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 rapid diagnostic tests for emerging variants

SARS-CoV-2 antigen-detecting rapid diagnostic tests (Ag-RDTs) provide laboratory-independent results at the point of care and are powerful tools for public health interventions. Clinical and analytical studies, published in 2021, showed SARS-CoV-2 Ag-RDT detection thresholds related to the presence of infectious virus in symptomatic SARS-CoV-2 infections.[1,2] However, the majority of Ag-RDT validation studies were done before SARS-CoV-2 variants of concern (VOC) or interest (VOI) emerged, with the VOCs currently outcompeting earlier lineages.[3] To date, data on routine diagnostic performance for VOCs and VOIs are sparse.[4,5] Furthermore, clinical validation studies comparing multiple VOCs in parallel are hardly feasible.

We investigated the analytical sensitivity of nine commercially available Ag-RDTs using cultured SARS-CoV-2, comparing lineage B.1.610 (first COVID-19 pandemic wave in Europe) with VOCs B.1.1.7, B.1.351, and P.1, and VOI P.2.

Infectious titres and RNA copies of virus stocks grown in Vero E6 were quantified by plaque titration (for infectious titres) and RT-PCR (E gene). Isolates were tested in serial dilutions, starting with 5·44 $\log_{10}$ PFU/mL, except for P.1, which had a maximum titre of $\log_{10}$ 4·24 PFU/mL. An infectious titre of 5·44 $\log_{10}$ PFU/mL corresponded to 10.26, 12.11, 9.86, and 11·23 $\log_{10}$ RNA copies per mL for B.1.610, B.1.1.7, B.1.351 and P.2. For P.1, the infectious titre of 4·24 $\log_{10}$ PFU/mL corresponded to 11·81 $\log_{10}$ RNA copies per mL.

Ag-RDT assays were done 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 BSL3 conditions. Results were read independently by two individuals. Any visible test band in the presence of a visible control band was considered as positive. Ag-RDT buffer without virus was used as negative control.

When analysing results normalised to PFU/mL, comparable or better performance to the early-pandemic lineage was observed for B.1.1.7, B.1.351, P.1, and P.2 for all assays (appendix). Overall sensitivity and specificity for individual isolates varied between Ag-RDTs, with the best-performing assay positive at dilutions as low as 2·43 $\log_{10}$ PFU/mL and the lower-sensitive assays positive at 4·54 $\log_{10}$ PFU/mL. Consistently, the highest sensitivity was seen for P.1 and P.2. Although testing for analytical sensitivity with cultured virus cannot fully replace clinical data, our data provide reassuring results for the use of Ag-RDTs to diagnose VOCs. Phenotypic properties, such as a large difference in the RNA–infectious virus ratio, could hint at production of defective viral particles and their effect on diagnostic test performance should be further investigated.

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See **Online** for appendix