Scientists developing low-cost, saliva-based COVID-19 test inspired by glucose test strips for diabetes

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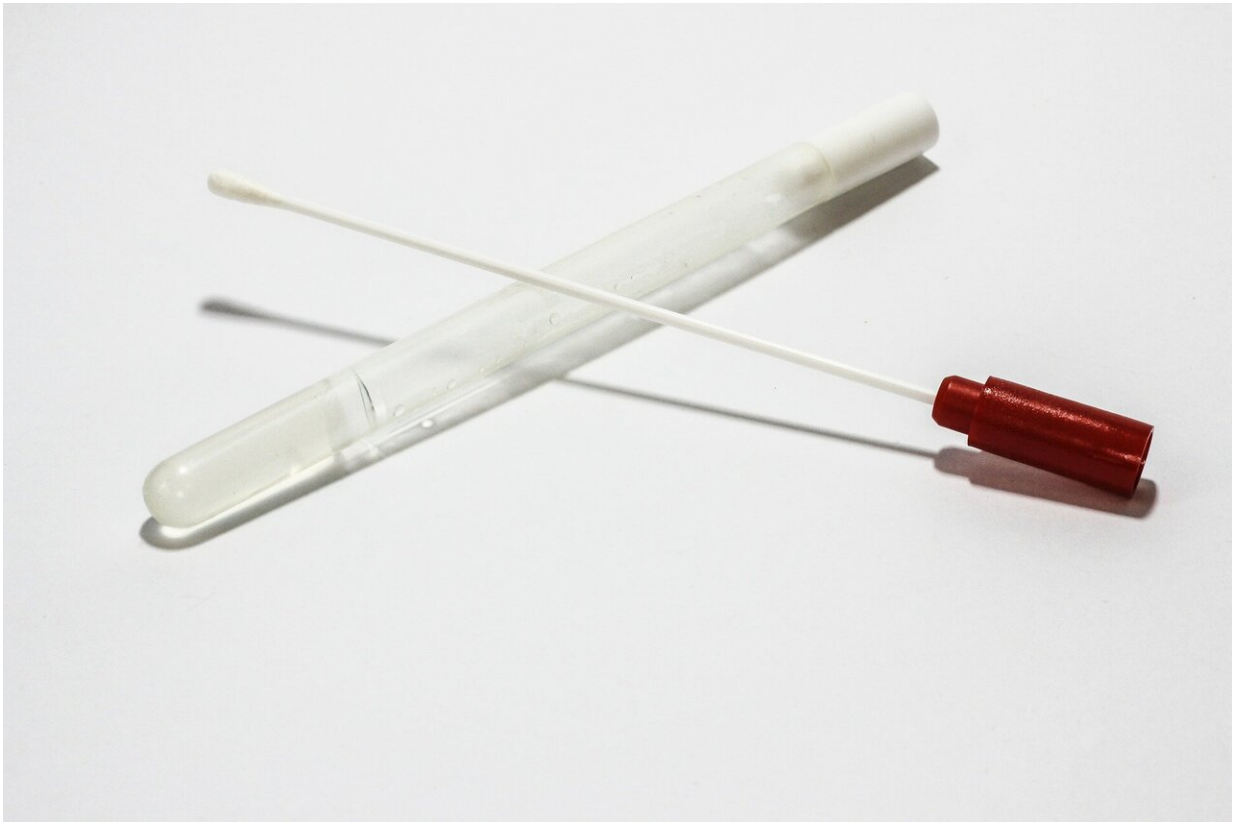

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Researchers are developing a rapid, low cost and mass manufacturable saliva-based biosensor test for COVID-19 inspired by the glucose test

strips used to check blood sugar levels in people with diabetes.

The team from the University of Strathclyde say that the test could eventually be mass manufactured for as little as 20 pence per test. It is designed for rapid in the field use, similar to a lateral flow test, to allow people in community settings to determine their COVID-19 status.

Saliva-based

When a person is self-testing, they would put saliva directly onto the test strip where the measurement is run by the instrument and the result produced on a display, avoiding the discomfort associated with nasopharyngeal swabs.

Compared to other diagnostic tests, glucose blood tests can already be manufactured at scale, with test strips and readers CE marked with regulatory approval for use in the management of diabetes. This means the route to producing a COVID-19 test based on the technology can be much quicker.

A paper published in Royal Society of Chemistry journal *Chemical Communications*, details how a special chemical treatment is applied to the sensor surface to produce the test, which uses the ACE2 enzyme—the receptor that coronavirus uses to bind on to cells—meaning clinically relevant detection levels of the virus can be achieved.

Working product

The team have patented the experimental technology, and using clinical samples provided by NHS Greater Glasgow & Clyde Biorepository will translate this proof of concept work into a working product.

It is being commercialised in the form of a spin out company called Aureum Diagnostics, supported by Norcliffe Capital, who will develop the test into a CE marked commercial product for real world use. The company is aiming to have a first version of the test for emergency use ready in 12 months and a fully CE marked test on the market in 18-24 months.

Lead investigator, Dr. Damion Corrigan from the department of Biomedical Engineering at Strathclyde, said:

"The test would provide a scalable route to sensitive, specific, rapid and low-cost testing for COVID-19, but in addition could serve as a low cost tool to rapidly diagnose other respiratory viruses and determine whether someone has COVID-19, flu or rhinovirus. This means it could enable screening of workers, at very low cost, for example in their place of work, identifying and isolating those with the disease and enabling those recovered to go back to work. "

"Initially, we will demonstrate this with COVID-19 and then commercialize the test so that we can work on using the underlying patent to produce new sensor technologies for other respiratory viruses and infectious diseases."

Diabetes strips

The team partnered with Lifescan in Inverness, one of the world's leading manufacturers of diabetes test strips.

Dr. Corrigan, added: "Very few other diagnostic technologies can compete in terms of cost and scale. By printing ACE2 onto the sensor, it means the strip is designed to selectively capture the coronavirus and also be mutation proof. The test should remain sensitive to different strains of the virus unlike tests based on polymerase chain reaction

(PCR) or antibody tests which only look for a small part of the viral material. "

Fifteen minutes

The experimental sensor was initially tested with inactivated virus samples at different concentrations, ranging from low to high, alongside negative samples from a commercially available molecular diagnostics standards kit. Hospital laboratory tests were then carried out on real patient samples provided by the NHS Greater Glasgow & Clyde Biorepository. The most recent set of experiments showed detection was possible in 15 minutes.

Dr. Michael Murphy, Consultant Microbiologist in the Department of Microbiology, at Glasgow Royal Infirmary, NHS Greater Glasgow & Clyde and co-investigator on the study, said: "COVID-19 has shone a massive spotlight on the need for rapid, affordable diagnostic tests produced at scale. There is a vital need to develop similar diagnostic tests for flu and other viral infections to help improve patient care, screen health care workers and reduce the risk of hospital acquired infections.

"At NHS Greater Glasgow & Clyde, we're working to prepare for future pandemics by working on innovative solutions to the challenges of rapid diagnostics."

Dr. Steve Setford, Director of Technology Development at LifeScan Scotland, said: "We have been pleased to have supported Dr. Corrigan and his team, with LifeScan drawing on its extensive experience of test-strip design, development and mass-manufacture to support development of the COVID-19 biosensor."

The team have also been working on transferring onto sensor substrates built by Livingston-based FlexMedical Solutions, which specializes in

the development and delivery of point of care diagnostic technologies, and which will eventually be CE marked.

Commercial promise

Kevin Fallon, FlexMedical Solutions CEO, said: "Dr. Corrigan and his team are developing a very capable electrochemical diagnostic which performs well technically whilst showing great commercial promise."

The project funding was awarded following a Rapid Research in COVID-19 call for research bids by the Chief Scientist Office on 25 March 2020, which saw 55 projects across Scottish universities share almost £5 million.

The Scottish Government awarded £649,993 to a total of five Strathclyde research projects which also focused on how to better understand the effects of infection, develop and test new treatments, investigate new disease surveillance approaches, inform interventions to prevent transmission of infection, support the mental health of frontline health and social care workers, and understand the physical and mental health implications of lockdown measures.

More information: Vincent J. Vezza et al, An electrochemical SARS-CoV-2 biosensor inspired by glucose test strip manufacturing processes, *Chemical Communications* (2021). DOI: 10.1039/D1CC00936B

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