Exhalation Technology Updates on Groundbreaking Clinical Trial for CoronaCheck – A Rapid (<5 min) Covid-19 Breath Test

New clinical data on the CoronaCheck Covid-19 exhaled breath test shows absolute specificity and sensitivity in a test taking under 5 minutes at under $10.

CoronaCheck uses exhaled breath to screen for Covid-19

CAMBRIDGE, UNITED KINGDOM, January 4, 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 have developed CoronaCheck, a rapid test specific for Covid-19 virus, exploiting their expertise in exhaled breath diagnostics. ETL is pleased to announce that with 62 patients tested so far, CoronaCheck has detected with 100% specificity and 100% sensitivity those patients who are either positive or negative for Covid-19. Some patients in the cohort who tested positive for Covid-19 were asymptomatic.

CoronaCheck outcomes were verified by verification with an industry standard, albeit non-POC laboratory test using rtPCR, the Hologic Panther system. CoronaCheck uses electrochemical sensor detection similar to that employed for glucose testing in diabetic patients, and is capable of mass production with an IP-protected approach.

> “Results from patients in our clinical study are very promising with absolute specificity and sensitivity in all patients tested. CoronaCheck has great promise for point of care testing globally.”
>
> *Helle Funch Nielsen*

ETL have also announced that CoronaCheck has been tested successfully against an FDA-approved panel of pooled respiratory viruses and bacteria, including a number of recognised Coronavirus variants. CoronaCheck confirmed with 100% accuracy the pools containing all Coronavirus variants, and reported as negative those

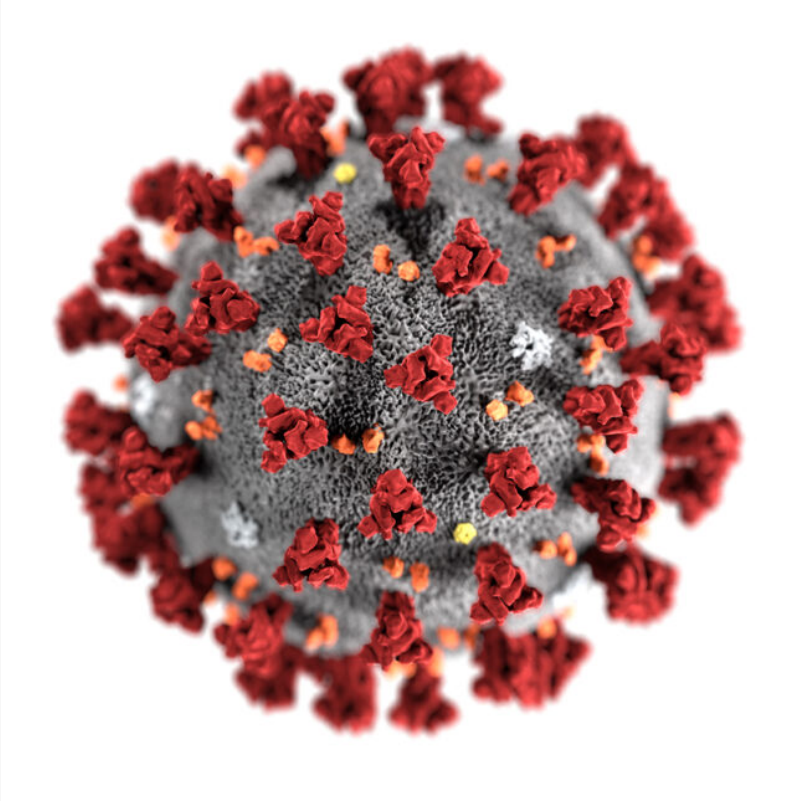
samples lacking Coronavirus but containing other standard respiratory viruses such as seasonal flu and other non-Corona respiratory viruses.

CoronaCheck is a rapid test (< 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.

ETL has initiated a process with the US FDA regulatory authorities to apply for Emergency Use Authorisation for CoronaCheck. The CoronaCheck test will be CE marked in Europe.

Before the initiation of clinical trials in the UK, CoronaCheck has shown very promising results on the laboratory bench in collaboration with Prof. Wendy Barclay in the Faculty of Medicine, Department of Infectious Disease at Imperial College, London:

- It is able to detect as few as <1.5 copies of virus per µl EBC; infected patients are expected to exhale as much as >20 copies per µl
- Test sensitivity is as great as 100% and specificity >90% at test time which aims to be under 5 minutes, yielding a rapid result at point of care
- CoronaCheck has been tested with live virus as well as in inactivated virus, and in controlled solutions as well as in "virus-spiked" Exhaled Breath Condensate (EBC)
- Tests with UV-inactivated influenza virus shows that CoronaCheck can distinguish between Covid-19 and other viruses such as



Covid-19 Virus

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

seasonal flu

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.

Exhalation Technology ("ETL") seeks a global strategic partner with which it can collaborate to exploit its new Covid-19 test. ETL has a strong history in development of diagnostic products based on analysis of the respiratory tract where Covid-19 is prevalent.

ETL has developed CoronaCheck, a very unique and timely, IP-protected test for rapid detection of Severe Acute Respiratory Syndrome CoronaVirus 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 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 are very promising with absolute specificity and sensitivity. Our CoronaCheck test is set to provide novel technology for high volume screening of individuals in a range of environments including schools, airports, shopping centers and sporting events, to name but a few. The technology is entirely innovative and our initial test is based on rapid testing in exhaled breath, a simple and convenient means of sample collection. Our collaboration with Imperial College in London and clinical centers in the UK such as the Clinic for Respiratory Medicine based in The Queen Alexandra Hospital, Portsmouth, is providing rapid proving and validation of this novel approach to Covid-19 testing."

Stig Lytke Brejl, Director of ETL, said "building on an existing CE marked IVD medical device platform has enabled a short time to market while at the same time de-risking the project significantly. Our search now is for a partner who can work with us to scale up the technology to provide potentially millions of tests per month globally."

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.

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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 – with confidence. By giving clinicians access to information related to underlying causes, ETL can strengthen their decision-making process – and create better outcomes for patients. Why? Because ETL believe monitoring and managing respiratory diseases should be simple and reliable – for everyone involved. ETL is committed to helping transform the way we diagnose, treat and monitor respiratory diseases. In improving patient outcomes, we help clinicians meet the challenges and opportunities in an ever-evolving respiratory healthcare world.

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