Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Original Research Article

Comparison of SARS-CoV-2 diagnosis by rapid antigen detection kit with RT-qPCR in a tertiary care setup in North Eastern India

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ABSTRACT

Purpose: Real time reverse transcriptase polymerase chain reaction (RT-qPCR) is still considered a gold standard for the diagnosis of COVID-19. However, due to several limitations, use of RT-qPCR is limited in a resource poor setting like North East India. Rapid antigen detection testing kit has revolutionized the diagnosis and management of COVID-19 in India. However, conflicting reports exist regarding the efficacy of the kits for diagnosis of COVID-19. This study aims to highlight the performance of Standard Q COVID-19® Antigen detection kit (SD Biosensor) compared with RT-qPCR in the setup of North East India.

Methods: Nasopharyngeal and oropharyngeal swab samples were collected from consenting patients attending the flu clinic in the period from 1st July to December 31, 2020. Samples were transferred to Viral Research and Diagnostic Laboratory (VRDL) for RT-qPCR test. Antigen detection from the patient samples were undertaken using Standard Q ® COVID-19 antigen detection kit (SD Biosensor, Republic of Korea). Data were then analyzed for comparison between RT-qPCR and antigen kit results.

Results: During the study period, 189 samples were collected, out of which 119 were positive by RT-qPCR. Out of 119 positive samples, calculated sensitivity and specificity of the rapid antigen kit was 63% and 100% respectively. Sensitivity and diagnostic accuracy increases in symptomatic patients as compared to asymptomatic patients. Cohen's Kappa coefficient showed a moderate association (0.6) between the kit and RT-qPCR test. The kit performed optimally at a CT value of ≤32.5 for N gene with a predicted sensitivity of 77.3% and specificity of 93.3%.

Conclusion: The study shows an overall acceptable sensitivity and specificity of the testing kit, with a better performance in symptomatic patients. The association of the kit result is moderate with the results obtained in RT-qPCR. In this study, the rapid antigen test kit performed optimally at N gene qRT PCR cut off value of ≤32.5.

1. Introduction

On 31st December 2019, China reported a cluster of 'cases of viral pneumonia of unknown cause' from Wuhan province [1]. The virus was named SARS-CoV-2 by ICTV and the disease was named as COVID-19 by WHO on 11th February 2020 [1].Since the declaration of the global pandemic on 11th March 2020, more than 2.9 billion confirmed cases have been reported worldwide with 5.4 million deaths till date [1,2].In India, ICMR reported the first case on 21st January 2020 [3].

Till today, Real Time Reverse Transcriptase PCR (RT-qPCR) is considered the gold standard for the diagnosis of COVID-19, as it detects SARS-CoV-2 RNA in the sample with high sensitivity and specificity [4]. But, RT-qPCR requires highly skilled laboratory personnel, pre established molecular laboratory setup and also has a long turnaround time [4].So, to facilitate early diagnosis of COVID-19 during a pandemic situation, a point of care test (POCT) was the need within an hour.

On 14th June 2020, Indian Council of Medical Research (ICMR) issued an advisory, recommending the use of Standard Q COVID-19 Ag detection kit (SD Biosensor, Inc., Gyeonggi-do, Republic of Korea) for rapid detection of COVID-19, based on the principle of rapid chromatographic immunoassay [5,6].The availability of rapid antigen detection kits has revolutionized early diagnosis and initiation of treatment in COVID-19 patients.

The minimum acceptance criterion for a POCT issued by ICMR outside a laboratory setup is, that it should have a sensitivity of 50% and above and specificity of 95% and above [6]. Although the manufacturer

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claims that the Standard Q RAT kit has a sensitivity of 96.52% (95% CI, 91.33–99.04%) and a specificity of 99.68% (95% CI, 98.22–99.99%) for detection of SARS-CoV-2 [7], several studies have reported a sensitivity ranging between 17.5% [8] to 89% [9] and a specificity between 92.4% [10] to 100% [11] worldwide. Studies in the Indian settings have also revealed highly variable performance of the rapid antigen detection kits, where sensitivity ranged between 37.5% and 71.9% and the specificity between 99.3% and 100% [4,12,13].

A point of care test to detect COVID-19 is of utmost importance, particularly in a resource poor setting like Northeast India. But very few literatures exist about the performance of such kits in comparison to RT-qPCR in detecting SARS-CoV-2 in India. The study aims to compare the performance of Standard Q COVID-19 Ag detection kit with RT-qPCR in a tertiary care hospital in Tripura, North- East India.

2. Materials and methods

The study was a retrospective, cross sectional study conducted at Viral Research and Diagnostic Laboratory (VRDL), Department of Microbiology, AGMC & GBP Hospital, Agartala, Tripura. The study period was 06 (six) months (July to December 2020) and it included samples from both adult and pediatric patients attending the flu clinic OPD of AGMC & GBP Hospital, Agartala. Nasopharyngeal and oropharyngeal swab samples from consenting patients were collected as per the protocol followed in VRDL, AGMC. Ethical approval was obtained from the institutional ethical committee (Ref.no.4 (6–11)-AGMC/Medical Education/Ethics Com./2018.), institutional ethics committee for clinical study, AGMC, dated 10.05.2019.

2.1. Patient and clinical specimens

Consecutive samples from the consenting patients attending the flu clinic, AGMC & GBP Hospital were included in the study. Three swab samples were collected simultaneously from each patient. One nasopharyngeal and one oropharyngeal swab sample were placed together in a 3 ml tube of viral transport media (VTM) (Hi-media) for Real time RT qPCR test. Another nasopharyngeal swab was placed in the buffer tube supplied with the Standard Q COVID-19 RAT kit as per manufacturer's protocol for rapid antigen detection test.

2.2. Nucleic acid amplification test

Viral RNA was extracted from the received samples by Qiacube HT automated nucleic acid extraction system (Qiagen) using QIAmp 96 virus QIAcube HT RNA extraction kit (Qiagen) as per manufacturer's protocol. 100 µl of elution volume was aliquoted and was used immediately after extraction for PCR or stored at −80 °C. Each aliquot was used only once to avoid the loss of viral genomic material during repetitive freezing and thawing.

RT-qPCR was performed using Superscript III one step RT-PCR system (Invitrogen, Darmstadt, Germany). Each reaction consisted of a 25 µL reaction mix containing 5 µL of RNA, 12.5 µL of 2 × reaction buffer provided with Platinum Taq Polymerase (containing 0.4 mM of each deoxyribonuclease triphosphates (dNTP) and 3.2 mM magnesium sulphate), 0.5 µL of reverse transcriptase/Taq mixture, 1.5 µL Primer and probe mix provided by NIV [13,14] and 5.5 µL nuclease free water. Thermal cycling was performed at 55 °C for 10 min for reverse transcription, followed by 95 °C for 3 min and then 45 cycles at 95 °C for 15 s, 58 °C for 30 s. Biorad CFX96® thermal cycler was used in this study. At first, samples were subjected to screening for detection of SARS-CoV-2 specific E gene. Positive samples were then analyzed for detecting the presence of Nucleocapsid (N) gene for confirmation. Samples showing exponential growth curve and a Ct value ≤ 35 were considered as positive as per NIV protocol. As detection of E gene was considered for screening purposes only, both E and N gene positive samples were included as RT-PCR positive samples. Detection of N gene being confirmatory, the performance of the RAT kit was assessed on the basis of the C_T value of the N gene only, irrespective of the C_T value of E gene.

2.3. Rapid antigen test

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. The test was carried out according to the manufacturer's instructions [7].Sample collection and tests were performed simultaneously at the flu clinic and reports were interpreted within 30 min of the test procedure.

2.4. Data analysis

Data were analyzed in Microsoft Excel and IBM SPSS ®statistics version 26 software. The results were expressed in percentages and central tendencies. To determine the predictive value of the antigen Test kit, sensitivity, specificity, positive and negative predictive values and accuracy were determined. The test results obtained by RT-qPCR as positive or negative were considered as gold standards. Cohen's Kappa coefficient for relatability with RT-qPCR was calculated. For Kappa coefficient, value of ≥0.4 was considered as weak association, ≥0.6 as moderate association, ≥0.8 as strong association and ≥0.9 as almost perfect association as per Ristic M and colleagues [14]. ROC curve was plotted and analyzed to detect the cut off C_T value of N gene to correlate with the optimal performance of the antigen test kit. P value < 0.05 was considered as significant at 95% CI.

3. Results

3.1. Clinicodemographic profile

During the study period, 189 non repeating samples were collected from the patients for both RT-qPCR and rapid antigen tests. Out of these samples, 143 (75.7%) were from male patients and 46 (24.3%) were from female patients. The mean age of the patients in the study was 36.65 ± 14.297Maximum number of patients belonged to the age group between 21 and 40 years of age (98, 51.9%), followed by those between 41 and 60 years (57, 30.2%).

Majority of the patients in the study were asymptomatic (143, 75.7%), while 46 (24.3%) patients were symptomatic. Among the symptomatic patients, fever was the predominant symptom (31, 67.4%) followed by cough (27, 58.7%) and body ache (18, 39.1%).

3.2. Sensitivity and specificity of the rapid antigen test

In this study, calculated sensitivity for the rapid antigen detection kit was 63% (95% confidence interval- 53.6%–71.5%) and specificity was 100% ((95% confidence interval-93.5%–100%). Positive predictive value, negative predictive value and accuracy were also calculated as 100%, 61.4% and 76.7% respectively (Table 1). The sensitivity, specificity and accuracy of the kit were also calculated for both symptomatic and asymptomatic patients (Table 2). Results show that the antigen testing kit had higher sensitivity (80.6%) among symptomatic patients compared to asymptomatic patients (56.8%). The negative predictive

Table 1
The performance charecteristics of rapid antigen test kit for diagnosis of SARS-CoV-2 infection as compared with real time PCR.

	Antigen positive	Antigen negative	Total
RT-qPCR positive	75	44	119
RT-qPCR negative	0	70	70
Total	75	114	189

1. Sensitivity = 63%,Specificity = 100%
2. Positive predictive value = 100%, Negative predictive value = 61.4%
3. Accuracy = 76.7%

Table 2
The performance charecteristics of rapid antigen test kit for diagnosis of SARS-CoV-2 infection among symptomatic and asymptomatic patients.

Charecteristics	Symptomatic	Asymptomatic
Sensitivity	**80.6%**	**56.8%**
Specificity	**100%**	**100%**
Positive predictive value	**100%**	**100%**
Negative predictive value	**71.4%**	**59.1%**
Accuracy	**87%**	**73.4%**

value and accuracy also decreased in asymptomatic patients. This shows that the kit performed better in case of symptomatic patients.

3.3. Calculation of Cohen's kappa coefficient for relatability of antigen testing kit with RT-PCR result

Cohen's Kappa coefficient was calculated as 0.6 (P value < 0.001 at 95% CI), which shows moderate association between the Standard Q Antigen detection kit with the RT-qPCR test. Kappa coefficient is higher among the patients in the age group of 21–40 years and more than 60 years with a value of 0.6. Kappa coefficient in symptomatic patients (0.7) is higher when compared to asymptomatic patients (0.5), P value < 0.001. This shows higher relatability among antigen detection kit and RT-qPCR in symptomatic patients as compared to asymptomatic patients.

3.4. Comparison of cycle threshold (C_T) values between concordant and discordant results

Among the positive samples by RT-qPCR test, the mean C_T value for the confirmatory N gene was 27.3 (20.6–34). The maximum C_T value detected was 35.0 while the minimum was 12.0. Among the asymptomatic and symptomatic patients, mean C_T value was 28.1 (21.2–35) and 26.9 (20.2–33.6) respectively. The distribution of C_T values for asymptomatic and symptomatic patients is shown in Fig. 1.

The mean C_T value for the N gene among the 75 concordant samples (both RT-PCR and antigen test positive) was 24.3 (17.9–30.7) and among the 44 discordant samples was 32.5 (29.3–35.7). The distribution of the C_T values for both PCR and RAT kit concordant and discordant samples are shown in Fig. 2.

To detect the cutoff of C_T values of N gene for antigen positivity in the RAT kit, a Receiver Operator Curve (ROC) analysis was performed by plotting C_T values of N genes against antigen positivity, which is shown in Fig. 3. The area achieved by the ROC curve (AUC) is 0.944 with a standard error of 0.022, which shows the antigen testing kit can detect COVID 19 patients with good accuracy. On calculating the ROC curve, it was found that the sensitivity of the RAT kit at C_T values ≤ 21.5, ≤ 30.5 and ≤ 31.5 were 100%, 97.7% and 93.2% respectively.

Youden's index was determined to set the cut off value to maximize sensitivity and specificity. Accordingly, the overall cut off CT value was determined at 32.5, where sensitivity is 77.3% and specificity is 93.3% for the RAT kit.

4. Discussion

Due to rapid transmissibility and virulence, SARS-CoV-2 has caused a widespread morbidity and mortality worldwide, for which a rapid, accurate and affordable test is of utmost importance for early detection of the patients, as well as to diagnose asymptomatic contacts and super spreaders [4].

As of September 2021, United States Food and Drug Administration (US FDA) has approved 235 molecular tests, 88 antibody detection tests and 34 antigen detection tests, out of which, 55 are Point of Care tests [15]. In India, till December 2021, 145 antigen based rapid kits had been validated by ICMR [6]. Out of them, Standard Q COVID-19 Ag detection kit (SD Biosensor, Inc., Gyeonggi-do, Republic of Korea) was the first one to be recommended by ICMR [5].

In this study, males were predominantly more affected (75.7%) as compared to females. The mean age of the patients was 36.65 ± 14.297, which was similar to the study by FIND for evaluation of SD Biosensor STANDARD Q COVID-19 Ag Test (35 in Germany, 37 in Brazil) [16]. The findings were also concordant with that of Kanaujia R and colleagues [4], although the median age was slightly lower than this study (32 years).

In this study, majority of the patients were asymptomatic (75.7%). Fever was the predominant symptom (67.4%) followed by cough (58.7%) and body ache (39.1%). The findings were similar to that reported by Kanaujia R and colleagues, where fever was the predominant symptom (67.4%) followed by cough (39.9%) [4].

Several studies had been conducted which reported a wide range of sensitivity and specificity for Standard Q COVID-19 Ag detection kit [16]. This study presented a sensitivity of 63% (95% confidence interval-53.6%–71.5%) and specificity of 100% (95% confidence interval-93.5%–100%) for the Standard Q COVID-19 antigen detection kit. The results were similar to that of the studies performed at Faculty Hospital Motol, Prague, Czech Republic (sensitivity of 62.6%, specificity of 99.5%) [17] and Homza M et al. (sensitivity of 61.9%, specificity of 99.0%) [18]. A meta-analysis study performed by Ristic M and colleagues had found a mean sensitivity of 72.1% and specificity of 98.6%, so the sensitivity was higher than the one found in this study [14]. The findings in this study were higher than that reported by Pandey AK and colleagues (Sensitivity 53.6%, specificity 97.35%) [19]. Most of the other studies conducted in Indian scenarios reported lower sensitivity of the kit as and when compared to this study such as 37.5% by Rana N and colleagues [13] and 44.5% by Prakash V and colleagues [12]. However, Kanaujia et al. reported a higher sensitivity of the kit when compared to this study (71.9%) [4]. Specificity of the kit, in most studies performed under Indian conditions, were comparable.

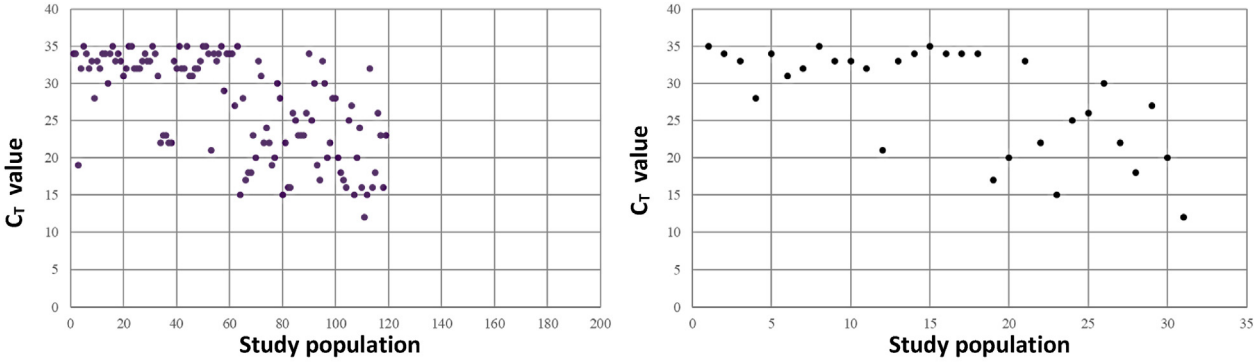

Fig. 1. C_T value for N gene among asymptomatic (A) and symptomatic (B) COVID-19 patients.

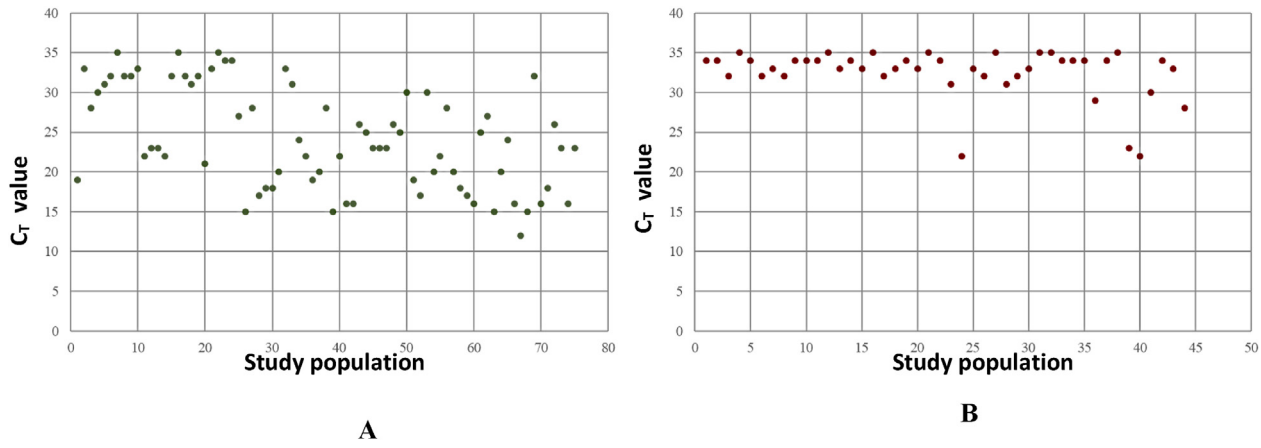

Fig. 2. C_T value for N gene among COVID-19 RT-qPCR positive patients with RAT positive (A) and RAT negative (B) results.

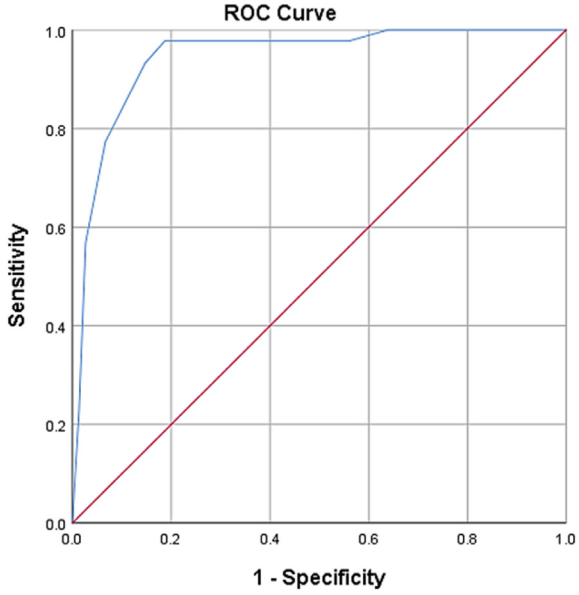

Fig. 3. Receiver Operator Curve (ROC) analysis of rapid antigen test kit. The kit achieved an area under the ROC curve (AUC) value of 0.944 with standard error of 0.022.

Sensitivity of the kit in symptomatic and asymptomatic patients, as calculated from the data was 80.6% and 56.8% respectively and specificity in both cases, was 100%. The findings were similar to that reported by Dinnes J and colleagues in their meta-analysis study (sensitivity of 80.1% and 61.1% among symptomatic and asymptomatic patients respectively, specificity of 98.1% and 99.6% respectively) [20]. However, the findings were noted to be higher than that reported by Pandey AK and colleagues in their study (sensitivity of 61% in symptomatic patients and 33.3% in asymptomatic patients [19].

The overall diagnostic accuracy of the antigen test kit as compared to the RT-qPCR test was calculated at 76.7%. Diagnostic accuracy was higher in symptomatic patients (87%) when compared to asymptomatic patients (73.4%). The overall test accuracy in the study was lower than the findings by Kanaujia R et al. (88.6%) [4]. The negative predictive value also increased in symptomatic patients (79.4%) than in asymptomatic patients (59.1%), although positive predictive value in both cases were the same (100%). A study by Munne K and colleagues demonstrated a negative predictive value of 59% in symptomatic patients and 72.3% in asymptomatic patients, which was opposite to the findings in the present study [21].

Cohen's kappa coefficient, as determined in the study, was found to be 0.6 (P value < 0.01), which displayed a moderate association between the Standard Q COVID-19 detection kit and RT-qPCR test. Association was higher among the patients belonging to the age group of 21–40 years and above 60 years (0.6). Also, Kappa coefficient was higher among symptomatic patients (0.7) as compared to asymptomatic patients. Findings were in the same line as reported by Ristic M and colleagues, who reported a higher Kappa coefficient in the age group of 14–30 years of age than the other age groups [14].

Among the patients who were detected positive by RT-qPCR test, mean C_T value for the N gene was calculated at 27.3. The findings were similar to that reported by the FIND study on evaluation of Standard Q COVID-19 antigen detection kit (25.5) [16], Ristic M et al. (26.5) [14] and Chaimayo C et al. (26.09) [22]. The mean C_T value was lower in symptomatic patients (26.9) when compared to asymptomatic patients (28.1) in the study.

In this study, the mean C_T value for the N gene among the 75 concordant or true positive samples by RAT kit was 24.3 and among the 44 discordant or false negative samples by RAT kit was 32.5. Thus, the mean C_T value was lower among the concordant samples, giving antigen positivity as compared to discordant samples which were negative by antigen test kit. The findings were similar to that reported by Ristic M and colleagues (mean C_T of 25 in concordant samples, 33 in discordant samples) [14].

After constructing an ROC curve for detection of a cut off value for the performance of Standard Q COVID-19 antigen testing kit, a curve with an area of 0.944 along with a standard error of 0.022 was obtained, which showed that the antigen kit can accurately detect COVID-19 patients. From the ROC statistics, a cut off value of 32.5 was calculated for C_T value of N gene for the optimal performance of the antigen detection kit using Youden's index to maximize sensitivity and specificity (Youden's index = Sensitivity + Specificity-100). Accordingly, at cut off value of 32.5, sensitivity of 77.3% and specificity of 93.3% was calculated. Most of the studies considered a C_T value of 29–30 for the Standard Q antigen detection kit [10,23–25], which was at par with the findings in this study.

5. Conclusion

In this study, the Standard Q COVID-19 antigen test kit showed an acceptable sensitivity of 63% and 100% specificity as per the criteria set down by ICMR for a POCT. The performance of the testing kit increased significantly in symptomatic patients. When compared with RT-qPCR, the kit presented a moderate association overall, although the association became stronger in symptomatic patients. The rapid antigen test performed optimally at N gene qRT-PCR cut off value of $\leq$32.5.

6. Study limitations

The study was performed with a small sample size (189 samples) over a time period of six months only. So, a study with a bigger sample size over a longer time duration is necessary to verify the findings of this study. Moreover, as sample collection was confined to the flu clinic OPD of the hospital only, the result of this study cannot be extrapolated to the community settings of the state.

Credit author statement

1. Saikat Majumder- Conceptualization, Methodology, Writing-original draft, Visualization.
2. Dr. Ankan Chakrabarti- Methodology, Software, Formal analysis, Writing review and editing, Visualization.
3. Banti Das- Validation, Resources, Writing original draft, Project administration.
4. Apurba Sarkar- Methodology, Writing-review and editing, Investigation, Data curation.
5. Dr. (Prof.) Tapan Majumdar- Conceptualization, Validation, Supervision, Writing review and editing.

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