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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Specificity and cross-reactivity of a test for anti-SARS-CoV-2 antibodies

Authors' reply

Kay Weng Choy raises several important issues about the point-of-care test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG and IgM antibodies from Livzon Diagnostics (Zhuhai, Guangdong, China), which we used for screening of health-care workers in Denmark.[1] The issues include risk of cross-reactivity against seasonal coronaviruses, other infections, and autoantibodies.

In our validation of the Livzon Diagnostics assay, sensitivity was 82·5% (95% CI 75·3–88·4) based on 155 patients with SARS-CoV-2 confirmed by PCR. Specificity reached 99·5% (95% CI 98·7–99·9). Validation of specificity was done on 651 archived plasma samples collected from blood donors during the winter of 2018–19—ie, before the first case of SARS-CoV-2 was reported. Samples from the winter season were chosen to ensure exposure to the highest possible natural prevalence of coronaviruses other than SARS-CoV-2, as well as of other viruses causing upper respiratory tract infections. As Sundell and colleagues[2] reported that up to 8% of asymptomatic individuals had positive PCR for respiratory virus, it is reasonable to assume an even higher prevalence of antibodies during the winter season. We have no reason to believe that the specificity was lower in the participating health-care workers.

The potential effect of cross-reactivity with autoantibodies present in the samples from patients with an autoimmune disease was assessed using plasma samples from 151 participants with an autoimmune disease. These samples were also obtained before December, 2019. Two inconclusive sample tests (one IgG and one IgM) were excluded from the analysis. In samples from the remaining 149 patients, two had false-positive test findings (one IgG and one IgM), corresponding to a specificity of 98·7% (95% CI 95·2–99·6)—ie, not substantially different from the specificity determined in blood donor samples. We did not validate the assay in immunodeficient patients with past infection with SARS-CoV-2, as we assume a low incidence of immunodeficiency in health-care workers.

We agree that the positive predictive value of the point-of-care test could be increased by doing a confirmatory test. We have stored blood samples from all participants in the study, and these are being analysed for antibodies using an ELISA from Wantai Biological Pharmacy Enterprise (Beijing, China). We have validated this test and found a sensitivity of 96·7% (95% CI 92·4–98·6) and a specificity of 99·5% (95% CI 98·7–99·8).[3] Results from this part of the study will be reported upon completion of the analyses.

We declare no competing interests.

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2 Sundell N, Andersson LM, Brittain-Long R, et al. PCR detection of respiratory pathogens in asymptomatic and symptomatic adults. *J Clin Microbiol* 2019; **57:** e00716–18.

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