Positive predictive value, NPV: Negative predictive value, RT-PCR: Real-time polymerase chain reaction

Table 4: Summary of the sensitivity, specificity, positive predictive value, negative predictive value of the rapid test for IgG compared to real-time polymerase chain reaction

Group	Rapid test result	Positive by RT-PCR	Negative by RT-PCR	Total	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	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	98.53	0	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							

PPV: Positive predictive value, NPV: Negative predictive value, RT-PCR: Real-time polymerase chain reaction

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On the other hand, the 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 vary largely depending upon the method and the manufacturer. WHO mentioned the sensitivity of RATs might be expected to vary from 34% to 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 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 RAT 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 front liners, 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 and enzyme-linked immunosorbent assay (ELISA) as other preferred tests for antibody determination. Since ELISA-based has the specificity of >99% and sensitivity of 96% with less cross-reactivity from viruses causing cold. However, these may not be used as the basis for screening compared to RT-PCR as the gold standard.

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The authors would like to declare that there is no conflict of interest in the choice of the 2019 nCov antibody test (Colloidal Gold) as the primary RAT kit for the study.

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Conflicts of interest

There are no conflicts of interest.

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