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.

SARS-CoV-2 antigen-detecting rapid tests for the delta variant

Given the emergence of novel SARS-CoV-2 variants of concern, the performance of available diagnostics for these new variants should be investigated. SARS-CoV-2 antigen rapid diagnostic tests (Ag-RDTs) offer quick, cheap, and laboratory-independent results at the point of care.[1,2] Although sensitivity is lower compared with RT-PCR, these tests enable reliable detection of high viral loads associated with the presence of infectious viral particles, making them important public health tools.[3,4] However, the majority of Ag-RDT validation studies were done before the emergence of SARS-CoV-2 variants of concern.[2,5] We previously performed an analytical sensitivity testing of nine commercially available Ag-RDTs for the first three identified variants of concern (alpha, beta, and gamma) and one former variant of interest (zeta).[2]

Since then, we have studied the delta variant using cultured SARS-CoV-2, in comparison with earlier variants of concern (alpha, beta, and gamma) and an early pandemic variant (B.1.610). All viruses were isolated from clinical samples and fully sequenced. Isolates were grown in Vero E6 cells as described previously.[2] The starting dilution of infectious titres for viruses used in this study was 4·24 $\log_{10}$ plaque-forming units per mL and corresponded to 8·15 $\log_{10}$ RNA copies per mL, 6·70 $\log_{10}$ RNA copies per mL, 7·18 $\log_{10}$ RNA copies per mL, 8·30 $\log_{10}$ RNA copies per mL, and 6·00 $\log_{10}$ RNA copies per mL of virus stocks for B.1.610, the alpha variant, the beta variant, the gamma variant, and the delta variant.

All Ag-RDT assays were performed according to the manufacturers' instructions with the exception that 5 µL of virus dilution was directly added to the proprietary buffer, and then applied to the Ag-RDT in duplicates under biosafety level 3 conditions.[2] Ag-RDT buffer without virus was used as a negative control. Results were read independently by two individuals. Any visible test band in the presence of a visible control band was considered as a positive result.

Performance of the tests to detect the delta variant was similar to the other variants for most of Ag-RDTs. A single test, the Sure Status COVID-19 Antigen Card Test (Premier Medical Corporation), showed a higher sensitivity for the alpha, beta, and gamma variants compared with the delta variant. Conversely, the Flowflex SARS-CoV-2 Antigen Rapid Test (ACON Laboratories) showed a higher sensitivity for delta compared with other Ag-RDT kits (appendix pp 1–2). In comparison with B.1.610, the delta variant, like the alpha, beta, and gamma variants, presented higher sensitivity.

In this study, the accuracy of 11 Ag-RDTs to detect variants of concern was determined. Analytical validation with cultured virus might be a proxy for clinical accuracy, but it is not a replacement for clinical evaluations. Nevertheless, we showed that, despite slight differences in sensitivity, Ag-RDTs remain, in principle, effective to detect variants of concern, including the now-dominant delta variant.

We declare no competing interests. This work was supported by the Swiss National Science Foundation (grant number 196383), the Fondation Ancrage Bienfaisance du Groupe Pictet, and FIND, the global alliance for diagnostics. The Swiss National Science Foundation and the Fondation Ancrage Bienfaisance du Groupe Pictet had no role in data collection, analysis, or interpretation. Antigen rapid diagnostic tests were provided by FIND and FIND was involved in methodology, data analysis, and interpretation. CE is an employee of FIND. MB and KA contributed equally.

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Published **Online** November 24, 2021 https://doi.org/10.1016/S2666-5247(21)00302-5

See **Online** for appendix