One COVID19 VIRUS RNA TESTING BY (RT-PCR)

DETECT *ACTIVE* INFECTIONS IN SALIVA AS WELL AS NP SWABS

SHIP SAMPLES AT ROOM TEMPERATURE

INTENDED USE

Our OneCOVID19 test is a real-time RT-PCR intended for the qualitative detection of viral RNA from the SARS-CoV-2 in respiratory samples from individuals suspected to have COVID-19 or who have been exposed to COVID-19. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of active infection with SARS-CoV-2 but do not rule out bacterial infection or coinfection with other viruses.

PROCESS

Register your account to order our COVID-19 specimen collection kit, the patient and drop the kit into a Fedex collection box. Results are available 24hrs after we receive the sample. Rush Service is available.

SPECIMEN COLLECTION IN SALIVA AND NP SWABS

Genomic Expression's Viral Transport Medium stabilizes the viral RNA for transportation at ambient temperatures. Proper collection of specimens is the most important step in the diagnosis of infectious diseases. A specimen that is not collected correctly may lead to false negative test results. The CDC standard recommended procedures can be accessed here:
https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

WHO SHOULD BE TESTED?

Clinicians can follow the CDC Guidelines on Evaluating and Testing Persons for Coronavirus Disease.

All patients whose specimens are tested with this assay should receive the Fact Sheet for Patients

RESULTS

A positive test result for COVID-19 indicates that RNA from SARSCoV-2 was detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

Genomic Expression's OneCOVID19 RT-PCR Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects. A negative test result for this test means that SARS-Cov-2 RNA was not present in the specimen above the limit of detection. However, negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Reporting

Genomic Expression must follow the standard testing and reporting guidelines according to appropriate public health authorities.

CDC webpages

https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html

FDA webpages

http://www.fda.gov/novelcoronavirus
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA).

COVID-19 PCR Test

based on CDC recommended guidelines identifies two known distinct regions within the genome of the virus that causes COVID-19 (SARS-CoV-2).

TAT

Within 1-2 days of sample receipt. We offer priority rush service and overnight shipping.

SENSITIVITY

100% at 6 copies/ul

SPECIFICITY

100% based on in silico analysis

FALSE POSITIVE RATE

1 out of +1 million

FALSE NEGATIVE RATE

1 out of +1 million

SAMPLE TYPES ACCEPTED

Upper and lower respiratory specimens eg:

- Nasal Swab
- Nasopharyngeal Swab
- Oropharyngeal Swab
- Saliva
- BALs
- Sputum
- Extracted RNA

FACT SHEET FOR PROVIDERS

http://bit.ly/COVID19FACT

FACT SHEET FOR PATIENTS

http://bit.ly/COVID194Patients

REGISTER AND ORDER KIT

covid19.genomicexpression.com

CONTACT

COVID19@genomicexpression.com

WEBSITE

genomicexpression.com/#covid-19

ADDRESS

Genomic Expression
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Partners

By analyzing RNA we can detect disease, monitor health and design next generation cures. Our data support that RNA outperforms DNA sequencing and enables truly individualized medicine.

Board of Directors
Dan Adams (exit of Protein Sciences to Sanofi for $750M),
Gitte Pedersen,
Morten Pedersen,
Kirsten Dinesen,
Melina Fan (observer Pipeline),
Kim Tennican (observer SWIF)

Boston Lab
Capacity of 5000 OneRNA® tests per year and 30,000 COVID-19 tests/month scaling to 1 million/week

Awards
- #2 Women's Founders
- Top 10 in XTC 2016
- Top 5 Molecular Tri-Conf
- Red Herring top 100
- Medtech top 50 innovator
- Won Lyfebulb award
- Won EIC Lifescience
- Won EUTop50
- Featured in Forbes
- Presented at GSTIC, UN and the European Parliament
- Semifinal of the XPRIZE
- Finals of GuideWell

Social media and website
www.genomicexpression.com
@dnabarcode (50,000 followers)

Company Video
http://bit.ly/GExVideo

OneRNA™ Video
http://bit.ly/OneRNAMovie

RNA DIAGNOSTIC COMPANY COVID-19 AND ONCOLOGY

OneRNA® - RNA Diagnostic Platform
Proprietary RNA sequencing technology that enables sequencing of real clinical samples and interpret the data clinically. Leveraging our RNA sequencing technology we can massively scale COVID-19 testing on the NextSeq platform, to a level enabling population screening in the XPRIZE semi-finals for rapid COVID19 testing.

Clinical Programs
4 funded clinical programs in oncology while moving COVID-19 to self collection in saliva.

Impact on COVID-19
We launched our PCR test under FDA EUA first and are leveraging our chemistry to enable massive scaling of testing to the level of population screening. PCR does not scale well. To produce 1 million test with the most automatic PCR platform requires a capital investment of $700M (COBIS by Roche).

Impact in oncology
Data from clinical programs indicate that OneRNA® could enable better outcome for most patients taking the OneRNA® test by identifying a handful of already approved drugs interrogating growth mechanism. Truly individualizing treatment by testing first and selecting treatment based on the OneRNA® data would disrupt standard of care in oncology which only prolongs life for 1 out of 4 cancer patients.

Vision for the future
We believe that we need to enable people to monitor and control health. Disease doesn't happen overnight and many chronic diseases can take a decade to develop. Often intervention is non-therapeutic during this time. Moving our OneRNA® platform into the liquid biopsy space provides a powerful platform to sustain health. Providing people control of their health is the only way we can reduce cost of care.

OneRNA® is portable outside oncology with an update to the cloud
Because OneRNA® is not using baits or panels, but uniquely identify and quantify +20,000 RNA's in ONE assay, it can keep pace with the rate of new discovery by updating the OneRNACloud® platform. That means that OneRNA® is portable outside oncology with an update to the actionable database making OneRNA® the most scalable platform in the market.

Background
Genomic Expression was the diagnostic partner in Denmark's first large sequence based project called "Genome Denmark". The project was funded by the Innovation Fund Denmark with $32 million. One of the objectives was to find novel oncovirus. The OneRNA® technology and vision was created as a result of this public private partnership. Access to historical samples in a single payer system enables us to develop various algorithms for any disease. We have subsequently received grants from Eurostars and Horizon2020 to validate OneRNA® in specific indications.

MANAGEMENT TEAM WITH PROVEN TRACK RECORD AND START-UP RNA

GITTE PEDERSEN
CEO is a former executive from Novo Nordisk, where she successfully developed and launched multiple products into multiple industries worldwide. She subsequently structured over $1B in pharma deals with Merck, Takeda, GSK, Wyeth and others and was an advisor the Danish Government.

MORTEN PEDERSEN
CSO, PhD is the inventor of our technologies with a very strong innovation track record inventor of novel sequencing sample prep and DNA technologies.

JESPER ZEUTHEN
CMO, PhD is the co-founder of GeneMap and DanDrit. He established the Danish Cancer Society and is a pioneer in immune oncology went to venture and came back to curing cancer.

BILL SOUTHWORTH
VP Data, MIT, creator of products. CEO and Vice President of Engineering and Marketing for public and private serial Entrepreneur companies. Coder at heart.

CHARLES SVITLIK
Adjunct Professor of Biology, Naugatuck Valley Community Technical College. 30 years of experience as virologist and clinical laboratory scientist.