Evaluation of an Antigen Detection Rapid Diagnostic Test for Detection of SARS-CoV-2 in Clinical Samples

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Background

Antigen detection rapid diagnostic tests have been developed for first-line large-scale screening given their rapidity, simplicity, and accuracy. This study evaluates the diagnostic performance of an antigen detection rapid diagnostic test (BLOK BioScience, London, UK) detecting SARS-CoV-2 nucleocapsid protein.

Methodology

In this study, 130 nasopharyngeal swab samples were collected, including 110 from COVID-19 patients and 20 from non-infected individuals with results confirmed by RT-PCR. Serially diluted SARS-CoV-2 isolate and samples from COVID-19 patients were tested using rapid diagnostic test to determine its sensitivity. Other viral isolates including SARS-CoV, common coronaviruses and respiratory viruses, together with samples from non-infected individuals, were tested for specificity. Ten clinical samples from COVID-19 patients with SARS-CoV-2 variants, including alpha, beta, gamma, delta, and eta variants, were collected to evaluate the test's potential application in detecting emerging variants.

Results

Overall sensitivity was 92%, stratifying into viral loads yielded 100% for Ct < 25 samples including SARS-CoV-2 variants, but 11.11% for Ct ≥ 30 samples. The analytical sensitivity of $\log_{10}$ $TCID_{50}$/mL 2.0 was identified for SARS-CoV-2. Ninety-seven percent specificity with only SARS-CoV cross-reactivity lead to the Youden index of 0.89.

Conclusion

The rapid diagnostic test has a high sensitivity for detecting SARS-CoV-2 in high viral load samples, possibly including emerging SARS-CoV-2 variants, but reduced sensitivity in low viral load samples. The ease-of-use, rapidity, cost-effectiveness and ability to detect SARS-CoV-2 including variants at a high viral load may suggest the rapid diagnostic test's potential application to decentralize and increase efficiency of COVID-19 testing, with its optimized usage as a complementary testing method to other tests such as RT-PCR, or as a point-of-care test for large-scale screening, particularly for pandemic areas or airport border infection control.

Figure 1. (a) Box plot of RT-PCR Ct value against rapid diagnostic test positivity for samples from COVID-19 patients; **(b)** Box plot of RT-PCR Ct value against rapid diagnostic test result expressed semi-quantitatively for samples from COVID-19 patients.

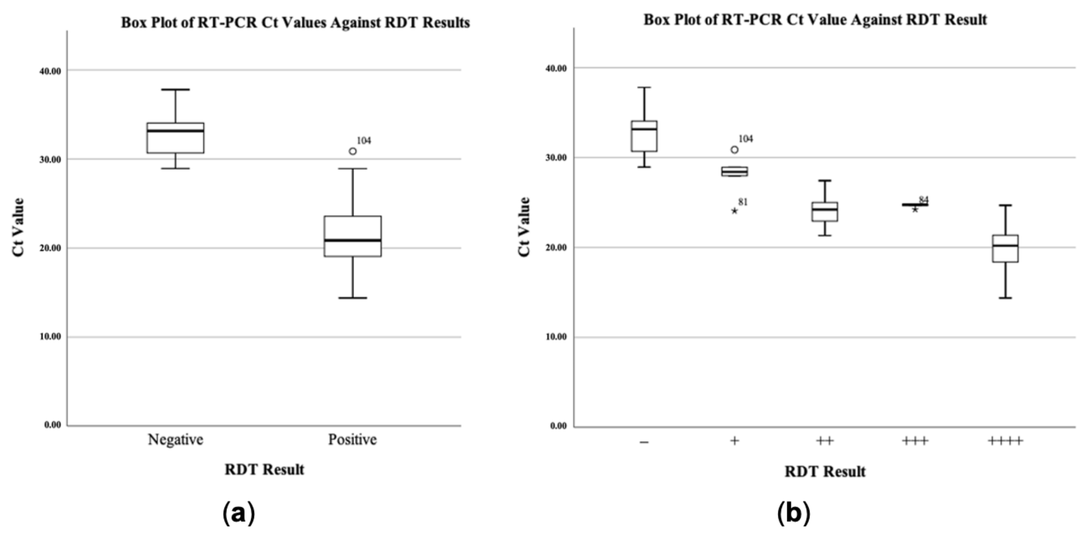

Figure 2. Stacked bar chart of percentages of positive and negative rapid diagnostic test results for samples from COVID-19 patients at different RT-PCR Ct value levels.

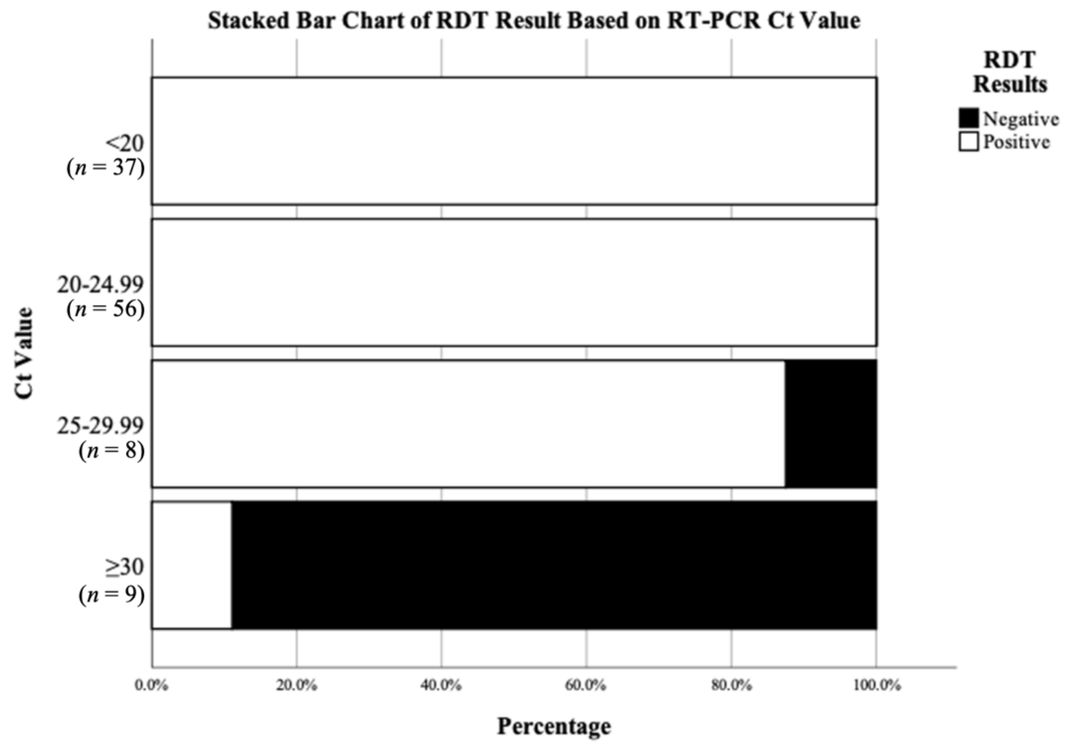

Table 1. Test performance characteristics of rapid diagnostic test.

Parameters	RDT [95% confidence interval (CI)]
Sensitivity	
Overall	92% (85-96%)
Ct <20	100% (91-100%)
20 ≤ Ct < 25	100% (94-100%)
25 ≤ Ct < 30	88% (47-100%)
Ct ≥ 30	11% (0-48%)
Specificity	97% (85-100%)
Positive predictive value (PPV)	99% (94-100%)
Negative predictive value (NPV)	79% (66-87%)
Youden index	0.89