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.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.
Short communication

Evaluation of the COVID19 ID NOW EUA assay

Stephanie L. Mitchella,⁎, Kirsten St. Georgeb

a Department of Pathology, University of Pittsburgh School of Medicine, Pittsburgh, PA, United States
b Laboratory of Viral Diseases, Wadsworth Center, New York State Department of Health, Albany, NY, United States

ARTICLE INFO

Keywords:
ID NOW
SARS-CoV-2
COVID-19
Point-of-Care

ABSTRACT

Background: The SARS-CoV-2 pandemic caused a major surge in needed diagnostic capacity. In response, many EUA assays have become available for clinical laboratories, and more recently, the point of care device, Abbott ID NOW.

Objectives: To determine the analytical performance of the ID NOW assay for detecting SARS-CoV-2.

Study design: Residual NP samples collected in viral transport media were tested by the ID NOW platform in two independent laboratories. Results were compared to either the CDC or New York EUA assays, which served as reference methods.

Results: Overall agreement of ID NOW was 78.7%. Sensitivity was 71.7% and specificity was 100%. Notably, all false-negative results correlated to those samples that were weakly positive.

Conclusions: ID NOW performs well for strong and moderately positive samples but has reduced sensitivity for weakly positive samples. This sensitivity, among other concerns, should be taken into consideration when using this test for patients with a low suspicion for COVID-19 disease.

1. Background

The SARS-CoV-2 pandemic caused a major surge in the diagnostic capacity needed for adequate response efforts. Many commercial companies have developed diagnostic assays that are available for clinical testing in the USA, if authorized through the FDA’s emergency use authorization (EUA) process. While most of the SARS-CoV-2 EUA assays for molecular detection must be performed in moderate- to high-complexity clinical laboratories, a few are authorized as point-of-care devices, such as the Abbott ID NOW. In addition to clinical laboratories, this assay can be performed by trained non-laboratory personnel in patient care settings such as Emergency Departments, physician’s offices or pharmacies, potentially bringing diagnostic testing for SARS-CoV-2 closer to the patient [1]. Among the marketing information for this new assay, potential advantages include its reported sensitivity (stated limit of detection (LOD) of 125 genome equivalents/mL) and run time (detection of SARS-CoV-2 RNA as early as five minutes and a negative result in thirteen minutes). Also, the ID NOW may provide rapid molecular results either from direct testing of nasopharyngeal, nasal, or oropharyngeal swabs or testing of the viral transport media (VTM) from swabs placed in this fluid after collection [2]. To date, reported performance of the ID NOW SARS-CoV-2 assay in the peer-reviewed literature has been variable. While Rhoads et al. showed 94% positive agreement between the ID NOW and a modified CDC laboratory developed test (LDT), other evaluations showed lower positive percent agreements for the ID NOW as compared to an LDT reference method, ranging from 75 to 87% [3–6].

2. Objective and methods

Given the potential advantages of this device over more traditional format molecular tests such as real-time RT-PCR, a small evaluation of the ID NOW COVID-19 test was conducted at two laboratories to assess its performance. Residual positive and negative nasopharyngeal patient samples collected in VTM were tested using the ID NOW EUA assay. Samples had been stored at -80°C prior to testing. Results from the ID NOW assay were compared to the original results from either the CDC EUA or the New York EUA assays, which served as the reference methods. Positive and negative samples were alternated to assess for potential carry-over contamination of either the patient sample or amplicon. Precision was assessed by running one strongly positive, one moderately positive and one negative sample in triplicate. At both facilities, the work was conducted inside a Class II biosafety cabinet (BSC) by certified laboratory personnel.

⁎ Corresponding author at: Department of Pathology, University of Pittsburgh, School of Medicine, 4401 Penn Ave, Main Hospital, Floor B, #269, Pittsburgh, PA, 15217, United States.
E-mail address: Mitchellsl5@upmc.edu (S.L. Mitchell).

https://doi.org/10.1016/j.jcv.2020.104429
Received 1 May 2020; Received in revised form 5 May 2020; Accepted 9 May 2020
1386-6532/ © 2020 Elsevier B.V. All rights reserved.
3. Results

In total 46 positive and 15 negatives were tested for a total of 61 samples. Overall agreement of the ID NOW with the reference method was 48/61 (78.7 %). Specificity was 100 % (15/15). However, sensitivity was 71.7 % (33/46) with the ID NOW producing false negative results in 13 of the 46 positive samples tested. Notably, all false-negative results corresponded to those that were weakly positive, with a cycle threshold (Ct) values between 35–40 for all targets (Fig. 1). This suggests that the ID NOW has acceptable performance for strongly or moderately positive samples but may lack sensitivity when the sample contains low amount of viral RNA. Importantly, in a review of more than 5000 positive SARS-CoV-2 results at Wadsworth, 18 % of the tests had Ct values in the 35–39 range (data not shown), which would suggest that the ID NOW would have failed to detect approximately 1 in 7 to 1 in 8 of all the positive samples tested. An alternative explanation for the lack of detection of these weakly positive samples could be the degradation of viral RNA during either storage or the single freeze-thaw step. Precisions studies testing 2 positive samples in triplicate revealed that the ID NOW missed one replicate of the moderately positive sample, resulting in a precision of 83.3 % (5/6).

4. Discussion

After this evaluation was performed, a notice was issued by the manufacturer, stating that samples collected in VTM were no longer acceptable for the ID NOW COVID-19 EUA assay, citing lower sensitivity for these specimens [7], which was also observed in our study. While removing this specimen type is an important step to reducing false-negative results, this now presents a challenge to both laboratories and patient care settings in verifying assay performance prior to implementation [8]. Given that only the direct swab is acceptable, with a cycle threshold (Ct) values between 35–40 for all targets (Fig. 1). This suggests that the ID NOW has acceptable performance for strongly or moderately positive samples but may lack sensitivity when the sample contains low amount of viral RNA. Importantly, in a review of more than 5000 positive SARS-CoV-2 results at Wadsworth, 18 % of the tests had Ct values in the 35–39 range (data not shown), which would suggest that the ID NOW would have failed to detect approximately 1 in 7 to 1 in 8 of all the positive samples tested. An alternative explanation for the lack of detection of these weakly positive samples could be the degradation of viral RNA during either storage or the single freeze-thaw step. Precisions studies testing 2 positive samples in triplicate revealed that the ID NOW missed one replicate of the moderately positive sample, resulting in a precision of 83.3 % (5/6).

CRediT authorship contribution statement

Stephanie L. Mitchell: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Resources, Writing - original draft, Writing - review & editing, Supervision. Kirsten St. George: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Resources, Writing - review & editing, Supervision.

References

[1] ID NOW COVID-19, FDA Authorization Letter- March 27, Abbott Diagnostics Scarborough, Inc., 2020 https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations (Accessed 18 April 2020) Last updated: April 17, 2020.
[2] ID NOW COVID-19, Instructions for Use, Abbott Diagnostics Scarborough, Inc., 2020 EUA2005047. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations (Accessed 18 April 2020) Last updated:
April 17, 2020.

[3] W. Zhen, E. Smith, R. Manji, D. Schron, G.J. Berry, Clinical evaluation of three sample-to-answer platforms for the detection of SARS-CoV-2, J. Clin. Microbiol. (2020).

[4] A. Harrington, B. Cox, J. Snowdon, J. Bakst, E. Ley, P. Grajales, J. Maggiore, S. Kahn, 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), https://doi.org/10.1128/JCM.00798-20.

[5] D.D. Rhoads, S.S. Cherian, K. Roman, L.M. Stempak, C.L. Schmotzer, N. Sadri, Comparison of Abbott ID NOW, DiaSorin Simplexa and CDC FDA EUA methods for the detection of SARS-CoV-2 from nasopharyngeal and nasal swabs from individuals diagnosed with COVID-19, J. Clin. Microbiol. (2020), https://doi.org/10.1128/JCM.00760-20.

[6] C.A. Hogan, M.K. Sahoo, C. Huang, N. Garamani, B. Stevens, J. Zehnder, B.A. Pinsky, Five-Minute Point-of-Care Testing for SARS-CoV-2: Not There Yet, J. Clin. Virol. (2020), https://doi.org/10.1016/j.jcv.2020.104410.

[7] ID NOW COVID-19 Technical Brief-April 2020, Sample Type Labeling Update, Abbott Diagnostics Scarborough, Inc, 2020 EUA2000047.

[8] S.L. Mitchell, et al., Verification Procedure for Commercial Tests with Emergency Use Authorization for the Detection of SARS-CoV-2, April 3, 2020, https://asm.org/Protocols/EUA-COVID-19-Testing-Protocol (Accessed 18 April 18 2020) (2020).