

A rapid antigen test for SARS-CoV-2 in saliva

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The Lumipulse G600II instrument (left) and the Lumipulse SARS-CoV-2 Ag kit (right), both manufactured by Fujirebio, which were used in this study for the quantification of SARS-CoV-2 in saliva samples. Credit: Shinichi Fujisawa

Scientists from Hokkaido University have shown that an antigen-based test for quantifying SARS-CoV-2 in saliva samples is simple, rapid, and more conducive for mass-screening.

More than a year into the COVID-19 pandemic, the RT-PCR test remains the gold standard for detection of the SARS-CoV-2 virus. This method requires trained personnel at every step, from collection of nasopharyngeal swab (NPS) samples to interpretation of the results; in addition, the entire process ranges from 24-48 hours on average. As the virus can be transmitted by an infected person before symptoms develop, and is even transmitted by individuals who are asymptomatic, the ability to screen a large number of people quickly is vital to controlling and preventing the spread of the pandemic. Faster methods to detect the SARS-CoV-2 antigens have been developed, but they are not as sensitive as the RT-PCR test. In June 2020, a novel antigenbased kit, Lumipulse SARS-CoV-2 Ag kit (Lumipulse), was developed by Fujirebio to quantitatively measure the viral antigen in biological samples within 35 minutes.

A team of scientists from Hokkaido University have used the antigen kit to detect SARS-CoV-2 in saliva samples, and have assessed the efficiency and accuracy of the test compared to RT-PCR. Their findings show that the antigen detection kit, which is used to perform chemiluminescent enzyme immunoassay (CLEIA), can rapidly detect SARS-CoV-2 with good accuracy in these samples. The study was published in the journal *The Lancet Microbe*.



The CLEIA test (y-axis) for SARS-CoV-2 correlates well with the RT-PCR test (x-axis). Orange circles indicate symptomatic cases and blue crosses indicate asymptomatic cases. Credit: Isao Yokota, et al. The Lancet Microbe. May 19, 2021

The scientists tested 2056 individuals from three cohorts: patients with clinically confirmed COVID-19, individuals who had contacted patients with COVID-19, and individuals tested on arrival at Tokyo and Kansai International Airports. Saliva samples were collected from all individuals and used for RT-PCR tests as well as CLEIA using



Lumipulse. The results of both were compared to determine the usefulness of CLEIA.

The scientists found that CLEIA is a reliable test, as it correlates well with RT-PCR. CLEIA alone can be used to detect SARS-CoV-2 within an hour; however, using CLEIA for screening and RT-PCR for confirmation increases the accuracy of diagnosis.

The benefit of using saliva samples is the ease of collection: it is quick and can be collected by the individuals being tested, reducing the risk that <u>healthcare workers</u> are exposed to the virus. Furthermore, self-collection of <u>saliva</u> allows multiple samples to be collected simultaneously for expeditious screening of visitors at large gatherings.

Combined CLEIA and RT-PCR testing on <u>saliva</u> <u>samples</u> has already been implemented at Japanese airport quarantines, and the authors recommend adopting it at a wider scale to rapidly screen for SARS-CoV-2.

More information: Isao Yokota et al, A novel strategy for SARS-CoV-2 mass screening with quantitative antigen testing of saliva: a diagnostic accuracy study, *The Lancet Microbe* (2021). DOI: 10.1016/S2666-5247(21)00092-6

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