

Exhalation Technology Announces Commercial Launch and Clinical Update on CoronaCheck - A Rapid Covid-19 Test

ETL has announced commercial launch and new results from a clinical study with its rapid (<5 mins) CoronaCheck diagnostic test for Covid-19 in exhaled breath.

CAMBRIDGE, UNITED KINGDOM, April 7, 2021 /EINPresswire.com/ -- Exhalation Technology (ETL), a Cambridge, UK-based company, announced updated results from its clinical study on humans with its novel, rapid (<5 minutes) CoronaCheck Point-of-Care diagnostic test for Covid-19 in exhaled breath condensate (EBC). ETL believes the CoronaCheck test will be the fastest and simplest Covid-19 test when it receives approval and achieves commercial launch.

ETL is advised by The Sage Group (www.sagehealthcare.com) who are seeking a global partner for CoronaCheck. Sage is an international transactional advisory firm in healthcare, based in US, Europe, China, Japan and India.

ETL announced that its CoronaCheck test will be CE marked in Europe by early May 2021 and also that it has applied to the US FDA for Emergency Use Authorisation (EUA). It hopes to gain this approval no later than end May 2021.

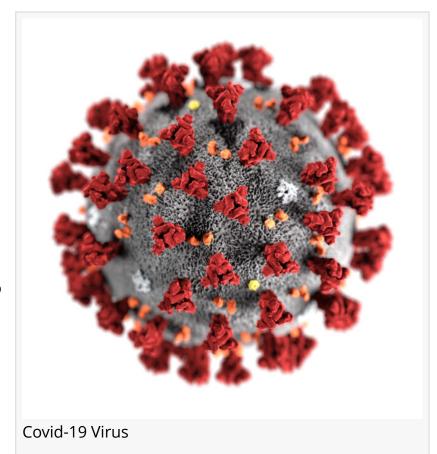
The CoronaCheck device for rapid Covid-19 testing is safe and easy to use

ETL has also announced that it has published an Instruction for Use video for the general public on YouTube at https://www.youtube.com/watch?v=X WsyBV7Csw. This video shows the simplicity of the CoronaCheck testing approach.

ETL have developed CoronaCheck, a rapid test specific for Covid-19 virus, exploiting their expertise in exhaled breath diagnostics. ETL has announced that is has now tested 134 patients to date, and CoronaCheck has detected with 99% specificity and 95% sensitivity those patients who are either positive or negative for Covid-19.

Within the Healthy Control cohort, CoronaCheck also detected Covid-19 in 14 asymptomatic humans in a blinded test which, like all of their trial results, was confirmed by "gold standard" rtPCR also to be positive. CoronaCheck also found 1 symptomatic patient who tested negative with CoronaCheck and was confirmed negative by rtPCR.

CoronaCheck uses electrochemical sensor detection for Covid-19 similar to that which has been employed for glucose testing in diabetic patients for more than 40 years, and is capable of mass production with an IP-protected approach. ETL have also announced that CoronaCheck is detecting all variants of the original Covid-19 virus which it has been able to test to date.



However, CoronaCheck does not detect any of the common respiratory viruses or bacteria associated with colds and seasonal flu.

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The novel Covid-19 sensor we have developed is highly sensitive and specific, able to deliver very reliable results in minutes and accurately detecting all known variants of the virus."

Helle Funch Nielsen

CoronaCheck is able to detect as few as 12 copies of virus on the sensor; infected patients are expected to exhale as much as 150 copies in the volumes being tested by CoronaCheck.

CoronaCheck is a rapid test (aims for a result in under 5 minutes) of high specificity and sensitivity for Covid-19, meeting the need for efficient and accurate testing in a wide range of environments including hospitals, care homes, airports, retail outlets, schools and similar spaces.

CoronaCheck has been developed in collaboration a leading virology laboratory in the UK and with Zimmer Peacock, a developer of electrochemical sensor technology based in the UK and Norway.

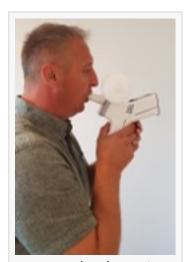
The ETL clinical trial program for CoronaCheck at the Clinic for Respiratory Medicine based in The Queen Alexandra Hospital, Portsmouth, is headed by professor Anoop Chauhan. This has enabled a cohort of up to 150 patients to be tested in an ethics-approved clinical trial on infected

and normal patients.

ETL have also announced it will initiate in April 2021 a large clinical study in Denmark comprising 400 symptomatic and 400 asymptomatic patients.

ETL is in discussion with several global strategic partners with which it can collaborate to exploit its new Covid-19 test.

ETL has developed CoronaCheck, a very unique and timely, IP-protected test for rapid detection of Severe Acute Respiratory Syndrome Corona Virus 2 (SARS-CoV-2 also known as Covid-19), using a novel biosensor housed in a safe breath analysis device suitable for rapid point-of-care coronavirus testing. The test measures directly the presence of virus in breath, as opposed to antibodies in the blood.



CoronaCheck Device for Covid-19 Testing using Exhaled Breath

CoronaCheck has safety features to prevent cross-infection and contamination, to measure the SARS-CoV-2 virus in exhaled breath.

Helle Funch Nielsen, CEO of ETL, said "Initial results from patients recruited into our clinical study at Portsmouth are highly impressive and encouraging, due to the very simple composition of exhaled breath condensate compared to other test environments such as blood, urine and saliva. The novel Covid-19 sensor we have developed with our partners Zimmer Peacock is proving highly sensitive and specific, able to deliver very reliable results in a matter of minutes and accurately detecting all known variants of the virus which we have been able to source."

Stig Lytke Brejl, Director of ETL, said "The successful trial of CoronaCheck has encouraged us to initiate a scaleup process which can take us eventually to 5 million tests per month, potentially more. Our partner discussions are encouraging in our search for one or more corporate entities who can work with us to scale up the technology and get the tests into the hands of a number of environments where reliable and rapid test results are badly needed.."

CoronaCheck does not require any laboratory equipment or special handling or training, and is likely to be CLIA-waived by FDA. The biosensor is mounted in a test cartridge which is inserted into the device into which the subject breathes with results obtained in minutes, whereupon the test cartridge is safely discarded and the device is ready for a new test cartridge and subject.

For more information about Exhalation Technology and partnering opportunities for its Covid-19 test, please contact:

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About Exhalation Technology

Exhalation Technology develops breath analysis devices for disease diagnosis, monitoring, and management. ETL aims to revolutionise respiratory care by providing clinicians the tools they need to provide optimal patient care.

In improving patient outcomes, we help clinicians meet the challenges and opportunities in an ever-evolving respiratory healthcare world and believe our CoronaCheck test will offer widespread testing capability at a low cost and on a very rapid timescale.

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