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Original Research Article

Comparison of Diagnostic Performance between Abbott Id Now ™ & Real-Time PCR for the Detection of SARS COV-2 in a Tertiary Care Hospital.

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Conflict of interest: Nil

Abstract:

Background: The incidence of the SARS-CoV-2 virus (Severe Acute Respiratory Syndrome Coronavirus 2) pandemic has posed to be crisis to the diagnostic laboratories around the world for seeking reliable methods to confirm the infection in a short span of time which helps in the treatment plan and also to isolate the patients to prevent the spread. Most of the laboratories presently use Real-Time reverse transcription-Polymerase Chain Reaction (RT-PCR) test to diagnose the infection which has many drawbacks including the need for a dedicated work area, skillful and trained staffs and long testing time. In order to reduce the above constrains; we decided to test the efficiency of Abbott ID Now ™ COVID-19 which is a cartridge based nucleic acid amplification assay that helps in a quicker diagnosis of the infected patients in a shorter span of time.

Methods: Nasopharyngeal swabs were collected from each patient and were processed in both Real-Time RT-PCR and ABBOTT ID NOW™ COVID-19 and the results are compared.

Results: Out of the 87 samples tested in both Real-Time PCR and ABBOTT ID NOW, 74 samples were tested negative (85.1%) and 13 samples (14.9%) were tested positive in Real-Time PCR and 69 samples (79.3%) were tested negative and 18 samples (20.7%) were tested positive.82 samples (94%) results were found to be concordant with RT PCR results and 5 samples (6%) were found to have discordant results in both Real Time-PCR and ABBOTT ID NOW. The Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for ABBOTT ID NOW were found to be 72.2% and 100% respectively.

Conclusion: The comparison between ABBOTT ID NOW™ and Real-Time PCR was found to be satisfactory. Hence, it can be used as a point of care testing in places where the resources are limited and swift results are anticipated. In addition, it offers extraordinarily good results in a low turnaround time for testing and can be considered not only in the healthcare set up but also as a best screening tool for passengers.

Introduction

The most recently evolved pandemic SARS-CoV-2 (Severe Acute Respiratory Syndrome-Coronavirus-2) which was first identified in a patient with severe respiratory distress in China, on December 2019 (COVID-19). On account of its rapid spread to many parts of the globe, the World Health Organization announced it as a pandemic worldwide on 11th March 2020 **[1].** Since its spread, it has imposed challenges on diagnostic laboratories to provide fast and reliable quality results to help the clinicians to

isolate and treat the infected patients as early as possible as it for a better health outcome **[2]**. Although the Real-time RT-PCR (Reverse Transcriptase Polymerase Chain Reaction) is the most common and popular diagnostic tool to detect COVID-19 infection, it needed robust infrastructure, skilled personnel to properly handle the PCR process and it consumes a lot of time to release the report **[3,4]**. The delay in reporting thus causes a menace in the management of critically ill patients such as in the Intensive Care Units and Emergency room. Hence the use of a testing procedure with an earlier detection time period and better quality of result is needed to medically manage the affected patients. Thus the need to evaluate ABBOTT ID NOW TM system is put forth, which uses the isothermal nucleic acid amplification technique and does not require expertise and could be performed with limited resources or where even PCR is not available **[5,6]**.

Objective:

The purpose of the study is to assess the accuracy of ABBOT ID NOW^{TM} in comparison with the Real Time PCR for detection of SARS Cov-2.

Methodology

Study Design: A prospective study was carried out in a COVID 19 testing center in tertiary care hospital in Chennai.

Setting: A total of 87 nasopharyngeal swab samples were collected over a period of three months, (from January 2022 to March 2022) in a COVID 19 testing center of a tertiary care hospital in Chennai. Ethical clearance was obtained from the Institutional Human Ethics Committee (Document no: PMCH&RI/IHEC/2021/77) prior to the initiation of the study.

Eligibility criteria: All age groups and genders categories are eligible to participate in this study. No specific exclusion and inclusion criteria are considered for this study.

Data sources: Data was collected from patients directly after getting proper consent.

Bias: Bias was prevented by masking the test results of the test such that the technicians who are performing one test were not aware of the other test result.

Sample size: Samples were collected from 87 individuals who visited the COVID 19 testing facility and willing to participate in the study.

Materials & Methods:

The performance of ABBOTT ID NOW^{TM} was evaluated by using the samples collected in a COVID 19 testing center of a tertiary care hospital in Chennai and results were compared with the Real-Time PCR test result. Two swabs were collected from each individual; one dry swab was used for performing ABBOTT ID NOW^{TM} and another swab was collected and transported in a VTM for Real-Time PCR test. Both the samples were processed as per respective kit protocol.

Sample Collection:

Nasopharyngeal Swab:

The patient's head was tilted back and two swabs were collected separately by passing it along the nasal septum, parallel to the floor of the nasal passage, until resistance was felt. The swab was kept in that place for a few seconds to absorb the nasal secretions and then it was slowly removed. After collection, one of the swabs was put in the Viral Transport Medium and the other was transported in a dry sterile container to the lab as early as possible and within one hour of sample collection **[7]**.

Oropharyngeal Swab:

Oropharyngeal swabs was collected by depressing the patient's tongue using a tongue depressor and then a swab was taken from the posterior pharynx behind the tonsils such that a gag reflex was elicited by the patient. The swab was twirled at least three times for 10 seconds and then was put in the same VTM tube in which the nasopharyngeal swab was collected **[7]**.

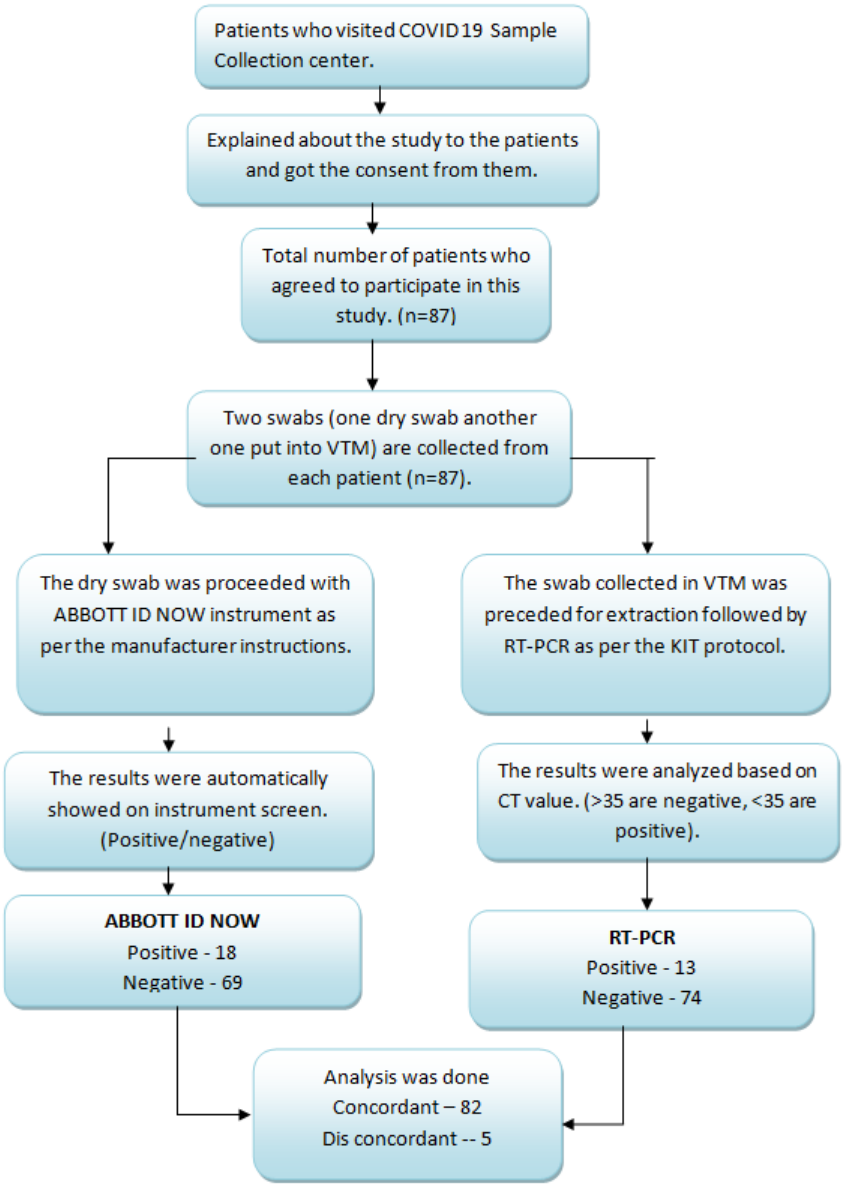
Abbott Id Now ^{TM}:

ABBOTT ID NOW ^{TM} COVID-19 is an automated system which is used for qualitative detection of SARS-CoV-2 by amplifying a specified portion, RdRp (RNA dependent RNA polymerase) of viral genome using isothermal nucleic acid amplification technology **[8]**. Fluorescently-labeled molecular beacons were used to recognize each of the amplified RNA target genes. Clinical specimens must be tested either immediately or within 1 hour of sample collection [**8,9**].The test base contains the reagents needed for the amplification of target gene of SARS-CoV-2, as well as serves as the internal control . The assay was performed by inserting the Sample Receiver (carrying elution/lysis buffer) and the test base (made up of two sealed reaction tubes, each consisting of a lyophilized pellet) into the ABBOTT ID NOWTM instrument. Then the sample swab was mixed into the lysis buffer in the sample receiver and transferred via the transfer cartridge to the test base, after which the target amplification process begins. Heating, mixing and detection steps are performed by the instrument. The results are automatically interpreted and displayed on the screen **[10]**.

Real-Time PCR:

Reverse transcriptase Real-Time Polymerase Chain Reaction (Real-Time PCR) was done by using Artus®

SARS COV-2 Prep & Amp UM kit as per the manufacturer's instruction. N1&N2 genes, sampling control gene and internal control (PCR inhibition) genes are detected in FAM (Green), HEX (Yellow) and Atto (Red) channels respectively. The cyclic threshold (CT) value more than 38 was considered as negative. The work was carried out in Class II Biological Safety Cabinet (BSC) **[11]**.



Results:

A total number of 87 patients were included in this study, out of which male patients (54%) were predominant when compared to female patients (46%) (Table 1).

Most of the study individuals belongs to 20 to 40 years age group (65.5%), followed by 40 to 60 years age group people (13.8%). Symptoms such as cough, cold, body pain, sore throat and fever were exhibited in 19 (21.8%) of the study individuals and the remaining 68 (78.2%) of the study individuals were asymptomatic. Most of the individuals (47.1%) were vaccinated against SARS CoV2, among which 5.7% of the study participants had taken their first dose of vaccine and 41.4% of the participants had taken their second dose of vaccine. Nearly 20.6% of patients had co-morbidities such as hypertension and diabetes (Table 1). The mean age of the study individuals was found to be 37.1 ± 16.9 and the mean CT value of the positive samples was found to be 30.5 ± 3.49. (Table 2) (Figure 2 & 3)

Totally 74 samples (85.1%) were tested negative and 13 samples (14.9%) were reported to be positive for COVID 19 in Real-Time PCR (Table 3) and 69 samples (79.3%) were found to be negative and 18 samples (20.7%) were tested positive for COVID 19 in ABBOTT ID NOW (Table 4). RT PCR test detected 15% of the tested sample to be positives and 85% to be negative (Table 3) and ABBOTT ID

NOW™ detected 21% positive samples and 79% were negative (Table 4) in a total of 87 samples tested in this study. The sensitivity and specificity of ABBOTT ID NOW was found to be 100% and 93.24% respectively. ABBOTT ID NOW was able be differentiate out all the negative samples more effectively than the positive samples (PPV – 72.2% & NPV – 100%). Thus the diagnostic accuracy of ABBOTT ID NOW was interpreted to be 94.25%. (Table 5) ABBOTT ID NOW was concluded to be efficient to differentiate between the positive and negative as the AUC was found to be 96.6% (Table 6) (Figure 1)

ABBOTT ID NOW result was found to be significantly associated with the symptoms of the tested individual (p = <0.001). Other characteristics such as age, gender, and vaccination status and co morbidities do not have any significance with the ABBOTT ID NOW results. (Table 7 & 8) In the case of RT PCR results were statistically significant with only symptoms and not with any other characteristics. (Table 9 &10)

The specificity of ABBOTT ID NOW was found to be higher among the asymptomatic individuals (96.83%) when compared with the symptomatic individuals (72.73%). But in the case of positive predictive value, symptomatic group showed higher value (72.73%) then asymptomatic individuals. (Table 11)

Specificity was found to be less (90.32%) in individuals who were vaccinated with 2 doses when compared with unvaccinated group (94.87%) and people vaccinated with a single dose (100%). (Table 12)

Table 1: Study population characteristics

Category		N	%
Gender	Male	47	54.0%
	Female	40	46.0%
	Total	87	100.0%
Symptoms status	Symptomatic	19	21.8%
	Asymptomatic	68	78.2%
	Total	87	100.0%
Number of symptoms	No	68	78.2%
	Two	5	5.7%
	Three or more	14	16.1%
	Total	87	100.0%
Symptoms	No	68	78.2%
	Fever	16	18.4%
	Cough	12	13.8%
	Sore throat	8	9.2%
	Myalgia	7	8.0%
	Loss of smell	6	6.9%
	Loss of taste	6	6.9%
	Dyspnea	5	5.7%
	Total	87	100.0%
Comorbidities	None	69	79.3%
	DM	7	8.0%
	HTN	4	4.6%
	DM + HTN	7	8.0%
	Total	87	100.0%
Vaccination status	Unvaccinated	46	52.9%
	1 dose	5	5.7%
	2 doses	36	41.4%
	Total	87	100.0%

Table 2: Descriptive table for age and CT value

	Age (years)	CT Value (If positive)
N	87	13
Mean	37.1	30.5
Std Dev	16.94	3.49
Median	31.0	30.3
Minimum	10.0	24.7
Maximum	81.0	36.0

Table 3: RT PCR Report Frequency Table

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	**POSITIVE**	13	14.9	14.9	14.9
	NEGATIVE	74	85.1	85.1	100.0
	Total	87	100.0	100.0	

Table 4: ID NOW ™ Report Frequency Table

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	**POSITIVE**	18	20.7	20.7	20.7
	NEGATIVE	69	79.3	79.3	100.0
	Total	87	100.0	100.0	

Table 5: Abbott Id Report * RT PCR Report Crosstabulation

			RT PCR REPORT		Total
			POSITIVE	NEGATIVE	
ABBOTT ID REPORT	**POSITIVE**	Count	13	5	18
		% within ABBOTT ID REPORT	72.2%	27.8%	100.0%
		% within RT PCR REPORT	100.0%	6.8%	20.7%
	NEGATIVE	Count	0	69	69
		% within ABBOTT ID REPORT	.0%	100.0%	100.0%
		% within RT PCR REPORT	.0%	93.2%	79.3%
Total		Count	13	74	87
		% within ABBOTT ID REPORT	14.9%	85.1%	100.0%
		% within RT PCR REPORT	100.0%	100.0%	100.0%
Sensitivity			100%	(77.19, 100.0)	
Specificity			93.24%	(85.14, 97.08)	
PPV			72.2%	(49.13, 87.50)	
NPV			100%	(94.73, 100.0)	
Diagnostic Accuracy			94.25%	(87.24, 97.52)	
Likelihood ratio of a Positive Test			14.8	(10.00 - 21.90)	
Likelihood ratio of a Negative Test			0.0		

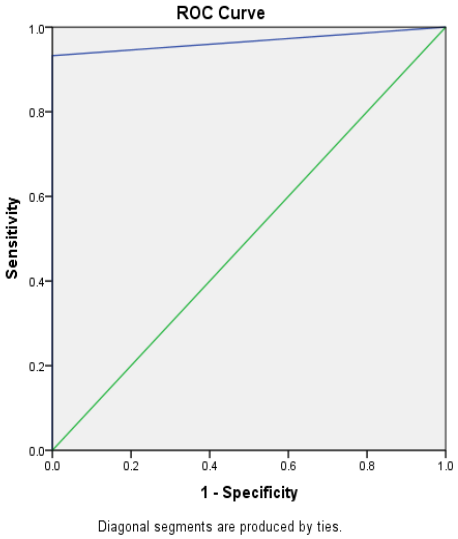


Figure 1: ROC curve

Table 6: Area under the Curve

Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
0.966	0.018	0.000	0.931	1.000

Table 7: Independent samples t-test to compare mean age between positive and negative cases (ABBOTT ID)

	ABBOTT ID Report	N	Mean	Std Dev	p-value
Age (years)	Positive	18	37.28	17.405	0.961
	Negative	69	37.06	16.949	

Table 8: Chi-Square test to compare proportions between positive and negative cases (ABBOTT ID)

		ABBOTT ID Report						p-value
		Positive		Negative		Total		
		N	%	N	%	N	%	
Gender	Male	11	23.4	36	76.6	47	100.0	0.498
	Female	7	17.5	33	82.5	40	100.0	
	Total	18	20.7	69	79.3	87	100.0	
Symptoms status	Symptomatic	11	57.9	8	42.1	19	100.0	<0.001
	Asymptomatic	7	10.3	61	89.7	68	100.0	
	Total	18	20.7	69	79.3	87	100.0	
Number of symptoms	No	7	10.3	61	89.7	68	100.0	<0.001*
	Two	2	40.0	3	60.0	5	100.0	
	Three or more	9	64.3	5	35.7	14	100.0	
	Total	18	20.7	69	79.3	87	100.0	
Comorbidities	None	13	18.8	56	81.2	69	100.0	0.349@
	DM	2	28.6	5	71.4	7	100.0	
	HTN	2	50.0	2	50.0	4	100.0	
	DM + HTN	1	14.3	6	85.7	7	100.0	
	Total	18	20.7	69	79.3	87	100.0	
Vaccination status	Unvaccinated	9	19.6	37	80.4	46	100.0	0.787*
	1 dose	1	20.0	4	80.0	5	100.0	
	2 doses	8	22.2	28	77.8	36	100.0	
	Total	18	20.7	69	79.3	87	100.0	

* Chi-Square for trend
@ Fisher's exact test

Table 9: Independent samples t-test to compare mean age between positive and negative cases (RT PCR)

	RT PCR Report	N	Mean	Std Dev	p-value
Age (years)	Positive	13	38.38	18.751	0.769
	Negative	74	36.88	16.733	

Table 10: Chi-Square test to compare proportions between positive and negative cases (RTPCR)

		RT PCR Report						p-value
		Positive		Negative		Total		
		N	%	N	%	N	%	
Gender	Male	10	21.3	37	78.7	47	100.0	0.072
	Female	3	7.5	37	92.5	40	100.0	
	Total	13	14.9	74	85.1	87	100.0	
Symptoms status	Symptomatic	8	42.1	11	57.9	19	100.0	0.001@
	Asymptomatic	5	7.4	63	92.6	68	100.0	
	Total	13	14.9	74	85.1	87	100.0	
Number of symptoms	No	5	7.4	63	92.6	68	100.0	<0.001*
	Two	1	20.0	4	80.0	5	100.0	
	Three or more	7	50.0	7	50.0	14	100.0	
	Total	13	14.9	74	85.1	87	100.0	
Comorbidities	None	9	13.0	60	87.0	69	100.0	0.382@
	DM	2	28.6	5	71.4	7	100.0	
	HTN	1	25.0	3	75.0	4	100.0	
	DM + HTN	1	14.3	6	85.7	7	100.0	
	Total	13	14.9	74	85.1	87	100.0	
Vaccination status	Unvaccinated	7	15.2	39	84.8	46	100.0	0.863*
	1 dose	1	20.0	4	80.0	5	100.0	
	2 doses	5	13.9	31	86.1	36	100.0	
	Total	13	14.9	74	85.1	87	100.0	

* Chi-Square for trend
@ Fisher's exact test

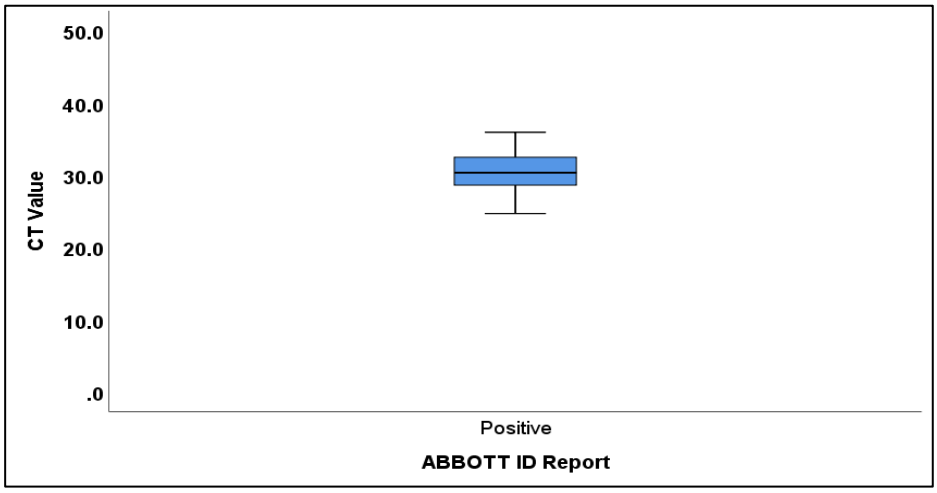


Figure 2: Box plot showing ABBOTT ID NOW positive samples CT value distribution

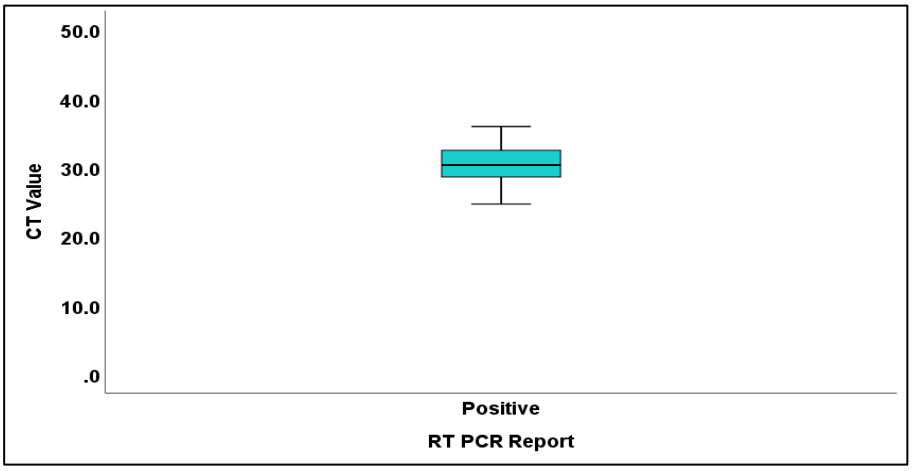


Figure 3: Box plot showing RT PCR positive samples CT value distribution

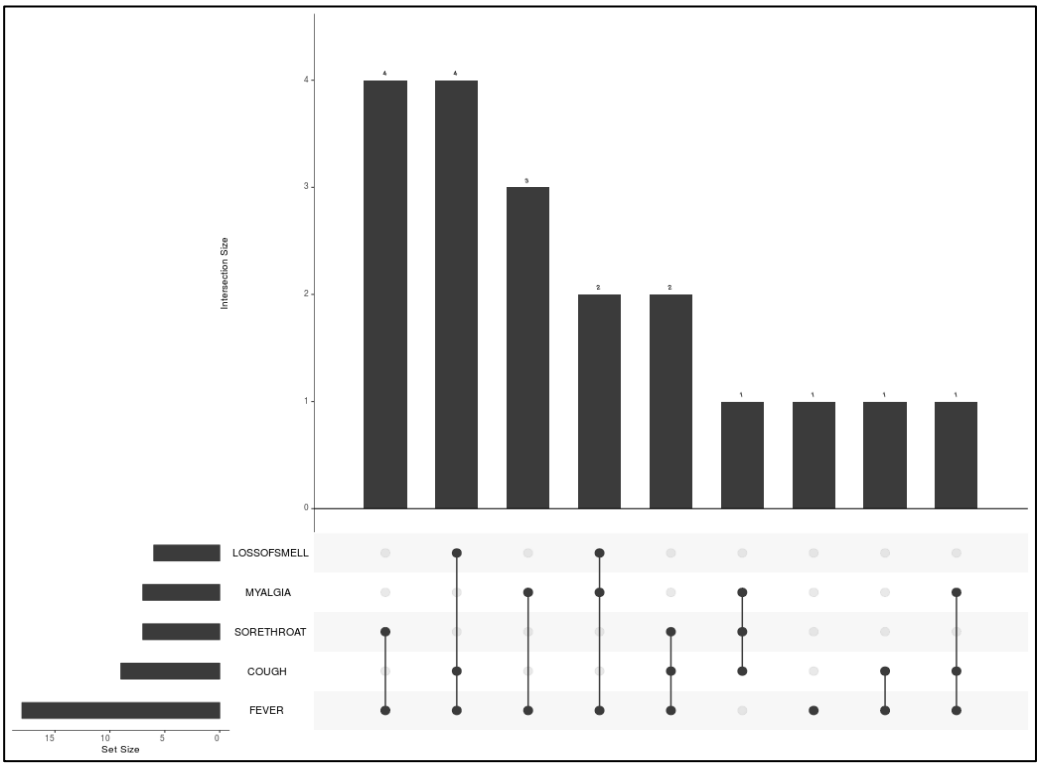


Figure 4: Upset plot showing co-occurrence of symptoms

Table 11: Sensitivity and specificity among different symptom groups

Parameter	Symptomatic	Asymptomatic
Sensitivity	100.00%	100%
Specificity	72.73%	96.83%
Positive Predictive Value	72.73%	71.43%
Negative Predictive Value	100.00%	100%
Diagnostic Accuracy	84.21%	97.06%
Likelihood ratio of a Positive Test	3.667	31.5
Likelihood ratio of a Negative Test	0.0	0.0

Table 12: Sensitivity and specificity among different vaccination groups

Parameter	Unvaccinated	One dose	Two doses
Sensitivity	100.00%	100%	100.00%
Specificity	94.87%	100%	90.32%
Positive Predictive Value	77.78%	100%	62.5%
Negative Predictive Value	100.00%	100%	100%
Diagnostic Accuracy	95.65%	100%	91.67%
Likelihood ratio of a Positive Test	19.5	'undefined'	10.33
Likelihood ratio of a Negative Test	0.0	0.0	0.0

Discussion:

Real-Time PCR assays are the standard diagnostic test to confirm the presence of COVID-19 infection which is widely used in various diagnostic laboratories. They are very sensitive and produce accurate results but have certain disadvantages like the need to have a robust infra-structure, well trained personnel and longer turnaround time **[3]**. In this study we evaluated the characteristics of ABBOTT ID NOW™ and implementation of best point of care COVID-19 testing service by providing quicker diagnosis to the patient.

Accurate results along with rapid turnaround time are the foremost important factors in COVID-19 testing for effective patient treatment management and also to reduce the community spread of the infection **[12]**. There was a high demand for COVID-19 diagnostic kits and reagents in healthcare centers due which many kits were approved through emergency use approval (EUA) mode. ABBOTT ID NOW™ COVID-19 Point of Care Testing (POCT) assay claimed to provide effective results in 13 minutes **[9]**. This study was intended to verify the accuracy and to evaluate its efficacy for clinical usage.

The current study reported a sensitivity of 100% which is in par with *Srivastava S et al.* study results where they have reported the sensitivity to be 93.22%. [13]

Discordant results were observed with the study published by *Pattnaik D et al*. in which they have reported the sensitivity to be 87%. [14] The variation in the sensitivity pattern may be due to the higher number of study participants rate and usage of different RT PCR kit.

A specificity of 93.24% was reported in the current study which is in agreement with the result reported by *Ismail G et al* wherein they reported the specificity to be 94.9%. [15] *Elisa Burdino et al*. reported 100% specificity in their study which is in contra indication with the current study. [16]

Our study showed PPV and NPV of 72.2% and 100% respectively which was concordant with the studies published by *Harrington, et al* and *Smithgal et al*. *Harrington, et al* reported PPV 74.33% and NPV 99.00% with RT-PCR as reference test. **[17]** Another study published by *Smithgal et al,* evidenced concordant results with PPV & NPV of 73.90% and 100% respectively with Roche cobas Assay as reference test and using the specimens taken in transport media and not the direct swab. [18] Our NPV 100% was concordant with the studies published by *Eric Farfour et al,* and *Smithgal et al.,* (Table:13) they all have reported NPV of 100%. A study by *Basu et al*. had shown comparison of ABBOTT ID NOW with Cepheid Xpert Xpress SARS COV-2 assay on 101 specimens has reported low PPV & NPV of 54.80% and 98.60% respectively, which is lower than our current study. [1] The lowest PPV & NPV may be due to the use of different reference method and type of sample collection like direct swab method and swab taken in viral transport medium.

Our study reported positive samples with CT values up to 35. The study conducted by *Smithgal et al* concluded that ABBOTT ID NOW reported samples with CT value less than 30. [18]

In this study, samples with threshold values of ≤ 35 were also detected correctly. 5 samples results were found to be mismatch when compared with the RT PCR result. *Eric Farfour et al*, also found that ABBOTT ID NOW™ COVID-19 in comparison to the reference Real Time PCR using a collection of 48 fresh nasopharyngeal swabs sampled on Viral transport media (VTM) yielded only 2 discordant

reports [5].They displayed PCR cycle threshold values of 37.5 and 39.2. The sensitivity and specificity reported in our study for symptomatic individuals was 100% and 72.73% which does not coincide with the study published by *William Stokes et al*. in which they reported the specificity to be 99.5% and a sensitivity of 92.5%. [19] The difference in the diagnostic parameters may be due to the usage of different RT PCR kit and sample collection method.

While there have been instances in our study where few samples was reported as positive in the ID NOW™ but the Real Time-PCR result was found to be negative, those samples may be true positives as they correlate clinically with the patient symptoms and radiological findings.

Table 13: Performance of ABBOTT ID NOW™ assay for detection of SARS COV2 against other molecular test

S.No.	Reference	No. of Case	Reference method	PPV (%)	NPV (%)
1.	Current study	87	RT-PCR	72.2	100
2.	Basu et al.,2020	101	Cepheid Xpert Xpress SARS COV-2	54.80	98.60
3.	Harrington, et al 2020	524	Abbott Real Time SARA COV-2	74.73	99.00
4.	Eric Farfour et al, 2021	48	RT-PCR	94.9	100
5.	Smithgal et al., 2020	113	Roche Cobas Assay	73.90	100.00

Limitation:

One of the main limitations of the study is that RT PCR does not detect the positive patients reporting to test center at an earlier stage of infection or at day 1 of symptom onset which thereby yields in false reports and repeat testing was not done for the 5 patients for whom we recorded discordant results. In ABBOTT ID NOW the samples should be tested within 1 hour of sample collection, anytime exceeding it may affect the sample integrity.

Conclusion:

The sensitivity and specificity of the ABBOTT ID NOW ™ COVID-19 was found to be acceptable and it also showed good results among the asymptomatic and symptomatic individuals. The test was also able to detect positive samples with a higher CT values (≤ 35 CT value).

Overall, the performance of the ABBOTT ID NOW™ COVID-19 method was found to be satisfactory when comparable to the Real Time-PCR method. Hence, it can be used as a point of care testing in places where the resources are limited and results are needed in a short turnaround time, especially to check for infection status for the individuals in critical care units and airports. It can improve the healthcare system by providing quality results to the patients who are in dire need of emergency medical attention.

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