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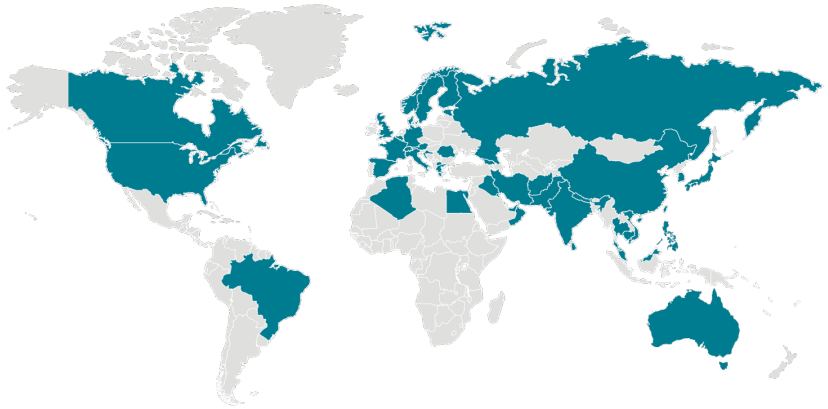
Novel Coronavirus SARS-CoV-2



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April 2, 2020

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Center *for*
Communicable
Disease Dynamics

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Testing

- Real Time PCR
- WHO endorses “Drosten” protocol
  - Targets 3 genes: E, RdRp, N
  - Utilized by much of the world
  - Hundreds of thousands of tests run with these primers now

Berlin, Jan 17th, 2020

Diagnostic detection of 2019-nCoV by real-time RT-PCR

-Protocol and preliminary evaluation as of Jan 17, 2020-

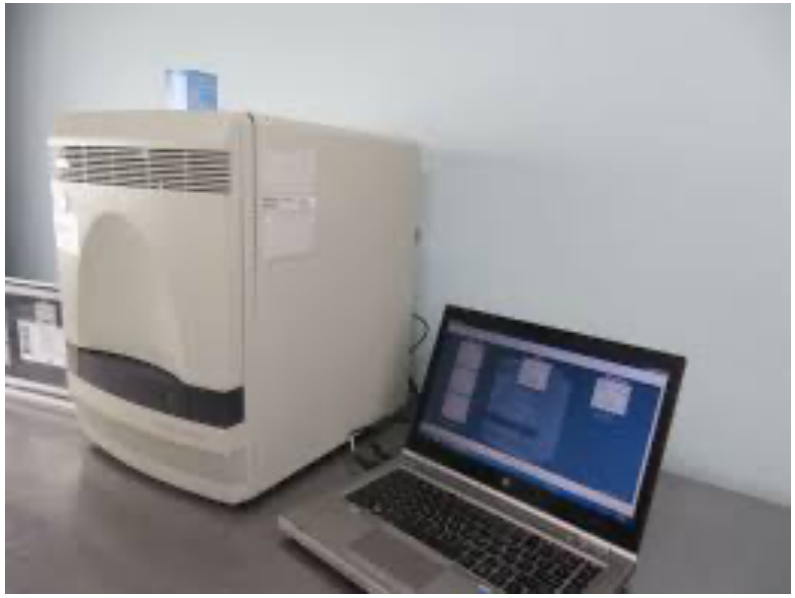
Victor Corman, Tobias Bleicker, Sebastian Brünink, Christian Drosten
Charité Virology, Berlin, Germany

- US CDC developed a 3-target test
  - All primers target Nucleocapsid (N) gene
  - Initially sent out to all state labs February 6
  - One Kit per state lab and ~700 tests per kit
  - Recalled for indeterminate results

Testing

- Blunders in getting test kits sent out has hampered US efforts for detection and preempting control
- Only hundreds of tests were run in US over first months of epidemic
- CDC Declaration of a public health emergency effectively restricted labs allowed to test to those endorsed by CDC (i.e. CDC + State Labs)
- Advanced molecular labs in hospitals around the country were unable to step in to fill the need for testing – without onerous EUA approval
- Low testing capacity in US initially led to restrictive case definition to warrant testing (i.e. recent travel to China or known infected contact)

Testing – CDC protocol Today



Real time PCR

Standard type of test that has been in use for decades
Requires skilled technicians but not experts
Cheap
Difficult to standardize well – Very manual

Mix Primers / Probes with sample and provides a fluorescent signal

If signal is above a particular cut-point (Ct value) then positive.

Can get indeterminate results if near the cut-point.

CDC uses 3 primer sets all targeting the N gene
3rd primer set is faulty – led to the recall
February 26: CDC announced it will allow testing in state labs to proceed with only considering first two primers

Testing – Recent advances (mid March)

Cepheid

Qiagen

Roche

Hologic

“Cartridge-based” real time PCR assays

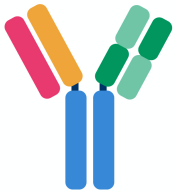
Simple to use – one-time-only
Fast – 30 – 60 minutes
Accurate
Moderate scalability
Deployable “light” instrumentation
Fast cheap start up – expensive to run

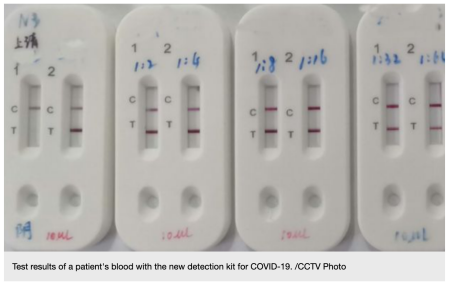
Nearly Cartridge-based real time PCR assays

Simple to use
Fast – 1-3 hours
Accurate
Scalable
”Heavy” instrumentation
High cost start up – cheaper in long run

https://news.cgtn.com/news/2020-02-15/China-develops-COVID-19-detection-kit-that-delivers-results-in-15-min

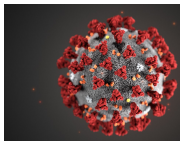
Looking forward – near future this year





Rapid "point of care" type diagnostics:

- IgM antibody detection (15 minutes)
  Look for specific immune response reflecting infection



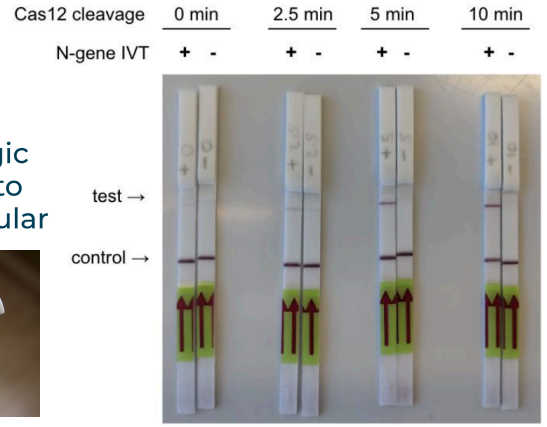
- **CRISPR** based diagnostics
  Look for the virus

Cepheid and Sherlock Biosciences Establish Collaboration on New GeneXpert Tests for Infectious Diseases and Oncology Leveraging CRISPR Technology

February 28, 2020

Sherlock Biosciences and Mologic Establish Strategic Partnership to Develop Instrument-free Molecular Diagnostic Tests

October 29, 2019



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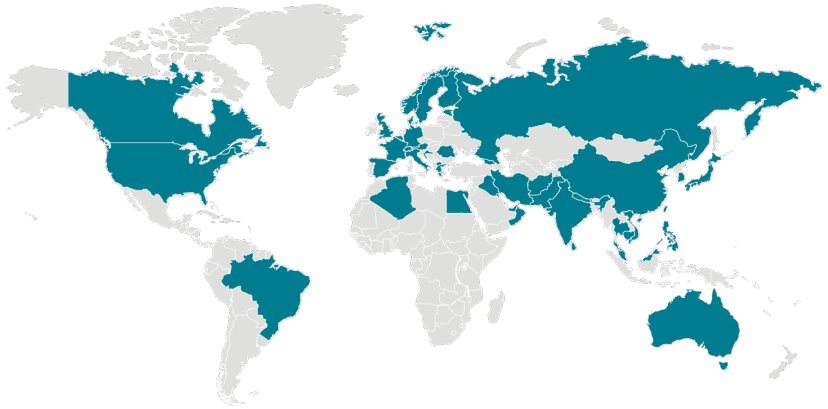

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