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Comparison of Abbott ID NOW, a novel isothermal amplification based COVID-19 diagnostic method with RTPCR

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ABSTRACT

Background: The emergent crisis of the COVID-19 pandemic has posed enormous challenges for clinical laboratories to speed up diagnostics. The current reference standard for the diagnosis of COVID-19 is real time reverse transcriptase PCR on various platforms. However, even with automation, the turnaround time is huge enough to keep up with ever increasing numbers of patients. With increasing surge of COVID cases we need rapid diagnostic tests with good sensitivity and specificity.

Objectives: Comparison between Abbott ID NOW COVID-19 and real time reverse transcriptase PCR as a reference method.

Materials and methods: Specimens from seventy-two individuals were obtained over a period of two months which were processed for ID NOW and RTPCR at a dedicated COVID-19 centre of AIIMS. Dry nasal swabs were used for ID NOW while nasopharyngeal swabs along with throat swab were used for RTPCR. Among the participants, 15 were healthcare workers. Mild COVID was seen in 36 participants, moderate in 19 and severe in 9. Eight participants had non COVID illness.

Results: From the given samples, we observed that ID NOW has a sensitivity of 93.22% (55/59) specificity 100% (13/13), PPV 100% (55/55) and NPV 76.47% (13/17).

Conclusion: ID NOW is a convenient, rapid molecular test which makes it suitable for both in laboratory use and as a point of care test. It can be a rapid rule-in test for COVID-19. Negative results, however, have to be interpreted as per the context.

1. Introduction

The severe acute respiratory syndrome corona virus 2 (SARS-CoV-2), first identified in Wuhan, China, in December 2019, eventually spread across the globe and was given pandemic status by World Health Organization on 11 March 2020. The cumulative number of cases reported globally now exceeds 400 million and the number of global deaths is above 5 million. (WHO (COVID-19) Dashboard). A cumulative of 4,26, 92,943 confirmed cases and 5,09,358 deaths have been recorded in India till February 2022 World Health Organization, 2020).

This rapidly evolving crisis in the India has led us to prioritize the expansion of diagnostic testing, more so towards rapid testing platforms in order to minimize turnaround times and help clinical decision making.

The other rapid molecular testing platform used in various Laboratories is Cepheid Xpert SARS CoV2. Xpert SARS CoV2 carries out the detection of E gene and N2 gene in the patient sample. The limits of detection of SARS-CoV-2 viral RNA, is 250 copies/ml (Xpert Xpress SARS-CoV-2 Assay). However, the assay run times of 45 min still has scope of shortening. Shorter turnaround time would help timely decision making in situations like screening area testing, cohorting, bed assignments for patients admitted in the emergency department (ED) and transferring to other departments following COVID status update. Hence, we evaluated the recently released Abbott ID NOW COVID-19 assay (ID NOW) which has the USFDA EUA status. In this study we evaluated the performance of the ID Now test by using the real time reverse transcriptase PCR (RTPCR) as the comparator reference method.

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2. Methods

2.1. Study setting and design

A Prospective study, conducted at the department of Microbiology of Jaiprakash Narayan Apex Trauma Centre, AIIMS, New Delhi, a dedicated COVID Center in north India, from April to May 2021. A total of 72 individuals were included. Informed consent was taken prior to sample collection.

2.2. Inclusion criteria

Patients and HCWs with mild, moderate and severe COVID were included in the study. (Case definitions applied as described by the AIIMS/ICMR COVID-19 National Task Force/ Joint Monitoring Group, Ministry of Health and Family Welfare (Clinical Guidance for Management of Adult Covid-19 Patients, 2021)

Mild COVID- upper respiratory tract infection, mild symptoms such as fever, cough, sore throat, nasal congestion, malaise, headache, without shortness of breath or hypoxia.

Moderate COVID- Adults with presence of clinical features of dyspnea and or hypoxia, SpO2 90 to ≤93% on room air, Respiratory rate ≥ to 24 per minute.

Severe COVID- Adults with clinical signs of Pneumonia plus one of the following; respiratory rate >30 breaths/min, severe respiratory distress, SpO2 < 90% on room air.

2.3. Demographic and comorbidity profile of participants

The patients included 38 females and 34 males, with an age range of 2–90 years. The clinical details and associated comorbidities of patients were obtained from hospital information system.

2.4. Sample collection

Nasal, throat and nasopharyngeal swabs were collected from patients. Nasopharyngeal and throat swabs were collected in viral transport medium (VTM) for the purpose of RTPCR. Dry nasal swabs were collected for ID NOW, in accordance with the manufacturer's instructions.

2.5. Specimen transportation and processing

The swabs provided in the test kit were used for collecting nasal specimen and were transported immediately to the Laboratory in a dry sterile screw capped tube at room temperature. The components of the kit were stored at 4–8 °C and they were brought to room temperature before use. Processing was performed as per instructions from manufacturer within an hour of sample collection.

Principle of the test- Detection of SARS CoV2 RNA is carried out on an instrument based isothermal nucleic acid amplification for the qualitative detection and diagnosis of SARS-CoV-2 RNA from nasal, nasopharyngeal and throat swabs. The ID NOW COVID-19 kit contains all components required to carry out an assay for SARS-CoV-2 on the ID NOW Instrument. It is comprised of a Sample Receiver, containing elution/lysis buffer, a Test Base, comprising two sealed reaction tubes, each containing a lyophilized pellet, a Transfer Cartridge for transfer of the eluted sample to the Test Base, and the ID NOW Instrument. The Test Base contains the reagents required for amplification of SARS-CoV-2, as well as an internal control. The templates (similar to primers) designed to target SARS-CoV-2 RNA amplify a region of the RdRp gene. Fluorescently-labelled molecular beacons are used to specifically identify each of the amplified RNA targets. The internal control is designed to control for sample inhibition and assay reagent function. The positive and negative control swabs provided with the kit are to be used with a new lot (ID NOW package insert, 2020).

Table 1
Statistical parameters addressed by ID NOW.

	TRUE POSITIVE (RTPCR)	TRUE NEGATIVE (RTPCR)	Total
IDNOW POSITIVE	55	0	55
IDNOW NEGATIVE	4	13	17
Total	59	13	**72**

The reference test was done on Nasopharyngeal and throat swabs collected in Viral Transport Medium (VTM) and transported at 4–8 °C for RTPCR testing. Total nucleic acid was extracted from the samples, using the MagMAX Viral Isolation Kit (Thermo Fisher Scientific, USA). A commercial rRT-PCR kit (BGI Genomics Co. Ltd., China, which has EUA from the US FDA and approval from the ICMR), was used to detect the SARS-CoV-2 ORF 1ab region of the genome by amplification of E gene and RdRp gene and human RNP as internal control., in an AriaMx real-time PCR instrument (Agilent, USA).

3. Statistical analysis

Statistical analysis was performed on MS Excel 2010 to determine the descriptive statistics.

4. Results

4.1. Participant profile

The patients included (38, 52.8%) females and 34 (47.2%) males, age range was 2–90 years (median =44 years). The diagnosis of COVID at admission was based on a rapid test such as Cepheid Xpert SARS CoV-2 (n = 27). Fifteen of the participants (20.83%) were healthcare workers who developed signs and symptoms such as fever, cough, sore throat, nasal congestion, malaise and headache.

4.2. Distribution of COVID categories among the participants

Overall, 36 participants had mild COVID, 19 had moderate and 9 had severe, and 8 had non COVID illness. Amongst the admitted patients (n = 57), thirty had mild disease, 18 had moderate disease and 9 had severe disease. Whereas, among the HCWs (n = 15), 6 had mild COVID and 1 had moderate COVID. Eight health care workers had febrile episodes without COVID.

4.3. Vaccination status

All the healthcare workers had received at least one dose of either of the available COVID-19 vaccines. Among the remaining patients only one was fully vaccinated.

4.4. Overall comorbidities involvement

Twenty-eight (38.8%) patients had one or a combination of comorbidities, which included type2 diabetes mellitus, hypertension, bronchial asthma, chronic kidney disease, malignancy and trauma. Four patients (5.55%) had fatal outcomes.

4.5. Comparison of results between Abbott ID NOW and RTPCR

As RTPCR is the current reference method in the diagnosis of COVID-19, the following statistical parameters were addressed. (Table 1).

Sensitivity was found to be 93.22% (55/59), 95% CI: 83.82–97.93%; Specificity was 100% (13/13), 95% CI: 77.19–100%; PPV was 100% (55/55), 95% CI: 94–100% and NPV was 76.47% (13/17), 95% CI:50–93%.

Table 2
A list of studies evaluating ID NOW.

Location	Sample size	Comparator test	Sensitivity/ PPA (%)	Specificity/ NPA (%)	Comments	Reference
France	48	RTPCR	94.9	100	Naso-pharyngeal swabs transported in VTM	(Farfour et al., 2021)
USA	974	RTPCR	91.3	100	Dry nasal swab from one anterior nare used for IDNOW and that from the other for RTPCR	(Tu et al., 2021)
USA	117	RTPCR	67	100	Naso-pharyngeal swabs transported in VTM	(Jin et al., 2020)
USA	88	Composite reference standard (CRS)	48	100	Dry nasal swabs kept at 4 °C and processed within 24 h	(Lephart et al., 2021 Jan)
USA	524	RTPCR	75	99	Dry nasal swabs used	(Harrington et al., 2020)
USA	113	RTPCR	95	99	Naso-pharyngeal swabs transported in VTM	(Ghofrani et al)
USA	184	RTPCR	91	100	Dry nasal swabs and nasopharyngeal swabs in VTM	(Cradic et al., 2020 Jul 7)
USA	198	RTPCR	79	100	Naso-pharyngeal swabs transported in VTM	(Moore et al., 2020)
USA	61	RTPCR	72	100	Naso-pharyngeal swabs transported in VTM	(Mitchell and George, 2020 Jul)
USA	108	RTPCR	88	100	Naso-pharyngeal swabs transported in VTM	(Zhen et al., 2020 Jul 23)
USA	101	Xpert Xpress	54.8	98.6	Dry nasal swabs used	(Basu et al., 2020 Jul 23)
USA	113	RTPCR	74	100	Naso-pharyngeal swabs transported in VTM	(Smithgall et al., 2020 Jul)
North America and Europe	812	RTPCR	73	99.7	Review and meta-analysis of 4 evaluations	(Dinnes et al., 2021)

5. Discussion

In the study we evaluated nasal swabs from the participants for the presence of SARS CoV2 RNA and compared the results with RT-PCR. As per the manufacturer's instructions, nasal swab, nasopharyngeal swab and throat swab can be used. We used nasal swabs which are more acceptable to patients and have an easier procedure of collection. The swabs provided in the test kit were used in the study, however rayon, foam, HydraFlock® Flocked swab (standard tip), HydraFlock® Flocked swab (mini tip), Copan Mini Tip Flocked Swab, or Copan Standard Flocked swabs can also be used to collect nasal swab samples. The sensitivity, specificity, PPV and NPV were found to be 93.22%,100%, 100% and 76.47% respectively. The evaluation of diagnostic performance of ID NOW on account of false negative results has been recommended by the USFDA in the past, for investigating into variations caused by swabs, viral transport media, and proficiency in following manufacturer's instructions (U.S. Food Drug Administration, 2020). A number of studies have been done, mostly in the USA, comparing the performance of ID NOW with RTPCR on various platforms. The sensitivity/ Positive percent agreement (PPA) determined in these studies ranges from 48% to 95%, while the specificity/ Negative percent agreement (NPA) ranges from 99% to 100%. In a recent Cochrane review and metaanalysis the sensitivity and specificity were found to be 73% and 99.7% (Dinnes et al., 2021). The broad variation in sensitivity is likely because of differences in protocols right from sample collection to transportation and storage. VTM/ universal transport medium (UTM) has been used for sample collection, until in April 2020, when the manufacturer's recommendation changed in favor of dry swabs. (ID NOW COVID-19 product insert, IN190000 Rev.3 2020/04:6-8). Consequently, many authors have not used dry swabs in their studies. The higher sensitivity in our study is likely because we followed manufacturer's instructions strictly, using dry nasal swabs and processing samples within two hours.

A list of studies evaluating ID NOW is shown in Table 2.

The failure to detect some of the true positives could be related to the difference in the amplification technology used. Isothermal nucleic acid amplification test (INAAT) is a promising tool, but it has been found to have lower sensitivity than RT-PCR for SARS-CoV-2 RNA detection (Thi et al., 2020). Poor sensitivity has also been noted in samples of low viral load. Smithgall et al. compared ID NOW against the Cobas Roche assay and noted positive agreement of 73.9% and Negative agreement of 100%. However, positive agreement for medium and high viral concentrations (Ct value <30) was 100% and 34.3% for Ct values > 30. The other possibility lies in individual patient characteristics, the four individuals who tested false negative had mild disease. However, an inadequate sample cannot be ruled out as the internal processing control does not have a human RNP gene to ensure proper swab collection. This was noted in one case of our healthcare workers (data not shown).

The strength of this study is the inclusion of diverse patient profile which includes healthcare workers who were partially or fully vaccinated which implies the application to extend to vaccinated individuals, who are expected to have lower viral loads or milder symptoms. This can be consequent to the lower limit of detection (LOD).

5.1. Limitations

One major limitation for ID NOW usage is to process swabs within an hour of collection. We processed the samples within the recommended time. The other problem is the high cost of each test that makes it unaffordable to smaller Laboratories.

Concluding this, Abbott ID NOW is a convenient, rapid molecular test with sensitivity somewhat less than other cartridge based or chipbased platforms, such as Xpert Xpress (97.8%) (Xpert Xpress SARS- CoV-2 Assay, ENGLISH Package insert) and TRUENAT Beta CoV (100%) (Truenat COVID 19 packinsert VER 04.). Specificity was found to be same (100%). The ID NOW Instrument occupies little space and is easy to use, making it suitable for a busy laboratory or as a POC test. The short turnaround time, which is about 5–13 min for Positive results and 13 min for Negative results makes this an attractive alternative for COVID-19 diagnosis. ID Now has utility as a rapid rule-in test for COVID-19, however, caution to be maintained for use as a single rule-out test, especially when the clinico-epidemiolocal findings suggest otherwise.

Ethics approval and consent to participate

Ethical Approval to carry out this research was obtained by Institute ethics committee, AIIMS, New Delhi Reference number (IEC 668/ 03.07.2020).

CRediT authorship contribution statement

Smriti Srivastava, Parul Singh contributed toward study design, conceptualization, literature search, figures, study design, patient

recruitment, testing of samples, data collection, data analysis, data interpretation, writing & revision of all drafts of the manuscript. Rajesh Malhotra, Purva Mathur contributed toward the statistical data analysis data interpretation & revision of the draft. Smriti Srivastava, Parul Singh contributed toward patient recruitment, testing of samples, and data collection. All authors have read & agreed to the submission of this version of the manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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