# An Initial Evaluation of the Agreement between Two SARS-CoV-2 Serologic Assays

## TO THE EDITOR:

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the viral pathogen of the current Coronavirus Disease 2019 (COVID-19) pandemic. While diagnosis relies on polymerase chain reaction (PCR) detection of the virus, serological testing for antiviral antibodies provides important information on previous exposure to the virus. As assays became available, the Food and Drug Administration (FDA) did not immediately mandate Emergency Use Authorization (EUA), which led to an influx of assays into the US market. Analytical and clinical performance had not been fully characterized and early studies comparing methods were not peer reviewed until recently *(1–3)*.

Currently, there are limited data comparing the performance of 2 highly automated commercial immunoassays from Roche Diagnostics and Abbott *(4)*. Here we evaluated the concordance between the Roche Elecsys anti-SARS-CoV-2 assay (total antibody) for use on the cobas platform and the Abbott SARS-CoV-2 IgG assay for use on the Architect analyzer. Both of these assays are currently approved for use under EUA.

Our study was approved by the local Institutional Review Board. Positive or negative results from each assay were determined by the signal to cutoff index based on the respective manufacturers' package inserts. We compared the results from 88 serum samples, of which 68 were from patients with prior positive SARS-CoV-2 PCR results. Onset of symptoms was determined for 63 of 68 patients. The onset of symptoms was $\geq$ 14 days (mean = 18.8, standard deviation = 6.6) for 30 patients and <14 days for 33 (mean = 5.4, standard deviation = 3.3). Negative control samples ($n = 20$) were remnant specimens that had been collected and stored frozen prior to the emergence of COVID-19.

Parallel testing of the two assays demonstrated agreement for 80 out of 88 samples for a total concordance of 90.9% (95% CI: 83.1%-95.3%) with a Cohen's Kappa of 79.0% (95% CI: 65.2%–92.9%). The 56 samples that were positive by both methods (93.3% positive agreement) all had prior positive SARS-CoV-2 PCR results. The 24 samples that were negative by both methods (85.7% negative agreement) included all 20 negative controls and 4 samples that had prior positive SARS-CoV-2 PCR results. Two of the samples that were PCR positive but negative by both serology platforms were from patients with less than 5 days since symptom onset. One of the four was from a patient on chemotherapy for lymphoma.

The remaining 8 samples were discordant and all had prior positive SARS-CoV-2 PCR results. Out of these 8, 4 were positive on Roche and negative on Abbott, and 4 were negative on Roche and positive on Abbott. Clinical history did not reveal any identifiable pattern to account for the discordance. However, 5 of the 8 samples' results were very close to the cutoff index values for either one or both assays (Table 1).

A limitation of our investigation includes that the timeline of onset of symptoms relative to blood draw for serology testing was determined by electronic medical record review of clinical notes and relied on patient self-reporting. Additionally, we did not investigate the effects of confirmed prior infection with non-SARS-CoV-2 coronavirus strains. With regard to our statistical analysis, we did not include predictive values given their dependence on prevalence, as our inclusion criteria artificially created a high-prevalence sample set. Further, we did not include the

**Table 1. Discordant results.**

| Patient sample# | Roche cutoff index (≥1.0 is positive) | Abbott cutoff index (≥1.4 is positive) | Onset of symptoms to serology testing (days) | Treatment setting |
|---|---|---|---|---|
| 1 | 0.91 | 2.44 | 3 | Inpatient |
| 2 | 0.97 | 2.77 | 19 | Outpatient |
| 3 | 0.97 | 2.02 | 17 | Outpatient |
| 4 | 0.49 | 2.56 | 9 | Outpatient |
| 5 | 1.44 | 1.15 | 15 | Inpatient |
| 6 | 1.99 | 0.37 | 10 | Inpatient |
| 7 | 1.10 | 1.32 | 30 | Outpatient |
| 8 | 4.41 | 1.36 | 4 | Inpatient |

calculations of specificity nor sensitivity in our analysis due to our small sample size. With no current gold standard for SARS-CoV-2 serology, we assessed the accuracy of the serology assays relative to the diagnosis of SARS-CoV-2 infection by a molecular method.

In conclusion, we found that the 2 assays had a good, but lower-than-expected, total agreement rate of 90.9%. A recent study showed that the total concordance between the Roche and Abbott assays was 89% with a positive agreement of 96% (4), which was similar to our findings. However, the negative agreement values did differ between our studies, 85.7% to 95.8%. This could be due to our much smaller negative sample set. Finally, our <14 days onset of symptom samples had a higher positive rate than what has been reported in other studies (4, 5). We emphasize that the onset of symptoms is a patient-reported data point that may have reliability limitations.

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