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INTERNATIONAL JOURNAL OF CURRENT RESEARCH

International Journal of Current Research
Vol. 13, Issue, 03, pp.16580-16582, March, 2021

ISSN: 0975-833X

DOI: https://doi.org/10.24941/ijcr.40931.03.2021

RESEARCH ARTICLE **OPEN ACCESS**

PERFORMANCE EVALUATION OF SD BIOSENSOR- STANDARD Q COVID-19 AG TEST IN COMPARISON WITH RT- PCR ASSAY FROM A TESTING SITE IN INDIA

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ARTICLE INFO

Article History:
Received 18th December, 2020
Received in revised form
07th January, 2021
Accepted 15th February, 2021
Published online 26th March, 2021

Key Words:
STANDARD Q,
Real Time PCR, COVID-19 Ag

ABSTRACT

Background: The current gold standard for the detection of SARS-CoV-2 is the RT-PCR test. The RT-PCR tests are not rapid (it typically takes 3–4 h for results), and it requires specialized laboratory equipment and skilled technicians. Timely and accurate COVID-19 testing is an essential part for surveillance. The aim of the study is to assess diagnostic accuracy of CE-approved POCT, the STANDARD Q COVID19 Ag for the detection of SARS CoV-2 nucleoprotein in NP swabs in comparison with the gold standard RT-PCR. **Methods:** RT-PCR (EURO Real Time SARS-CoV-2 RT PCR test) and Rapid Antigen testing (STANDARD Q COVID-19 Ag test) was performed following manufactures instructions. **Results:** The STANDARD Q COVID-19 Ag Test showed a sensitivity of 97.11% and a specificity of 100%. There were no Invalid Test results while using Standard Q Covid-19 AgTest. **Conclusion:** The rapid test provided comparable results with RT- PCR in terms of sensitivity, specificity, accuracy, negative and positive predictive values

Citation: Dr. Vandana Govindan, Dr. Veena Umesh, Shincy M.R., Dr. Venkatesha V .T. and Dr. RaviKumar K.L. " Performance evaluation of SD Biosensor- STANDARD Q COVID-19 Ag Test in comparison with RT- PCR assay from a testing site in India "" 2021. *International Journal of Current Research, 13, (03), 16580-16582.*

INTRODUCTION

The Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) emerged in the year 2019, was declared as a pandemic by WHO on March 11th 2020. Since then, WHO has emphasized the importance of diagnostic testing as part of a comprehensive strategy to control COVID-19. In order to strengthen global diagnostic capacity, use of rapid and easy-to-perform diagnostic methods is of high priority, to shorten the time of result-reporting. The current gold standard for the detection of SARS-CoV-2 is the RT-PCR test conducted using different types of specimens including sputum, nasopharyngeal swabs, pharyngeal swabs and saliva (Atul Sharma, 2020).

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However, the RT-PCR tests are not rapid (it typically takes 3–4 h for results), and it requires specialized laboratory equipment and skilled technicians. In addition, transportation of clinical samples increases the turnaround time from sample collection to reporting of the result up to 48 hours (Michael, 1996). Timely and accurate COVID-19 testing is an essential part for surveillance, contact tracing, infection prevention and control, and clinical management of COVID-19. The immediate availability of test results is useful for faster patient management and for handling of more patients in a diminished time frame. Point-of-care antigen tests to detect current SARS-CoV-2 infection have the potential to allow earlier detection and isolation of confirmed cases compared to laboratory-based diagnostic methods, with the aim of reducing household and community transmission (Jacqueline Dinnes, 2020). If the target antigen is present in sufficient concentrations in the sample, it will bind to specific antibodies generate a visually

detectable signal, typically within 30 minutes. The antigen (s) detected are expressed only when the virus is actively replicating; therefore, such tests are best used to identify acute or early infection (Basant Giri *et al.,* 2021). The efficiency of the test depends on severe factors including the time from onset of illness, the concentration of virus in the specimen, the quality of the specimen collected from a person and how it is processed, and the precise formulation of the reagents in the test kits. The sensitivity of these tests varies from 34% to 80% depending upon the time of collection of samples from the onset of symptom. In this study we aimed to assess diagnostic accuracy of CE-approved POCT, the STANDARD Q COVID19 Ag for the detection of SARS CoV-2 nucleoprotein in NP swabs in comparison with the gold standard RT-PCR. 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 nasopharynx. POCT performances were studied in terms of sensitivity, specificity, negative and positive predictive values.

MATERIALS AND METHODS

Ethical issues: This study was approved by the Institutional Review Board of KIMS Medical College (Protocol Ref no: KIMS IEC/S09-2020).

Clinical specimens: Nasopharyngeal swabs, were collected from 503 cases from October to December 2020 at Central Research Laboratory, KIMS.

Study Design

- Prospective
- Randomized (negative and positive samples are tested at random)
- Blinded (test operators are unaware of the PCR result when using the antigen test)

Statistical analysis

Descriptive statistics were used to describe general information of patients. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) were calculated using an online statistical tool.

Method

RT-PCR (EURO Real Time SARS-CoV-2 RT-PCR test) and Rapid Antigen testing (STANDARD Q COVID-19 Ag test) was performed following manufactures instructions.

RESULTS

Demographic characteristics: A total of 104 COVID-19 cases and 399 controls (total 503) were included in this evaluation. The majority were males (52.4%) and the overall mean age was 34 years (95% CI: 32 – 35; Table 1)

Table 1. Demographic characteristics of study participants

		Gender		Total
Participants	Mean Age (95% CI)	Males	Females	
Cases	40.3	55	49	104
Controls	35.3	211	188	399
Total	75.6	266	237	503

Performance Characteristics

Test result distribution: The distribution of STANDARD Q COVID-19 Ag Test results against the qRT-PCR results are presented in Table 2.

Table 2. Standard q covid-19 Ag test result compared to the qRT-PCR reference assay

Type of Sample		EURO Real Time SARS-CoV-2		
		Positive	Negative	Total
Standard Q Covid-19 Ag	Positive	101	0	101
	Negative	3	399	402
	Total	104	399	503
Sensitivity-97.12%		Specificity-100%		

Sensitivity and Specificity: The STANDARD Q COVID-19 Ag Test showed a sensitivity of 97.11% and a specificity of 100%. There were no Invalid Test results while using Standard Q Covid-19 Ag Test.

Positive Predictive and Negative predictive value

- OPA (Overall Percent Agreement) =**97.1%**
- PPA (Positive Percent Agreement) = **100%** (95% CI 77.58% to91.22%)
- NPA (Negative Percent Agreement) = **99%** (95% CI 99.15% to100%)

The Positive Predictive Value of the STANDARDQ COVID-19 Ag Test using nasal swab as specimen and RT-PCR Test as reference assay is 100% and the negative percent agreement is 99%.

Association between Ct Values and STANDARD Q COVID-19 Ag Test result: STANDARD Q COVID-19 Ag Test, was positive for all the samples positive for RT PCR with a CT value less than 31.3 positive samples with a CT value of 31.4 ,31.9 and 31.7 were negative by STANDARD Q COVID-19 Ag test. Concordance between the two techniques was 97.1%.

DISCUSSION

Significant diagnostic problems aroused due to acute respiratory syndrome corona virus 2 (SARS-CoV-2) and the resulting COVID-19 pandemic. Most RT-PCR based testing is conducted in designated, specialized laboratories which are far from sample collection sites leading to long turn around time, delayed reporting and thereby increasing the spread of the infection. Other methodologies like mobile PCR platform and Genexpert were introduced to reduce the turn around time, but issues like reagent supply, cost and testing facility still remains a challenge. There are several antigen and molecular point-of-care tests available to classify or exclude current infections, or to screen for past infections and immune responses. Point-of-care antigen tests have the potential to allow earlier detection and isolation of confirmed cases compared to laboratory-based diagnostic methods, with the aim of reducing household and community transmission. In this study we analysed the Ct value of the nasopharyngeal samples collected in the month of October to December 2020 and evaluated the performance of the rapid antigen testing kit. Our results indicated that, although RT-PCR is suitable for monitoring and assessing the true infection given its higher detection sensitivity, antigen

rapid testing can also effectively detect infected patients at their initial visit. Rapid antigen test correctly detected 97.1% of the RT-PCR positive samples as positive, suggesting it is a useful tool to identify high-risk patients from the population who are suspected to be infected with SARS-CoV-2 during an epidemic. Some studies confirmed that the clinical performance of POCTs primarily depends on the viral load and the conditions under which they are used. The sensitivity of tests was higher in specimens obtained within seven days following the onset of symptoms. and for samples with lower Ct value at RT-PCR testing indicating higher viral load. Our data confirm, in accordance with recently published works, that this POCT is effective within a few days after the onset of symptoms when the viral load in the upper respiratory tract is at its peak during the acute/recent stage of the disease [Lambert-Niclot, 2020; Harcourt, 2020; Mavrikou, 2020; Mertens, 2020]. Moreover, Rapid antigen testing has several advantages over RT-PCR; it is rapid, requires no equipment and investment, easy to interpret, with limited technical skill and infrastructure.

Independent evaluations were performed in several countries, predominantly in symptomatic populations. The sensitivities and specificities were calculated against RT-PCR tests and ranged between 29% (95%CI 15.7-42.3) and 93.9% (95% CI 86.5-97.4) for test sensitivity and between 80.2% (95% CI 71.1-86.7) and 100% (95% CI 98.8-100) for test specificity. The substantial differences in performance noted between the tests and between the studies can be partially explained by different populations and time of testing (proportion of persons that were tested early versus late in the course of the disease), and may also be affected by different RT-PCR assays used as gold-standard comparators, extraction methods or type of samples. The sensitivity and specificity of the STANDARD Q COVID-19 Ag test was 97.12% and 100% respectively. Our data suggest that the platform has similar or greater sensitivity and specificity than other rapid assays using dry swabs. While, other rapid tests require viral transport medium and a simple sample transfer step, using STANDARD Q COVID-19 Ag test, swabs are loaded directly into a fully sealed cartridge, which allows safe testing outside a laboratory setting, including primary care and community settings.

Conclusion

STANDARD Q COVID-19 Ag Test exhibited an optimal performance in this evaluation. This rapid test will decrease the burden of virology testing during mass screening process and can be considered as one component of the testing strategy in symptomatic persons that is required to contain the COVID-19 pandemic.

Financial support and sponsorship: Nil.

Conflicts of interest: There are no conflicts of interest.

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