INTERNATIONAL JOURNAL OF ADVANCE RESEARCH, IDEAS AND INNOVATIONS IN TECHNOLOGY

ISSN: 2454-132X
Impact Factor: 6.078
(Volume 7, Issue 4 - V7I4-1280)
Available online at: https://www.ijariit.com

Clinical evaluation of Standard Q Rapid Ag TEST vs RT PCR

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ABSTRACT

The Pandemic COVID-19 poses the major problem in diagnosing which requires skilled technician and well equipped infrastructure. To overcome we have evaluated the Standard Q rapid Ag test for SARS-CoV-2 virus from nasal swab at POC sites which was eventually compared with RT PCR as reference assay. A maximum of 505 samples were collected from the patients who visit hospitals and laboratories for different purposes with appropriate consent form. It is found to be that rapid Ag test shows good sensitivity, specificity and predictive value range with RT PCR and it will be also useful in swarm screening and in emergency conditions.

Keywords: *Rapid Antigen Test, SARS-CoV-2, RT-PCR.*

1. INTRODUCTION

The corona virus are enveloped RNA virus belongs to the family of corona viridae that cause serious infections in birds and mammals.[4] The corona virus species such as Middle East respiratory corona virus syndrome (MERS - CoV) and severe acute respiratory syndrome (SARS - CoV) can cause severe respiratory infections with high mortality rate. At the end of 2019, WHO proclaimed the outbreak of novel corona virus in China and named it as COVID 19, which is now pandemic (WHO, 2020). As this had a very high rate of incidence worldwide within certain time limits, the public diagnostic laboratories pretenses a great challenge.[4]

Molecular method of detection have been revolutionized the clinical microbiology laboratories in detecting pathogens. Though the standard PCR protocols were gold standard and have high sensitivity and high specificity results, they are time consuming[2] and needs high throughput RT PCR systems. To account these disadvantages, rapid antigen test (RAT) has been used for COVID-19. RATs strengthen the identification rapidly. However, this method also gives high number of false negatives. RAT reads only the high number of virus as positive and small amount of virus cannot be detected in RAT method.[3]

Apart from these disadvantages, point of care diagnostics of novel COVID viral antigen can used as a rapid screening test and first aid test. With these intended purpose, SD biosensor pvt ltd has provided the Standard Q COVID Ag test to access the diagnostic accuracy compared with that of RT PCR test of nasal swab specimens.

2. MATERIALS AND METHODS

To evaluate the diagnostic accuracy of Standard Q COVID Ag test at POC in comparison with RT-PCR test. A total of 505 patients who visit hospitals and lab either with symptoms or asymptoms was selected randomly and got signed in consent form. Nasal swab and nasopharyngeal, oropharyngeal swabs were collected to perform Standard Q COVID Ag test and standard PCR test respectively. The study was also reviewed and approved by IRB (IRB number: IORG0010284).

Standard Q Ag test was conducted at the point of collection by lay provider and collected NP/OP swabs were brought to laboratory in VTM and it was preceded to RNA extraction and RT PCR. The obtained results were compared and statistically calculated for sensitivity and specificity.

The data were analyzed statistically for diagnostic sensitivity, positive predictive value (PPV) and diagnostic specificity, negative predictive value (NPV).

3. RESULTS

In the study period of 1 month, a total of 505 patients were tested for both Standard Q Ag test and RT PCR, of the total, 123 patients were diagnosed with symptoms and 382 were asymptomatic. The no. of days of onset of symptoms was tabulated.

Table-1: No. of Samples with days of Onset of Symptoms

Symptoms Onset Date	No. of Samples
0-3 days	81
4-7 Days	42

Of the total 123 symptomatic patients, 105 were detected positive for SARS-CoV-2 in RT PCR and 18 were detected as negative for SARS CoV-2 RT PCR. At POC diagnostics, 103/105 RT PCR positive samples were found to be positive for standard Q Ag Test. The remaining 402 samples were negative for both SARS CoV-2 RT PCR and standard Q Ag Test. The sensitivity and specificity of the tests were shown in the table.

Table-2: Sensitivity and Specificity of the Tests

Sample Type		EURO Real Time SARS-CoV-2		
		Positive	Negative	Total
Standard Q Covid-19 Ag	Positive	103	0	103
	Negative	2	400	402
	Total	105	400	505
Sensitivity- 98.10% (95% CI, 93.29% to 99.77%)				
Specificity- 100% (95% CI, 99.08% to 100%)				

The diagnostic performances were calculated and it showed that positive predictive value of 100% and negative predictive value of 99.50%.

4. DISCUSSION AND CONCLUSION

The outbreak of pandemic COVID-19 desires an essential tool to diagnose the SARS-CoV-2 virus in a rapid and cost effective approach. It is also crucial to diagnose at POCT, due to its rapid spread among the populations. The standard Q Ag rapid test identifies 97.18% of RT PCR positives with 100% specificity. However, it also had high sensitivity with samples of 4-7 days of onset of symptoms and 97% of sensitivity with 0-3 days of onset of symptoms due to low viral load.

The major advantage of rapid Ag test is that requires only nasal swab which also show concordance with RT PCR results. The results can also be interpreted very easily; do not require high skilled technicians and infrastructures.[1] The POCT diagnosis is decisive for mass screening and on emergency situations.

5. REFERENCES

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