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.

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Letter to the Editor

Kinetics and performance of the Abbott architect SARS-CoV-2 IgG antibody assay

Dear Editor,

We read with interest your recent article validating multiple SARS-CoV-2 antibody assays in hospitalized patients.[1] In that paper, Tuaillon et al. tested six point-of-care tests and three commercial ELISA's for the detection of SARS-CoV-2 antibodies. They found that nearly all assays were negative in the first week since PCR testing, but sensitivity improved over time, with the best assays having a sensitivity of up to 90% by day 15.

In this letter, we present data on the Abbott Architect SARS-CoV-2 IgG assay performed on both hospitalized and non-hospitalized patients. This assay is now widely used and runs on the commercial Architect platform, allowing automated high volume testing. PHE evaluated the Abbott SARS-CoV-2 IgG antibody test based on testing 96 COVID-19 patient samples and 760 presumed negative samples. They found a sensitivity of 93.9% (95%CI 86.3–98.0), and specificity of 100.00% (95% CI 95.9–100.0) by 14 days post symptom onset.[2] Of note, all patients who tested negative in that cohort were those with mild, non-hospitalised disease.

For our study, we tested patients from three groups: patients with laboratory confirmed or clinically suspected COVID-19 enrolled into our HRA-approved DISCOVER study ($n = 167$),[3] healthcare workers at North Bristol NHS Trust with laboratory confirmed COVID-19 ($n = 166$), and pre-pandemic respiratory infection controls ($n = 20$). All testing was performed according to the manufacturer's instructions on EDTA plasma (either fresh or stored at −80 C). For the DISCOVER cohort, patients with confirmed (PCR+) and suspected (PCR-) COVID-19 were prospectively recruited and samples were taken on admission. Time was calculated from reported symptom onset date. Some patients were followed up in clinic and had serial plasma samples collected. For the healthcare worker cohort, testing was performed as part of NHS England's strategy for healthcare worker antibody testing. We included all healthcare worker who had received a positive PCR for SARS-CoV-2 at the PHE South West regional virology laboratory and went on to have antibody testing. Timing was calculated from the time of the positive PCR test. At the time of this study, PCR healthcare worker screening was not in place and therefore all positive PCR tests among healthcare worker were assumed to be due to symptomatic disease. As far as we are aware, less than 5 healthcare workers were admitted during this time, so this can be described as a cohort of 'mild' COVID-19.

For the controls, 20 pre-pandemic plasma samples of patients with respiratory infection were extracted from an established tissue bank (the Pleural Investigation Database).

In total, 263 individual tests were performed, on 241 individuals. Assay sensitivity is shown in Table 1 for the three separate cohorts. There was a marked difference in performance between hospitalised patients and healthcare workers. For confirmed PCR+ cases, all antibody tests performed at >20 days were positive, whereas for healthcare workers 17 out of 114 tests performed at this timepoint were negative.

The hospitalised patients (DISCOVER) had a median age of 58, and comorbidities were common, with hypertension in 44 (27%), prior heart disease in 43 (26%), and prior lung disease in 42 (25%). 13 patients (8%) went to intensive care, while 15 patients (9%) died. 35 patients were suspected (PCR-) and 114 confirmed (PCR+). Of note, the time and rate seroconversion was not significantly different between suspected and confirmed cases, as demonstrated in Fig. 1. The median date of seroconversion of PCR+ cases was 13 days (IQR 12–15). For the PCR+ cases, all samples ($n = 26$) taken >20 days post symptom onset were positive.

In the healthcare workers testing cohort, 97 of 114 healthcare workers (85.%) who had positive PCR results subsequently went on to have a positive antibody test. The median time to test was 45 days (range 32–51 days), and all 17 negative antibody tests were obtained with samples taken 32–60 days after the first positive PCR result whereas antibody positive samples were collected 21–64 days after the first positive PCR result. All ($n = 20$) pre-pandemic controls were negative. This corresponds to a specificity of 100% (83.9–100%).

Our results describe real world performance of the Abbott Architect SARS-CoV-2 IgG assay. There was a significant difference in timing and overall rate of seroconversion between healthcare workers, who had predominantly mild disease and hospitalised cases, with all hospitalised patients with PCR confirmed COVID-19 tested after 20 days having a positive test, but only 83% of symptomatic healthcare workers having a positive result at this point. Interestingly, seroconversion dynamics seemed similar in PCR negative and PCR positive cases, suggesting clinical diagnosis is accurate for COVID-19.

These results are similar to the more conservative estimates reported in the literature,[4–7] and suggest the assay is less sensitive than the manufacturer reports and the PHE validation. This may reflect the differential antibody response in hospitalised patients, with only one paper definitively including 46 non-hospitalised patients, with the sensitivity in that paper being similar to ours (84.6%, 95% 73.6–92.4%).

In summary, the sensitivity of the Abbot Architect SARS-CoV-2 IgG assay increases over time, with sensitivity not peaking until 20 days post symptoms. Performance varied markedly by setting, with sensitivity significantly worse in symptomatic healthcare workers than in the hospitalised cohort. Clinicians, policymakers, and patients should be aware of the reduced sensitivity in this setting.

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Table 1.
Sensitivity across all three cohorts.

Cohort:	PCR+ hospitalised patients ($n = 114$)		PCR- hospitalised patients ($n = 35$)		Healthcare worker testing ($n = 114$)	
Days from onset:	*IgG+/total tested*	*Sensitivity (CI's)*	*IgG+/total tested*	*Sensitivity (CI's)*	*IgG+/total tested*	*Sensitivity (CI's)*
<5	5/10	44.4% (18.9–73.3%)	1/8	12.5% (2.2–47.1%)	n/a	n/a
5–9	14/43	32.6% (20.5–47.5%)	4/14	28.6% (11.7–54.6%)	n/a	n/a
10–14	15/23	65.2% (44.9–81.2%)	4/5	80% (37.6–96.4%)	n/a	n/a
15–20	8/12	66.7% (39.1–86.2%)	1/2	50% (9.5–90.5%)	n/a	n/a
>20	26/26	100% (86.2–100%)	5/6	83.3% (43.6–97.0%)	97/114	85.1% (77.4–90.5%).
>42	24/24	100% (87.1–100%)	5/6	83.3% (43.6–97.0%)	55/66	83.3% (72.6–90.4%)

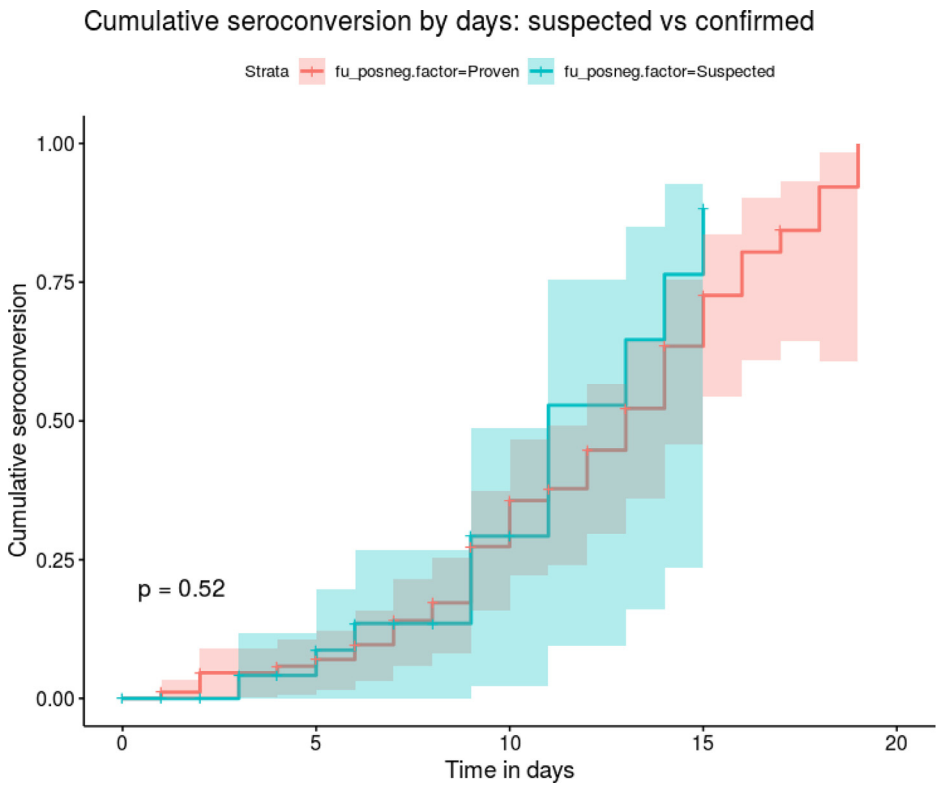

Fig. 1. Cumulative seroconversion by days: suspected vs confirmed.

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