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.

Journal of Clinical Virology 128 (2020) 104410

Contents lists available at ScienceDirect

Journal of Clinical Virology

journal homepage: www.elsevier.com/locate/jcv

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Five-minute point-of-care testing for SARS-CoV-2: Not there yet

Testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is essential to rapidly identify acute infection. Early in the pandemic, clinicians experienced the pressing need to access rapid and accurate testing for the diagnosis of SARS-CoV-2 to guide management. As a result, diagnostic manufacturers and laboratories developed over 40 new assays receiving emergency use authorization (EUA) by the U.S. Food and Drug Administration, spanning variable amplification methods, viral targets, and turnaround times. The Abbott ID NOW COVID-19 (Abbott Laboratories) test commanded early attention as the most rapid diagnostic test on the market, requiring only 5 min for positive results and 13 min for negative results [1]. This small-sized platform, previously developed for diagnosis of Influenza A/B, was granted EUA approval for the diagnosis of SARS-CoV-2 on March 27 [2]. We compared the test performance of this assay to samples previously characterized with the Panther Fusion SARS-CoV-2 EUA assay (Hologic, Inc.). Testing was performed at the Stanford Health Care Clinical Virology Laboratory in Palo Alto, from nasopharyngeal samples collected from adults and children from March 24, 2020 to April 1, 2020. A total of 100 samples (51 positive, 49 negative) were assessed, including positive samples with a range of cycle threshold (Ct) values (median 28.4, interquartile range [IQR], 23.6–32.1). The ID NOW assay detected 41/51 positive samples, corresponding to a positive percent agreement of 80.4 % (95 % confidence interval [CI], 66.9–90.2). Repeat ID NOW testing was performed on 8/10 discrepant samples, and 2 then resulted as positive. False-negative samples had a median Panther Fusion Ct value of 35.9 (IQR, 31.2–39). The ID NOW reported 47/49 negative samples as negative, for a negative percent agreement of 95.9 % (95 % CI, 86.0–99.5). Discrepancy analysis was performed using a laboratory-developed EUA [3,4] method and confirmed one of the two samples as true positive with a late Ct value of 37.6, and the other as false-positive.

The rapid development of numerous SARS-CoV-2 assays has demonstrated the tremendous momentum the diagnostics industry and clinical laboratories have achieved to improve access to diagnostic testing. The availability of five-minute testing for SARS-CoV-2 was touted as 'game-changing'. However, the low sensitivity observed has important implications for COVID-19 control as missed diagnoses may increase risk of viral transmission. Sensitivity may vary depending on the range of Ct values tested, and has been reported to be higher in a separate study with 94 % positive percent agreement compared to the modified CDC assay [5]. Furthermore, concerns about risk of aerosolization during sample processing suggest this test may be only safely performed within a biosafety cabinet or with full personal protective equipment [6]. As shown in this comparative diagnostic accuracy study, the performance of the 5-minute point-of-care test has significant limitations for the diagnosis of COVID-19. We suggest that repeat testing be performed in a clinical laboratory with EUA for patients with a moderate to high pre-test probability who test negative with this device.

Funding

None.

Declarations of Competing Interest

None.

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https://doi.org/10.1016/j.jcv.2020.104410
Received 25 April 2020

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