New rapid test to detect coronavirus antibodies developed

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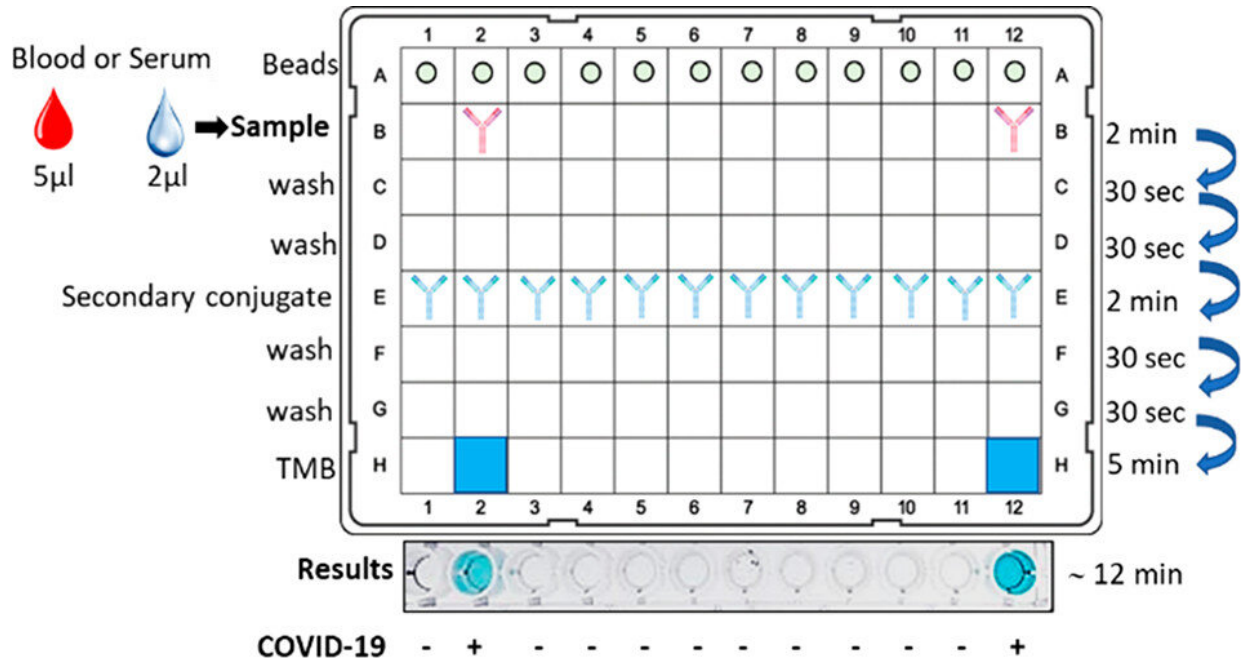

An international research team involving the universities of Paraná (Brazil) and Tübingen (Germany) has developed a rapid test that can reliably identify COVID-19 antibodies in the blood within minutes. As the researchers report in the journal *ACS Sensors*, the new process is based on a simple measuring principle making it easy to carry out without expensive instruments, and is therefore suitable for use at

mobile testing centers or by laboratories in less economically developed regions. The new diagnostic method is also far faster than the enzyme linked immunosorbent assay (ELISA) procedure, which for decades has been seen as the gold standard for laboratory diagnosis of antibodies.

"Only a small sample is needed for the test: a single drop that contains two microliters of serum is sufficient," says the lead author of the study, Professor Luciano F. Huergo from the University of Paraná: "It's also possible to use whole blood, in other words the separation of soluble blood components that is normally necessary can be omitted." So, the test can be used on site at care homes and testing centers. "It isn't absolutely necessary to have a fully-equipped laboratory or use special equipment to carry it out." In addition, the total response time is 15 times shorter than that of the classic ELISA test, as Huergo explains: "It means hundreds of samples can be tested in just a few hours."

The new test is based on magnetic nanoparticles that are coated with viral antigens. To conduct the test blood serum or blood is applied to the test surface. After roughly two minutes the nanoparticles are washed and treated with a developer reagent. If the blood sample displays antibodies to coronavirus, a color change occurs. While the traditional ELISA test produces results after about three hours, study results show that the new method only takes twelve minutes.

Potentially useful for those who are acutely ill or recovered

Antibodies to the SARS-CoV-2 coronavirus generally form eleven to 16 days after symptoms occur. However, some patients produce detectable concentrations of antibodies as early as two to four days after the first symptoms of the disease. Therefore, immunological tests can function as additional tools to identify patients in the acute phase of COVID-19 or

patients who receive a false negative from a PCR test.

"In particular for samples with low antibody titers, our test came off better than the ELISA procedure," says Professor Karl Forchhammer from the Interfaculty Institute for Microbiology and Infection Medicine (IMIT) of the University of Tübingen. "The method worked with a sensitivity of 87 percent and a specificity of 99 percent of the tested COVID-19 samples." Positive and negative results can be established simply with the naked eye, and by using additional instruments, such as a microplate reader, the precision of the test can be further increased. "Another advantage over the ELISA procedure is that the color result of our new procedure is directly proportional to the concentration of antibodies," says Huergo. "In other words, the new method delivers data on the quantity of antibodies and not just whether any are present."

In addition, the study shows that the new technology can also be applied to the serological diagnosis of other diseases. Professor Huergo says that the new procedure has the potential to replace the ELISA test, which has been in use since the 1970s: "We believe this technology represents a milestone in the development of immunological diagnostics." There are no reports in the research literature on an immunology test for COVID-19 that delivers data as quickly, as precisely and above all as cheaply.

The study authors assume that in future it will be possible to offer the new test at a comparable price to the ELISA test. "The test only requires minimal instrumentation in all production phases and will now be evaluated with a larger number of samples and for mass production, and we believe that our fast and quantitative method for detecting SARS-CoV-2 antibodies can help to track cases of COVID-19, especially in developing countries like Brazil, who do not have the luxury of doing regular PCR-based tests, at point of care units," says Dr. Khaled Selim, head of the German team at the University of Tübingen. The technology

is available to research, development and innovation partners via the innovation agency of the University of Paraná, which holds the statutory and patent rights.

More information: Luciano F. Huergo et al. Magnetic Bead-Based Immunoassay Allows Rapid, Inexpensive, and Quantitative Detection of Human SARS-CoV-2 Antibodies, *ACS Sensors* (2021). DOI: 10.1021/acssensors.0c02544

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