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Clinical performance of a rapid test compared to a microplate test to detect total anti SARS-CoV-2 antibodies directed to the spike protein

The recent emergence of the SARS-CoV-2 pandemic has posed formidable challenges for clinical laboratories. While immunoassays are already available, their diagnostic accuracy and optimal use remain undefined. Serologic tests could be used as complements to assays for virus nucleic acid in the diagnosis of COVID-19 [1–3]. Serologic assays that accurately assess prior infection and immunity to SARS–CoV-2 are essential for retrospective diagnosis, epidemiologic studies, ongoing surveillance and vaccine studies [1,4].

We have evaluated 2 serological assays that detect total anti-SARS-CoV-2 antibodies. One is a rapid immunochromatographic test (SARS-CoV-2 Ab Rapid Test, Beijing Wantai Biological Pharmacy Ent, Bejing, China) and the other is a microplate assay (SARS-CoV-2 Ab ELISA, Beijing Wantai Biological Pharmacy Ent, Bejing, China). Both are based on the spike antigen of SARS-CoV-2. A previous study found good performance of these assays, but did not find sensitivity variation with the time post disease-onset of sampling and lacked asymptomatic patients [5]. The two immunoassays were used to test 30 negative sera collected in 2019 at our hospital and 69 serum collected from PCR-confirmed SARS-CoV-2 infected patients. The COVID-19 infected patients provided 40 samples collected 2–14 days post symptom-onset (group 1) and 29 collected 15–45 days post symptom-onset or after contact with a positive case, including 3 asymptomatic patients (group 2).

All 30 negative samples tested negative with both assays, corresponding to 100 % specificity (confidence interval 95 %, (CI95 %): 82.1–100 %). The overall sensitivity of the Rapid test was 87 % (60/69) (CI95 %: 75.2–98.8 %) and that of the ELISA test was 100 % (69/69) (CI95 %: 88.2–100 %, $p < 0.01$) (Table 1). The Rapid test was 82.5 % sensitive (33/40) (CI95 %: 67–97.9 %) in tests on the 40 group 1 samples, while the ELISA test was 100 % sensitive (40/40) (CI95 %: 84.5–100 %, $p = 0.01$). Similarly, the Rapid test was 93 % sensitive (27/29) (CI95 %: 74.8–100 %) when tested on the 29 group 2 samples, and the ELISA test was 100 % sensitive (29/29) (CI95 %: 81.8–100 %, $p = 0.49$). The 2 group 2 samples that tested negative with the Wantai rapid test had low index values (< 8) when tested with the Wantai ELISA assay and these samples were from 2 of the 3 asymptomatic patients.

Table 1
Serological results for patients with a PCR-confirmed SARS-CoV-2 infection.

	All samples N = 69	samples collected < 14 days post-onset n = 40	samples collected > 14 days post-onset n = 29
Wantai Rapid test			
Positive	60	33	27
Negative	9	7	2
Wantai ELISA			
Positive	69	40	29
Negative	0	0	0

We therefore find that the Wantai rapid test and the microplate assay have excellent specificity but the rapid test appears to be less sensitive than the microplate assay. Although the rapid test could be ideal for point-of-care use because it requires no highly skilled personnel, no batch testing with a result in less than 15 min, our evidence indicates that the diagnostic performance of the two assays may differ in the early stages of infection and for asymptomatic patients. Despite small sample size, our data could be useful for defining the practical application of these assays that detect anti-SARS-CoV-2 antibodies.

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Declaration of Competing Interest

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