Laboratory evaluation of the Abbott ID NOW rapid severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) amplification assay and its potential use in the emergency department

Georgios Meletis PhD[1], Ioanna Gkeka MD[1], Areti Tychala MSc[1], Barbara Fyntanidou PhD[2], Lydia Kouroudi MD[1] and Lemonia Skoura PhD[1]

[1]Department of Microbiology, AHEPA University Hospital, S. Kiriakidi str. 1, 54636, Thessaloniki, Greece and [2]Department of Emergency Medicine, AHEPA University Hospital, S. Kiriakidi str. 1, 54636, Thessaloniki, Greece

To the Editor—Rapid laboratory detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is of outmost importance nowadays and affects clinical and epidemiological decisions regarding therapy initiation, carrier isolation, and adoption of public health measures. The implementation of rapid antigen tests even in the form of self-testing has been recently applied in some countries to reduce the turnaround time to result required to perform real-time reverse-transcription polymerase chain reaction (RT-PCR).

However, molecular techniques remain the gold standard.[1]

Isothermal amplification technology (IAT) provides an alternative that improves dramatically the time to result, reduces costs, and maintains the molecular basis of SARS-CoV-2 identification in clinical samples. IAT is the amplification of nucleic acids without thermocycling, and unlike PCR, it does not require skilled personnel and specialized laboratory equipment.[2]

The Abbott ID NOW COVID-19[3] is a loop-mediated isothermal amplification (LAMP) assay[2] that was recently evaluated in our hospital as a rapid alternative to the already present real-time RT-PCR–based techniques that are used in everyday practice. We obtained 30 nasopharyngeal samples from patients with clinical suspicion of COVID-19 admitted at the emergency department of our hospital, which is one of the referral settings for COVID-19 in northern Greece. The samples were tested in parallel with the Abbott ID NOW, the NeuMoDx SARS-CoV-2, and the Abbott RealTime SARS-CoV-2 assays according to the manufacturers' respective instructions. Regarding the ID NOW, a dry swab without transport medium (as recommended by the US Food and Drug Administration) was used.[4]

In our evaluation, the performance of ID NOW was identical to that of NeuMoDx and was comparable to that of the Abbott RealTime SARS-CoV-2 assay, except for 2 cases (cases 14 and 28, Table 1). Compared to the Abbott RealTime SARS-CoV-2 assay, the sensitivity of ID NOW was 85.71%, the specificity was 100%, the positive predictive value was 100%, the negative predictive value was 88.89%, and the κ coefficient of agreement was 0.805 ($P < .005$). The time to result of ID NOW was 5 minutes or less for positive samples and 10–15 minutes for negative samples. The rapid times to positive results of the ID NOW were achieved regardless of the Ct values obtained by NeuMoDx and Abbott RealTime assays for the respective positive samples.

Previous studies have reported low sensitivity for the ID NOW test using nasopharyngeal swabs in transport media.[5–8] In a recent large study by Sepulveda et al[9] in which dry swabs were used, ID

Table 1. Result Comparison Between Abbott ID NOW, NeuMoDx SARS-CoV-2 Assay, and Abbott RealTime SARS-CoV-2 Assay

Test No	Test ID	ID NOW	NeuMoDx (N Ct/Nsp2 Ct)	Abbott RealTime (RdRp and N Ct)
1	93781	POS	POS (28.70/28.68)	POS (18.48)
2	93908	POS	POS (14.78/16.18)	POS (3.70)
3	94126	NEG	NEG	NEG
4	94122	POS	POS (14.70/16.01)	POS (4.16)
5	94130	NEG	NEG	NEG
6	94146	NEG	NEG	NEG
7	94222	NEG	NEG	NEG
8	94219	NEG	NEG	NEG
9	94258	POS	POS (21.18/22.29)	POS (11.44)
10	94269	POS	POS (18.11/19.27)	POS (7.31)
11	94271	POS	POS (14.80/16.09)	POS (3.65)
12	95003	NEG	NEG	NEG
13	95048	POS	POS (21.32/22.49)	POS (9.99)
14	95047	NEG	NEG	POS (28.43)
15	95069	NEG	NEG	NEG
16	95150	NEG	NEG	NEG
17	95154	NEG	NEG	NEG
18	95160	NEG	NEG	NEG
19	94600	POS	POS (20.12/21.08)	POS (9.30)
20	94626	POS	POS (13.62/14.68)	POS (3.55)
21	94628	POS	POS (22.29/23.99)	POS (11.63)
22	94733	NEG	NEG	NEG
23	93783	POS	POS (16.42/17.39)	POS (5.41)
24	126056	NEG	NEG	NEG
25	128922	NEG	NEG	NEG
26	129073	NEG	NEG	NEG
27	129085	NEG	NEG	NEG
28	129128	NEG	NEG	POS (31.49)
29	136905	NEG	NEG	NEG
30	137058	POS	POS (26.88/27.16)	POS (15.34)

Note. POS, positive; NEG, negative; Ct, cycle threshold; N, nucleocapside gene; Nsp2, nonstructural protein 2 gene; RdRp, RNA-dependent RNA polymerase gene.

Author for correspondence: Georgios Meletis, E-mail: meletisg@hotmail.com

Cite this article: Meletis G, *et al.* (2022). Laboratory evaluation of the Abbott ID NOW rapid severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) amplification assay and its potential use in the emergency department. *Infection Control & Hospital Epidemiology*, 43: 1729–1730, https://doi.org/10.1017/ice.2021.360

NOW showed very high sensitivity for detection of patients with high levels of SARS-CoV-2 RNA but lower overall sensitivity compared with the Xpert SARS-CoV-2 assay. In our evaluation, the 2 cases of disagreement with the Abbott RealTime SARS-CoV-2 assay had high Ct values, indicating the presence of low viral loads.

Considering that low-viral-load samples are commonly unable for viral growth in cell cultures,[9] the clinical impact of ID NOW should be approached with respect to the advantage of saving time in detecting infected patients and the disadvantage of false negatives with lower viral loads. Even though IATs are not yet ready to entirely replace real-time RT-PCR, the implementation of assays such as ID NOW could be beneficial in reducing turnaround times, especially in emergency departments, as well as the overall costs of SARS-CoV-2 detection.

Acknowledgments.

Financial support. No financial support was provided relevant to this article.

Conflicts of interest. All authors report no conflicts of interest relevant to this article.

References

1. Lim J, Lee J. Current laboratory diagnosis of coronavirus disease 2019. *Korean J Intern Med* 2020;35:741–748.
2. James AS, Alawneh JI. COVID-19 infection diagnosis: potential impact of isothermal amplification technology to reduce community transmission of SARS-CoV-2. The carbapenemase menace: do dual mechanisms code for more resistance? *Diagnostics (Basel)* 2020;10:399.
3. Canadian Public Health Laboratory Network and the Canadian Society of Clinical Chemists. Interim guidance on the use of the Abbott ID NOW instrument and COVID-19 assay. *Can Commun Dis Rep* 2020; 46:422–426.
4. Office of the Commissioner. Coronavirus (COVID-19) update: FDA informs public about possible accuracy concerns with Abbott ID NOW point-of-care test. US Food and Drug Administration website. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-informs-public-about-possible-accuracy-concerns-abbott-id-now-point. Published 2020. Accessed July 3, 2021.
5. Basu A, Zinger T, Inglima K, *et al.* Performance of Abbott ID Now COVID-19 rapid nucleic acid amplification test using nasopharyngeal swabs transported in viral transport media and dry nasal swabs in a New York City academic institution. *J Clin Microbiol* 2020;58:e01136–20.
6. Harrington A, Cox B, Snowdon J, *et al.* Comparison of Abbott ID Now and Abbott m2000 methods for the detection of SARS-CoV-2 from nasopharyngeal and nasal swabs from symptomatic patients. *J Clin Microbiol* 2020;58: e00798–20.
7. Smithgall MC, Schebekova I, Whitter S, Green DA. Comparison of Cepheid Xpert Xpress and Abbott ID Now to Roche cobas for the rapid detection of SARS-CoV-2. *J Clin Virol* 2020;128:104428.
8. Zhen W, Smith E, Manji R, Schron D, Berry GJ. Clinical evaluation of three sample-to-answer platforms for detection of SARS-CoV-2. *J Clin Microbiol* 2020;58:e00783–20.
9. Sepulveda JL, Abdulbaki R, Sands Z, *et al.* Performance of the Abbott ID NOW rapid SARS-CoV-2 amplification assay in relation to nasopharyngeal viral RNA loads. *J Clin Virol* 2021;140:104843.

Challenges associated with using cycle threshold (Ct) value of reverse-transcription polymerase chain reaction (RT-PCR) as a criteria for infectiousness of coronavirus disease 2019 (COVID-19) patients in India

Saad Ahmed Jamal MBBS, Mir Umar Farooq MBBS and Vishwanath Bidari MBBS

To the Editor—We read with great interest the article "COVID-19 Admission Screening, and Assessment of Infectiousness at an Academic Medical Center, Iowa 2020" by Alsuhaibani et al,[1] in which the cycle threshold (Ct) value of severe acute respiratory coronavirus virus 2 (SARS-CoV-2) reverse-transcription polymerase chain reaction (RT-PCR) was one of the criteria used to determine the degree of infectiousness in patients.

Having suffered a disastrous second wave resulting from a severe shortage of resources, India ranks 155 of 167 countries, with 5 hospital beds and 8.6 doctors per 10,000 people.[2] With health experts predicting an impending third wave, it is essential for hospital administrations to revise admission criteria and triage policies. One criterion that has garnered attention is the Ct value of SARS-CoV-2 RT-PCR tests. However, many challenges are associated with using Ct values as a reliable criterion for infectiousness.

The Ct value is the cycle of amplification at which fluorescence indicates a positive result.[3] It is explained as the number of cycles of amplification of viral copies it takes for the RT-PCR to register a positive test. The Ct score is inversely proportional to the viral load present within the sample.

The widely used RT-PCR testing for SARS-CoV-2 utilizes nasal or nasopharyngeal samples via swab collection. One of the important issues with using Ct value as an indicator of infectiousness is the variation in the skill of the swab collectors, along with the tolerance of the patients. Having faced a huge shortage of healthcare workers, state governments across India have employed swab collectors from various professions as well as students outside health care to cope with shortage of manpower, training them for 3–5 days.[4] The skill level of these swab collectors varies greatly. A news article from the city of Bengaluru reported one case of a student volunteer who collected 385 samples over 5 hours.[5] Although this procedure speeds testing, it also leads to the collection of imprecise quantities of samples. Dahdouh et al[6] reinforced the large amount of variation in samples

Author for correspondence: Dr. Saad Ahmed Jamal (M.B.B.S.), E-mail : saad.gx@gmail.com

Cite this article: Jamal SA, Farooq MU, and Bidari V. (2022). Challenges associated with using cycle threshold (Ct) value of reverse-transcription polymerase chain reaction (RT-PCR) as a criteria for infectiousness of coronavirus disease 2019 (COVID-19) patients in India. *Infection Control & Hospital Epidemiology*, 43: 1730–1731, https://doi.org/10.1017/ice.2021.357