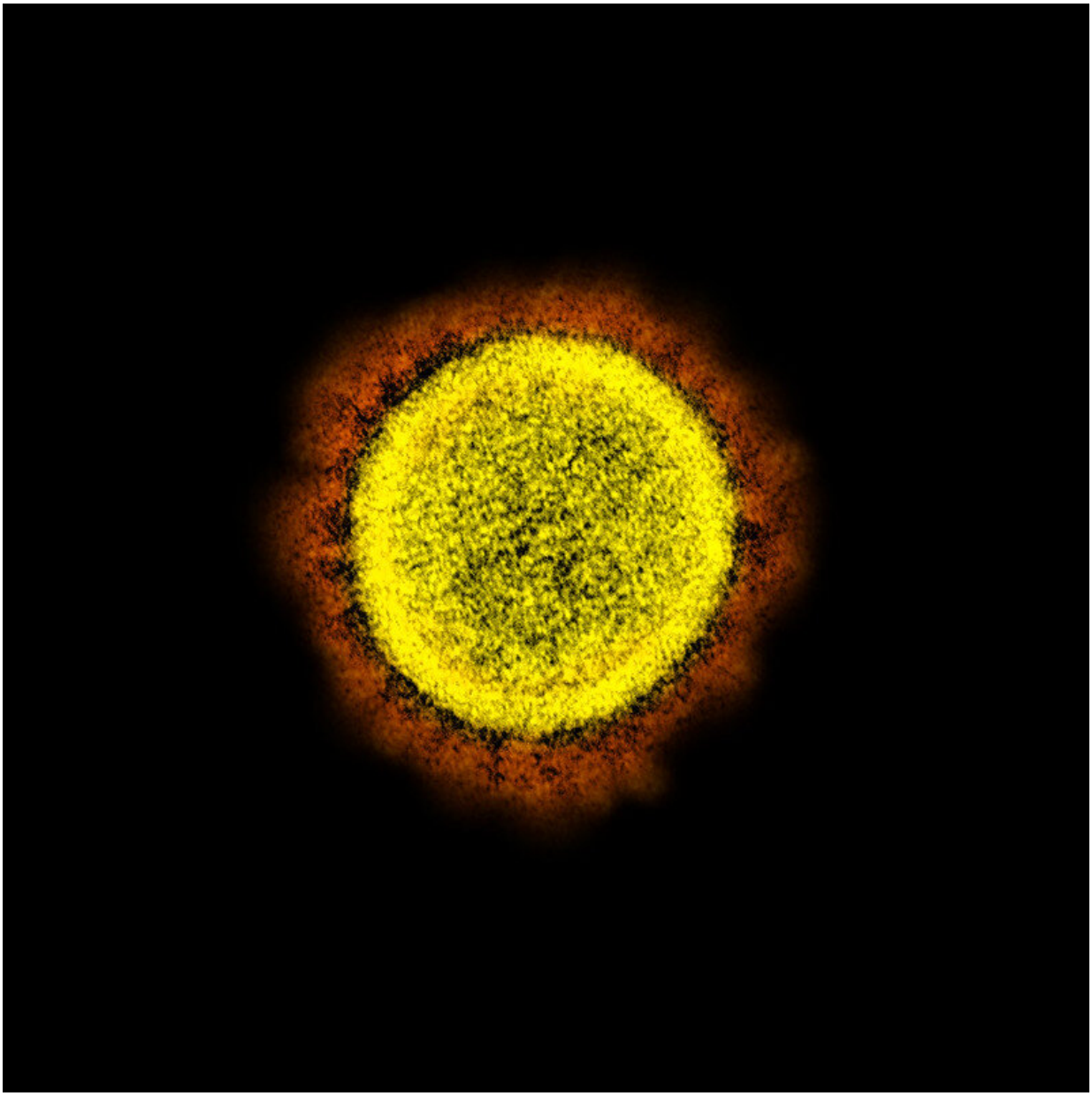
Team develops a rapid test to measure immunity to SARS-CoV-2

June 13 2022



Novel Coronavirus SARS-CoV-2 Transmission electron micrograph of SARS-CoV-2 virus particles, isolated from a patient. Image captured and color-enhanced at the NIAID Integrated Research Facility (IRF) in Fort Detrick, Maryland. Credit: National Institute of Allergy and Infectious Diseases, NIH

Mount Sinai researchers have developed a rapid blood assay that measures the magnitude and duration of someone's immunity to SARS-CoV-2, the virus that causes COVID-19. This test will allow large-scale monitoring of the population's immunity and the effectiveness of current vaccines to help design revaccination strategies for vulnerable immunosuppressed individuals, according to a study published in *Nature Biotechnology* in June.

The test takes less than 24 hours to perform and is scalable to use broadly in the population. It measures the activation of T cells, which are part of our adaptive immune response to SARS-CoV-2 infection or vaccination and help protect against severe disease outcomes or death.

"The assay we have created has the ability to measure the population's cellular immunity and broadly test the efficacy of novel vaccines," said one of the study's senior authors, Ernesto Guccione, Ph.D., Professor of Oncological Sciences, and Pharmacological Sciences, at The Tisch Cancer Institute at Mount Sinai. "We know that vulnerable populations don't always mount an antibody response, so measuring T cell activation is critical to assess the full extent of a person's immunity. Additionally, the emergence of SARS-CoV-2 variants like Omicron, which evade most of the neutralizing ability of antibodies, points to the need for assays that can measure T cells, which are more effective against emerging variants of concern."

Long-term protection from viral infection is mediated by both antibodies

and T cell response. Many recent studies point to the importance of determining T cell function in individuals who have recovered from or been vaccinated against COVID-19 to help design vaccination campaigns. However, before this study, measurement of T cell responses has been rarely performed because of the associated technical challenges .

In conducting this study, Mount Sinai researchers and partners at Duke-NUS Medical School optimized qPCR-based assays that had the potential to be globally scalable, sensitive, and accurate tests. Researchers narrowed their focus to the two assays that offered the most scalability. One, the qTACT assay, was accurate and sensitive but had a relatively longer processing time of 24 hours per 200 blood samples, a moderate price, and a medium level of technical skill. The other, the dqTACT assay, was accurate and had a reduced processing time and cost, and required minimal lab experience, making it easy to implement.

The dqTACT assay has recently been granted the European CE-IVD (*in vitro* diagnostics) certification, while U.S. Food and Drug Administration and European Medicines Agency clinical validation is ongoing.

"The assays presented here are based on the ability of SARS-CoV-2 T cells to respond to peptides covering different proteins of the virus," said another senior author, Jordi Ochando, Ph.D., Assistant Professor of Oncological Sciences at the Tisch Cancer Institute at Mount Sinai and Assistant Professor of Medicine (Nephrology), and Pathology, Molecular, and Cell-Based Medicine at the Icahn School of Medicine at Mount Sinai. "With the possibility of using different peptide pools, our approach represents a flexible strategy that can be easily implemented to detect the presence of T cells responding to different viral proteins. These T cells have an important role in protection from emerging mutant strains, thus immediately gauging the impact that viral mutations might

have on cellular immunity."

Megan Schwarz, a graduate student at Icahn Mount Sinai and first author of the study, added, "Precise measurement of cellular responses underlying virus protection represents a crucial parameter of our levels of immune defense."

This new study was conducted using laboratory diagnostic services of Synlab and Hyris System, Hyris' signature qPCR technology.

More information: Antonio Bertoletti, Rapid, scalable assessment of SARS-CoV-2 cellular immunity by whole-blood PCR, *Nature Biotechnology* (2022). DOI: 10.1038/s41587-022-01347-6. www.nature.com/articles/s41587-022-01347-6

Provided by The Mount Sinai Hospital