30 Days from Genetics to Coronavirus: A Strange Journey

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SARS-CoV-2? Never heard if it (5 months ago)

• The Human Genetics Institute of New Jersey is a RU Research Institute on Busch campus in Piscataway

• Its members, all of whom are SAS faculty in the Division of Life Sciences, research diverse subjects ranging from cancer, kidney disease, fear, the evolution of limbs, genomics and neuropsychiatric disorders such as schizophrenia and Tourette disorder.

• RUCDR Infinite Biologics® is a Center within HGINJ
But RUCDR is a highly automated and programmable genomics laboratory.
RUCDR grant and contract research funding on the genetic bases of common diseases
And then we learned about Coronaviruses

- Coronaviruses are positive-strand RNA viruses with large genomes (≥27,000 bases).
- Both alpha and beta types cause disease in humans, account for 10-30% of cases of the common cold (Pubmed 31971553).
- Very stable for RNA viruses – CoV OC43 isolates from 1960s and 2001 had only 2 amino acid changes (Pubmed 15280490).
- Easily hops between species
  - MERS-CoV hopped from camels to humans
  - SARS-CoV hopped from bats to civets and humans
  - SARS-CoV-2 hopped from bats to humans
  - It seems humans with colds gave mice hepatitis, or vice versa

SARS-CoV-2 is 29,811 bases
SARS-CoV-2 Coronavirus

Electron microscope image
Hard work & teamwork develop novel saliva test for SARS-CoV-2

Assay development started in March: EUA approved April 10, Home collection approved May 7, 2020

Andrew Brooks, PhD, RUCDR COO and Professor of Genetics, SAS
ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
SARS-CoV-2 ASSAY
(Rutgers Clinical Genomics Laboratory)

For in vitro diagnostic use
Rx only

For use under Emergency Use Authorization (EUA) Only

(The Rutgers Clinical Genomics Laboratory TagPath SARS-CoV-2 Assay will be performed in the Rutgers Clinical Genomics Laboratory, a Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratory, per the Instructions for Use that were reviewed by the FDA under this EUA).

INTENDED USE
The Rutgers Clinical Genomics Laboratory TagPath SARS-CoV-2 Assay is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal swab, mid-turbinate nasal swab and saliva specimens from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to Rutgers Clinical Genomics Laboratory (RCGL) at RUCDR Infinite Biologies – Rutgers University, Piscataway, NJ, that is a Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratory.

Results are for the detection and identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

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.
FDA Approves First At-Home Saliva Collection Test for Coronavirus
How to use the saliva collection kit
SARS-CoV-2 (COVID-19) diagnostic assay

1. Extract viral RNA from saliva (Chemagic bead method) - 96 samples
   - Afterwards, robots move extracted samples to 384 well format
2. Reverse transcribe RNA into (stable) DNA
3. Add short DNA probes (oligonucleotide) and perform real time quantitative PCR (polymerase chain reaction)
   - The assay targets three specific genomic regions of the SARS-CoV-2 nucleocapsid (N) gene, spike (S) gene, and ORF1ab region.
4. Determine number of cycles (Ct value) for detection (or not)
   - A sample is considered positive for SARS-CoV-2 RNA if amplification is detected with at least two of the three SARS-CoV-2-specific target sequences.
PCR Basics
Advantages of the saliva test

• Sensitivity
• Home Collection
  • With or without telemedicine assistance
  • Does not require patient travel & potential exposure of others
• Huge reduction in risk to medical personnel
  • No virus exposure of healthcare workers if done at home
  • Obviates the need for PPE, a limiting resource
  • Requires far fewer healthcare workers
• Large numbers of tests can be done on any day
  • Testing lab capacity becomes the main issue
Caveats

• 1. Test must be prescribed by a healthcare provider

• 2. Healthcare provider must suspect COVID-19: Generally means patient must present with symptoms

• Interpretation: No test, including RUCDR test, is currently authorized for population screening of well individuals.
RUTGERS

IT WASN'T HARVARD OR YALE THAT CAME UP WITH A BETTER COVID TEST

IT WAS A PUBLIC UNIVERSITY FROM JERSEY