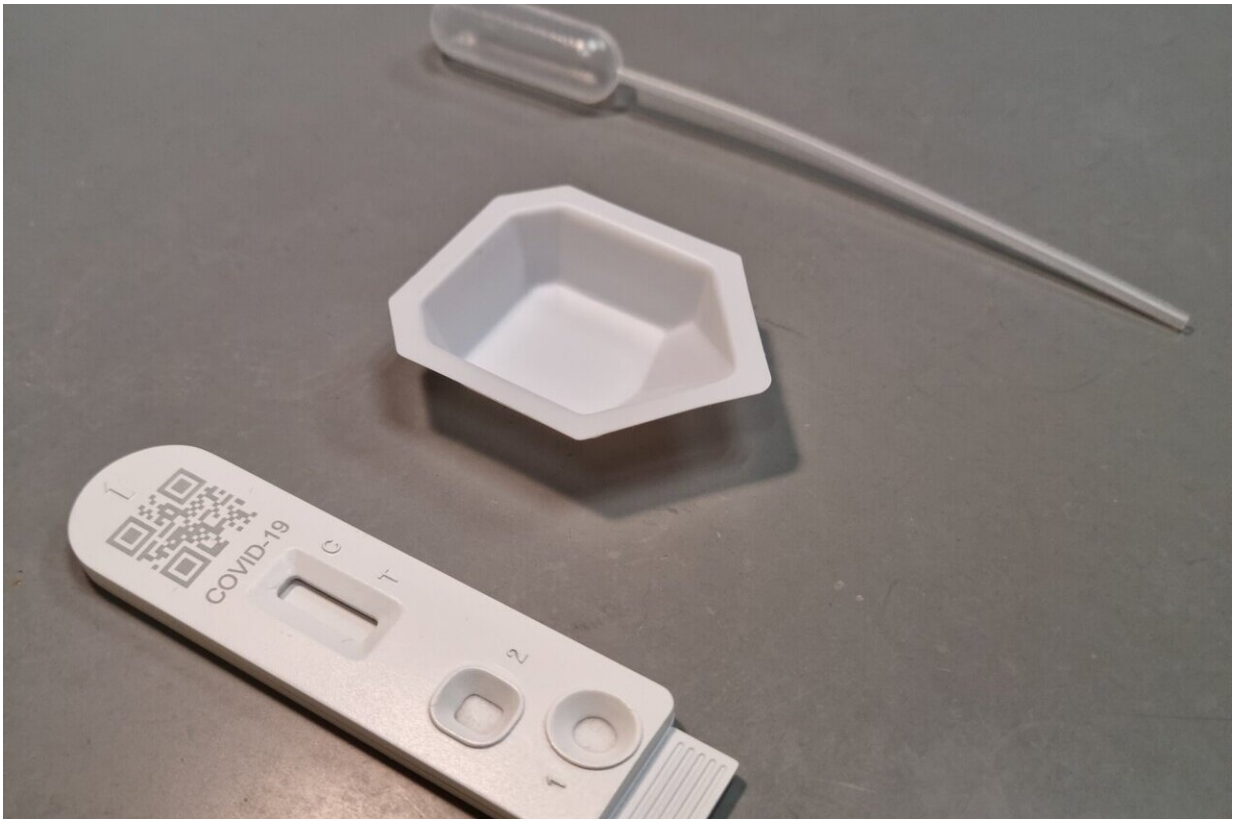
Breakthrough COVID-19 saliva amplified antigen rapid test is as sensitive as PCR test

December 8 2021, by Federico Graciano



PASPORT, a new saliva-based COVID-19 ART test, is easy to self-administer, deliver results in minutes, and has sensitivity close to the gold standard PCR test. Credit: Duke-NUS Medical School

A potentially game-changing antigen rapid test (ART) technology to diagnose COVID-19 has been developed by scientists in Singapore.

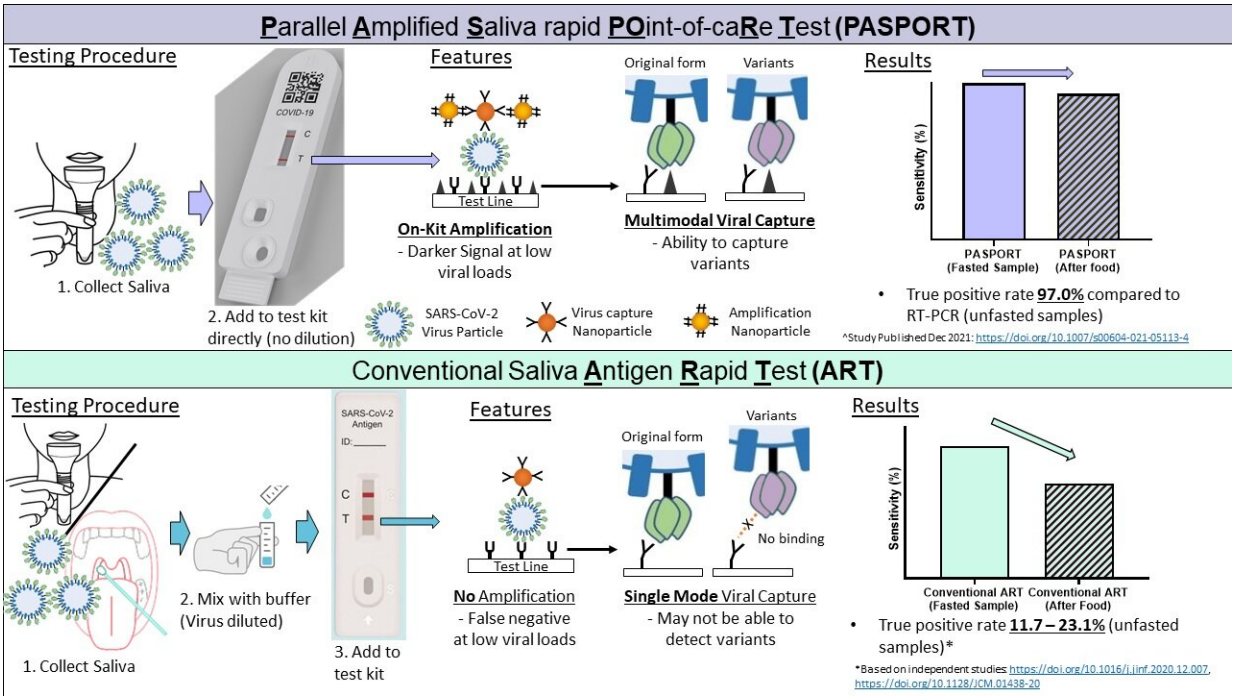
Using a proprietary on-kit amplification technique, a person's saliva can be self-administered or tested for the SARS-CoV-2 virus at the point-of-care with sensitivity higher than current ART tests and close to that of laboratory-based polymerase chain reaction (PCR) tests.

Dubbed the Parallel Amplified Saliva rapid POint-of-caRe Test (PASPORT), the technology produces results in minutes, without the need for additional equipment or specially-trained personnel. The invention was borne out of a research collaboration between Duke-NUS Medical School, Singapore General Hospital (SGH) and National Cancer Centre Singapore (NCCS)—collectively member institutes of the SingHealth Duke-NUS Academic Medical Centre—and the National University of Singapore (NUS).

With the impending availability of oral antiviral drugs against SARS-CoV-2, COVID-19 could potentially be diagnosed and treated in the primary care setting in the future. A test that can be done on-site will enable doctors to diagnose COVID-19 accurately and prescribe the drugs appropriately. Moreover, with its anticipated low cost and ease of use as compared to PCR tests, PASPORT could aid Singapore and countries around the world in making early diagnosis of COVID-19 to initiate appropriate case management. The research was published online on Monday, 6 December, 2021, in the journal *Microchimica Acta* as a feature article in their series, 'From Bench to Hand'.

"Testing is an indispensable tool in the management of COVID-19 cases. Although PCR has been the gold standard, it requires trained personnel and laboratory infrastructure," said lead inventor Dr. Danny Jian Hang Tng, Medical Officer at the Department of Infectious Diseases, SGH, and an adjunct Research Fellow at Duke-NUS' Emerging Infectious Diseases (EID) Programme. Dr. Tng, who graduated from Duke-NUS in 2019, added, "A reliable and painless saliva antigen test that is affordable and convenient to perform would encourage more to be

tested, and more frequent testing. This may enable us to manage COVID-19 more effectively not only at the point of care, but also in settings such as airports, conventions and even at home."



Comparison between how PASPORT and a conventional saliva-based ART processes samples. Credit: Duke-NUS Medical School

Unlike tests that use nasal or throat swabs, saliva-based tests are convenient and are more easily self-administered. But, until now, saliva tests for detecting SARS-CoV-2 have not been considered reliable enough to roll out at large scale. This is because the concentration of viral particles in saliva drops steeply after an individual eats or drinks. As a result, saliva antigen tests are usually only reliable when they are performed first thing in the morning, after an overnight fast and before breakfast or brushing teeth. This makes testing of saliva samples at other

times of the day less reliable.

The researchers remedied this by using a two-stage process. Like other ARTs, PASPORT uses nanoparticles to bind the virus. But uniquely, it also adds a second type of nanoparticle that binds the first set of nanoparticles to amplify the signal. This makes testing using PASPORT more sensitive at finding and flagging the virus, and allows it to be used at any time of the day—its sensitivity is not compromised even after eating or drinking. Compared to other amplification techniques, PASPORT is able achieve detection even at much lower viral loads, enabling it to be extremely sensitive. In a clinical study involving over 100 participants conducted at SGH, PASPORT's sensitivity in detecting the virus was 97 percent and its specificity, 90.6 percent, compared to the gold standard PCR test.

Professor Ooi Eng Eong, from the Duke-NUS EID Programme, who is one of the senior co-inventors, said, "Like COVID-19 vaccines, the availability of oral anitiviral drugs will be another game changer in our fight against COVID-19. But these drugs will need to be given as early as possible after illness onset for maximal benefit. A test that can be self-administered or used on-site at the primary care setting may mitigate the need for cases to be managed at the hospitals."

Professor Soo Khee Chee, Benjamin Sheares Professor in Academic Medicine at the SingHealth Duke-NUS Oncology Academic Clinical Programme, a Senior Advisor to Duke-NUS, and a senior co-inventor, said, "Our invention ticks all the boxes for an ideal rapid test: ease of collection of saliva; highly accurate with very low false negative results, making it an invaluable screening tool; and can be done at any time of the day, making it possible to be used at point of care, with reliable authentication. With this, we hope that more people will do the test as a personal act of social responsibility before engaging, especially, in large-scale events or gatherings."

Duke-NUS and SingHealth have filed intellectual property protection for the invention, and have entered into a license agreement with Digital Life Line Pte Ltd, a Singapore-based company. The inventors hope that through close collaboration with commercial partners, the product can be out in the market as soon as possible to serve healthcare needs in Singapore and beyond.

More information: Danny Jian Hang Tng et al, Amplified parallel antigen rapid test for point-of-care salivary detection of SARS-CoV-2 with improved sensitivity, *Microchimica Acta* (2021). DOI: 10.1007/s00604-021-05113-4

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