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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Another false-positive problem for a SARS-CoV-2 antigen test in Japan

To the Editor,

A recent article in your journal states that the antigen test for SARS-CoV-2 is insufficiently sensitive and of little clinical significance [1]. The ongoing use of the quantitative antigen test in Japan since June 2020 is increasingly causing serious clinical problems because of its high incidence of false positives.

The quantitative antigen test Lumipulse G SARS-CoV-2 Ag (Fujirebio, Tokyo, Japan) has a 91.7 % (22/24 cases) and 97.3 % (293/301 cases) positive and negative concordance rate compared with RT-PCR, respectively. Eight of the 30 antigen-positive patients were reported to have negative RT-PCR results. [2]. Although it is true that the sensitivity of RT-PCR for SARS-CoV-2 is insufficient [3], RT-PCR is the current golden standard in clinical practice. Therefore, although difficult to accurately evaluate, some false-positive results can be expected with this antigen test. In addition, because the Japanese MHLW permits definitive diagnosis of COVID-19 without PCR if the antigen test is positive [4], concerns arise about the potential for false-positive patients to be admitted to the same medical room as patients with a true COVID-19 diagnosis.

A patient with a false-positive result for COVID-19 was recently admitted to our facility. The patient was a 96-year-old woman who tested positive on the Lumipulse G SARS-CoV-2 Ag, had a general malaise, and had no abnormal lung shading on chest computed tomography. However, in accordance with MHLW policy, the local health authorities recognized her as a confirmed COVID-19 case. Furthermore, because all COVID-19 cases in Japan require hospitalization, the patient was admitted to our hospital. We considered the possibility of false-positive result for this patient and decided to admit her to a private room isolated from true COVID-19 cases. After two subsequent RT-PCR tests performed more than 24 hours apart were negative, we determined that the patient's condition was not COVID-19, and we discharged her. If instead—with no suspicion of a false-positive result—had the patient been admitted to the same room as a true COVID-19 patient, then she could have been at risk for a nosocomial infection.

Because Lumipulse G SARS-CoV-2 Ag is a quantitative test, raising the cutoff value could prevent the occurrence of false positives. If the cutoff were raised to 100 pg/mL of antigen volume, the results would be 38.7 % (12/31cases) with a positive concordance rate and 99.6 % (293/294 cases) with a negative concordance rate, resulting in 1 RT-PCR negative result for 13 positive antigen tests, meaning fewer false positives [2]. However, the sensitivity of the test would be significantly lower. The use of antigen tests in Japan that are prone to false positives, coupled with the current MHLW policy, is creating a situation in which false-positive patients who are not infected with SARS-CoV-2 are at risk of nosocomial infection. Since Fujirebio has initiated the clinical trial to gain U.S. Food and Drug Administration approval [5], this test will be used outside of Japan. Because the characteristics of antigen tests vary among products, we believe it is important to fully understand their use.

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Declaration of Competing Interest

The authors report no declarations of interest.

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