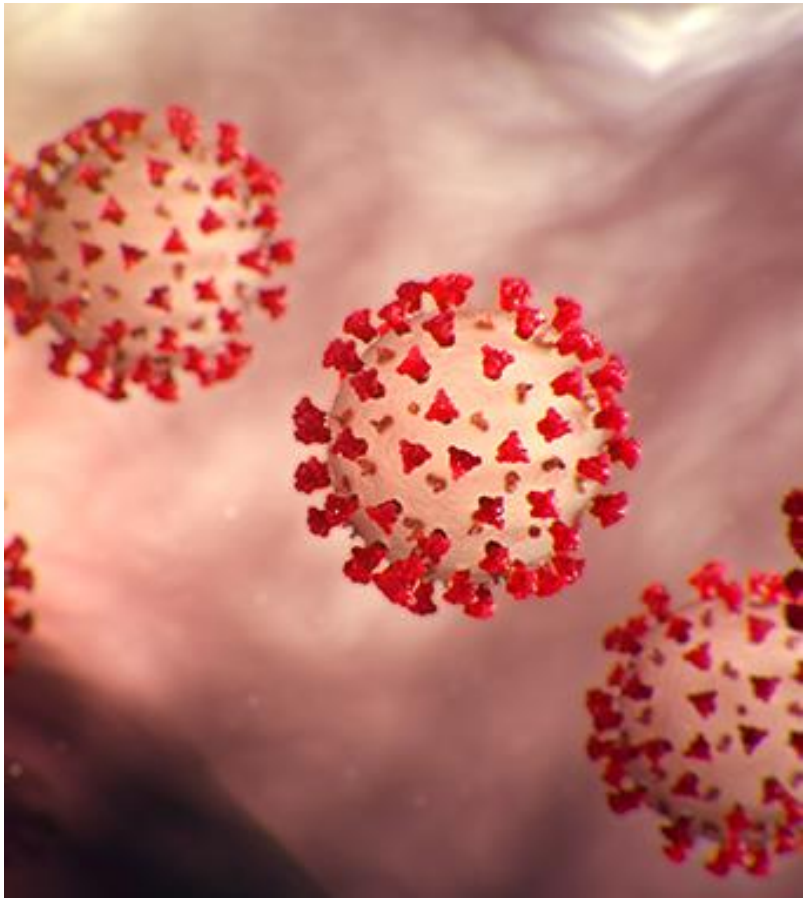
UNIVERSITY of WASHINGTON

COVID-19 Diagnostic testing: Where are we today?



Lucy A. Perrone, MSPH, PhD
Assistant Professor, Department of Global Health
Adjunct Assistant Professor, Department of Laboratory Medicine
University of Washington, Seattle, WA, USA
perronel@uw.edu

April 27, 2020

GLOBAL HEALTH

UNIVERSITY of WASHINGTON

COVID-19 Diagnostic Testing

TIMELINE OF EVENTS

THE FIRST TESTS

THE UW RESPONSE

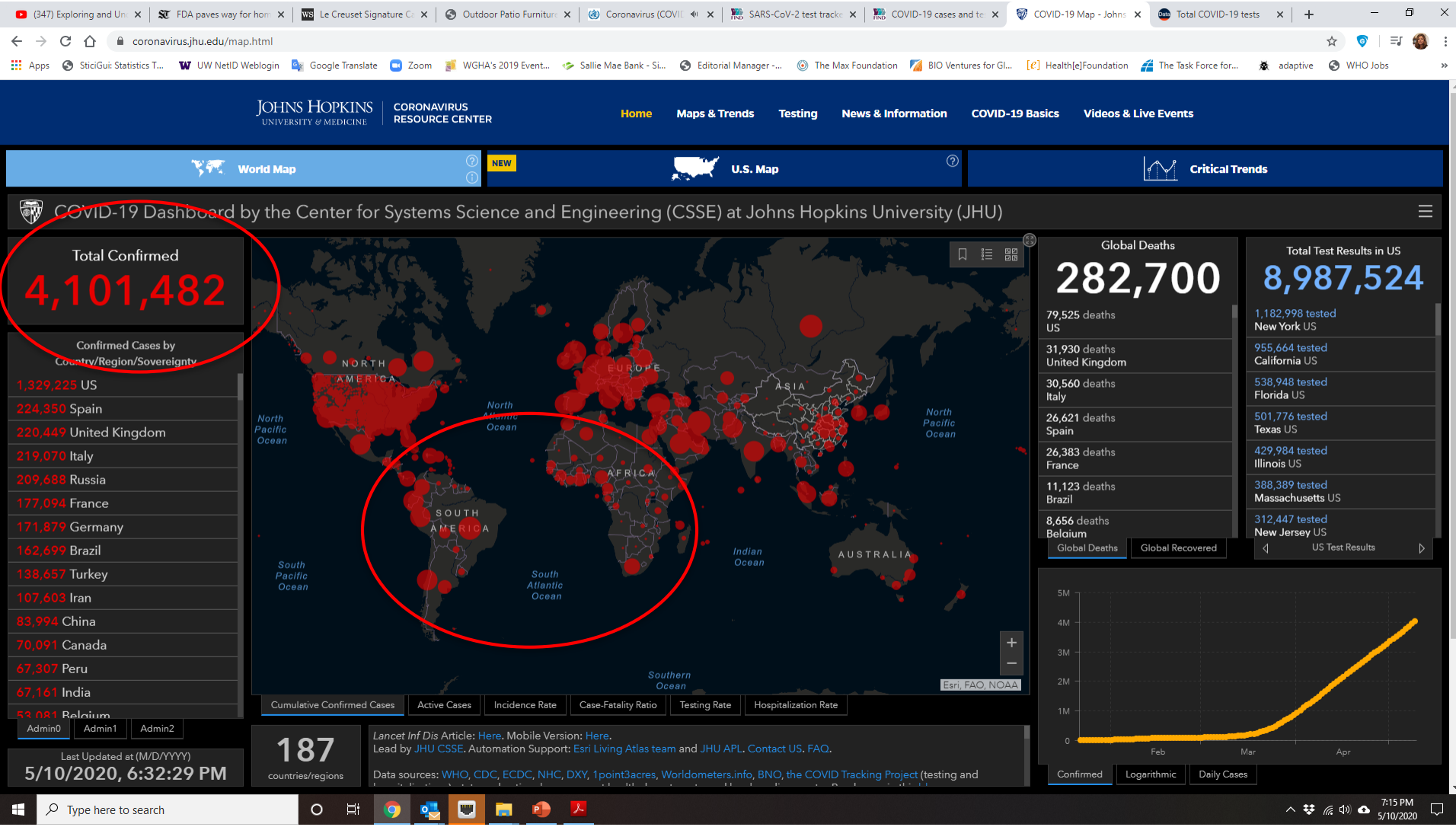
WHERE ARE WE NOW?

WHAT HAVE BEEN THE CHALLENGES?

THE ROAD TO OPENING

GLOBAL HEALTH

COVID-19 Cases as of May 10



https://coronavirus.jhu.edu/map.html

COVID19 Outbreak Timeline: Critical Events

December 31, 2019: China reports the novel SARS-2-CoV coronavirus to the World Health Organization.

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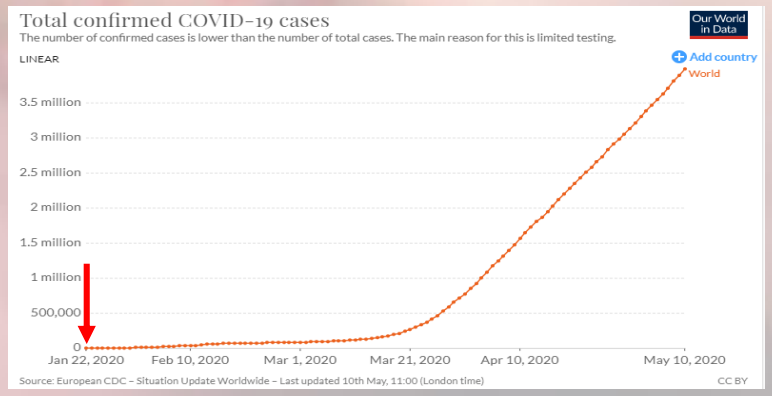
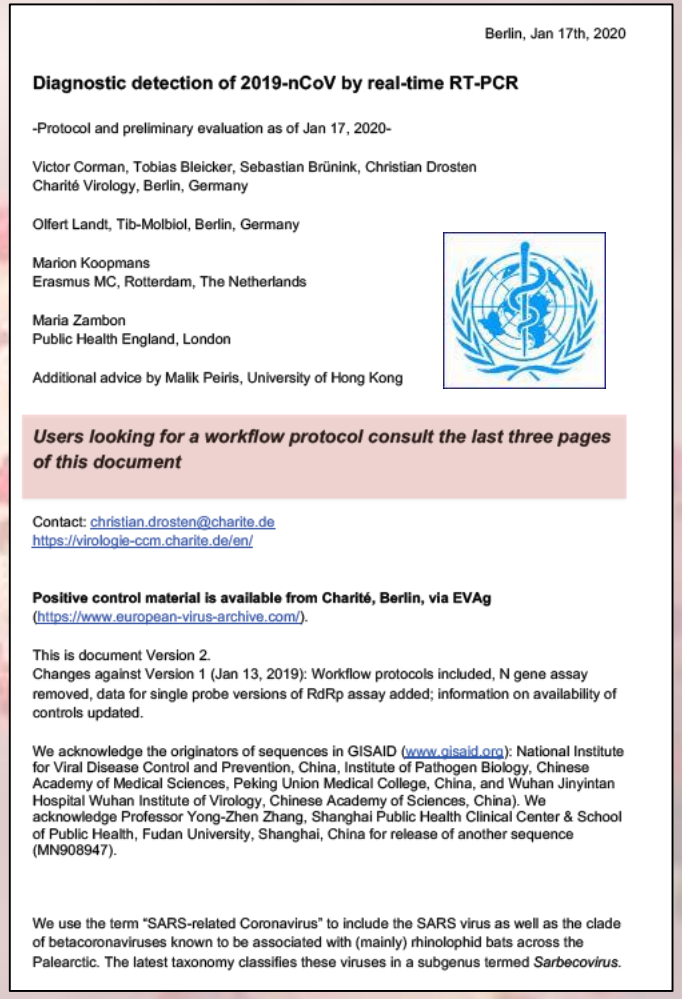
21: The first U.S. case is confirmed in a WA man who traveled from Wuhan.

30: The WHO declares global health emergency. The CDC confirms person-to-person spread of COVID-19 within the U.S.





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

Olfert Landt, Tib-Molbiol, Berlin, Germany

Marion Koopmans
Erasmus MC, Rotterdam, The Netherlands

Maria Zambon
Public Health England, London

Additional advice by Malik Peiris, University of Hong Kong

Users looking for a workflow protocol consult the last three pages of this document

Contact: christian.drosten@charite.de
https://virologie-ccm.charite.de/en/

Positive control material is available from Charité, Berlin, via EVAg (https://www.european-virus-archive.com/).

This is document Version 2.
Changes against Version 1 (Jan 13, 2019): Workflow protocols included, N gene assay removed, data for single probe versions of RdRp assay added; information on availability of controls updated.

We acknowledge the originators of sequences in GISAID (www.gisaid.org): National Institute for Viral Disease Control and Prevention, China, Institute of Pathogen Biology, Chinese Academy of Medical Sciences, Peking Union Medical College, China, and Wuhan Jinyintan Hospital Wuhan Institute of Virology, Chinese Academy of Sciences, China). We acknowledge Professor Yong-Zhen Zhang, Shanghai Public Health Clinical Center & School of Public Health, Fudan University, Shanghai, China for release of another sequence (MN908947).

We use the term "SARS-related Coronavirus" to include the SARS virus as well as the clade of betacoronaviruses known to be associated with (mainly) rhinolophid bats across the Palearctic. The latest taxonomy classifies these viruses in a subgenus termed *Sarbecovirus*.

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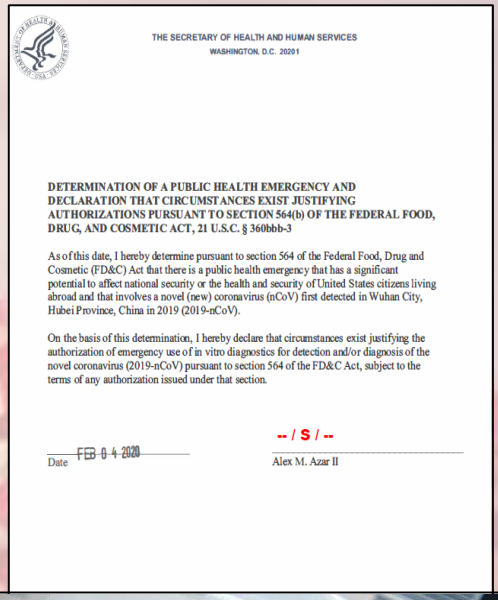
February

4: US declares public health emergency and authorizes the FDA for Emergency use Authorization (A. Azar, HHS Secretary)

5: The CDC begins shipping its diagnostic tests to state and local health agencies.

8: Labs report problems with the CDC's tests.



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

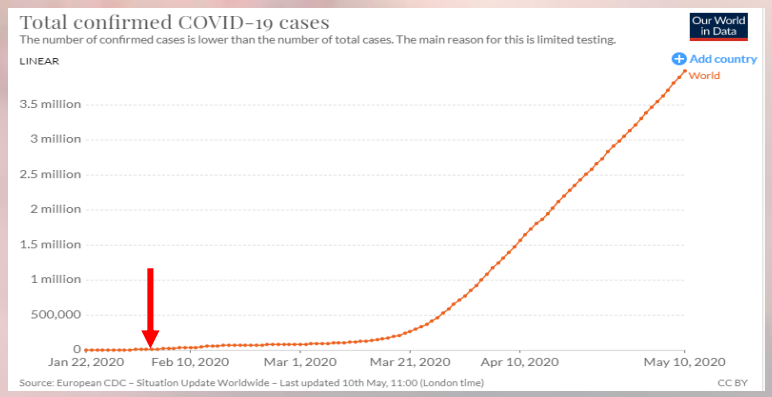
DETERMINATION OF A PUBLIC HEALTH EMERGENCY AND DECLARATION THAT CIRCUMSTANCES EXIST JUSTIFYING AUTHORIZATIONS PURSUANT TO SECTION 564(b) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, 21 U.S.C. § 360bbb-3

As of this date, I hereby determine pursuant to section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV).

On the basis of this determination, I hereby declare that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Date FEB 04 2020

-- / S / --
Alex M. Azar II



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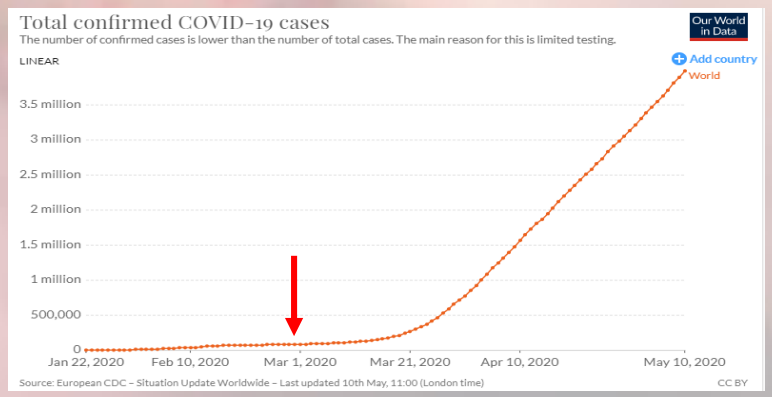
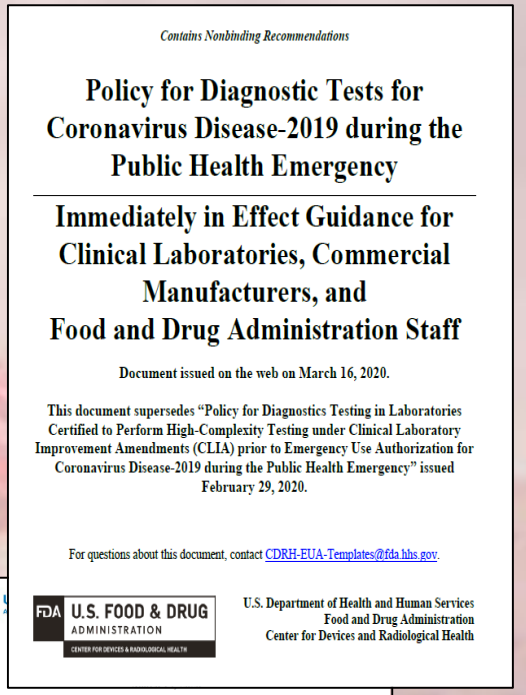
29: Washington state reports the first COVID-19 death in the U.S.

29: The Food and Drug Administration allows academic labs to develop and begin testing coronavirus testing kits while reviewing pending applications.





Contains Nonbinding Recommendations

Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency

Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff

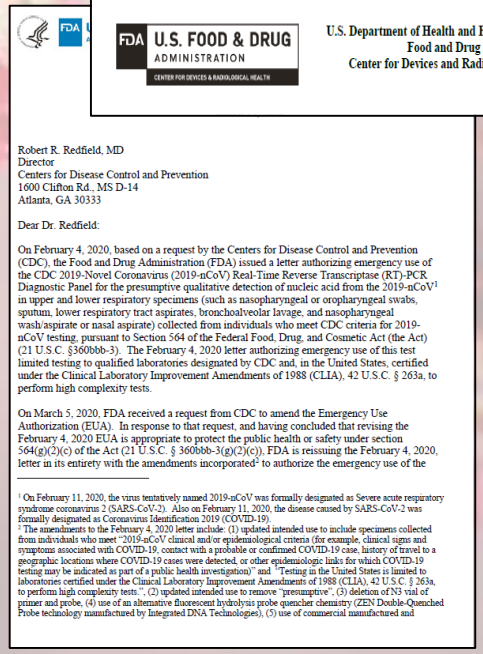
Document issued on the web on March 16, 2020.

This document supersedes "Policy for Diagnostics Testing in Laboratories Certified to Perform High-Complexity Testing under Clinical Laboratory Improvement Amendments (CLIA) prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency" issued February 29, 2020.

For questions about this document, contact CDRH-EUA-Templates@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health



Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Dear Dr. Redfield:

On February 4, 2020, based on a request by the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) issued a letter authorizing emergency use of the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV[1] in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet CDC criteria for 2019-nCoV testing, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The February 4, 2020 letter authorizing emergency use of this test limited testing to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

On March 5, 2020, FDA received a request from CDC to amend the Emergency Use Authorization (EUA). In response to that request, and having concluded that revising the February 4, 2020 EUA is appropriate to protect the public health or safety under section 564(g)(2)(c) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the February 4, 2020, letter in its entirety with the amendments incorporated[2] to authorize the emergency use of the

[1] On February 11, 2020, the virus tentatively named 2019-nCoV was formally designated as Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was formally designated as Coronavirus Identification 2019 (COVID-19).
[2] The amendments to the February 4, 2020 letter include: (1) updated intended use to include specimens collected from individuals who meet "2019-nCoV clinical and/or epidemiological criteria (for example, clinical signs and symptoms associated with COVID-19, contact with a probable or confirmed COVID-19 case, history of travel to a geographic locations where COVID-19 cases were detected, or other epidemiologic links for which COVID-19 testing may be indicated as part of a public health investigation)" and "Testing in the United States is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.", (2) updated intended use to remove "presumptive", (3) deletion of N3 vial of primer and probe, (4) use of an alternative fluorescent hydrolysis probe quencher chemistry (ZEN Double-Quenched Probe technology manufactured by Integrated DNA Technologies), (5) use of commercial manufactured and

COVID19 Outbreak Timeline: Critical Events

March

1: UW Virology opened for COVID-19 testing (The First Clinical Lab in the US)

13: Pres. Trump declares a national emergency, mobilizing resources. US reports 1896 cases.

16: FDA issues revised EUA policy for COVID-19 testing

17:Coronavirus now present in all 50 states

17: Washington State issues stay at home orders.

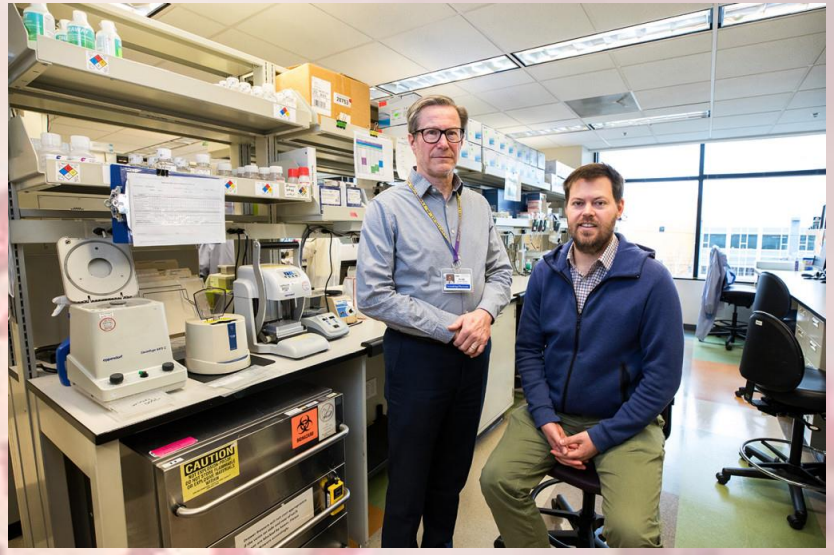
23: Nine states had stay-at-home orders by now.

26: The U.S. now leads world in coronavirus cases. 12 more states issue stay-at-home orders, totaling 21.

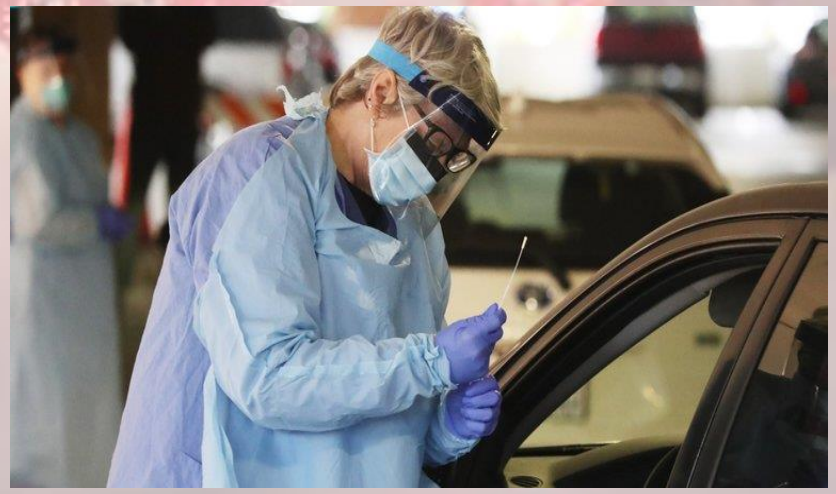
29: VP Pence and the COVID Task Force issue a letter to US testing labs to conform to a reporting process for all tests being conducted so FEMA can track supplies.

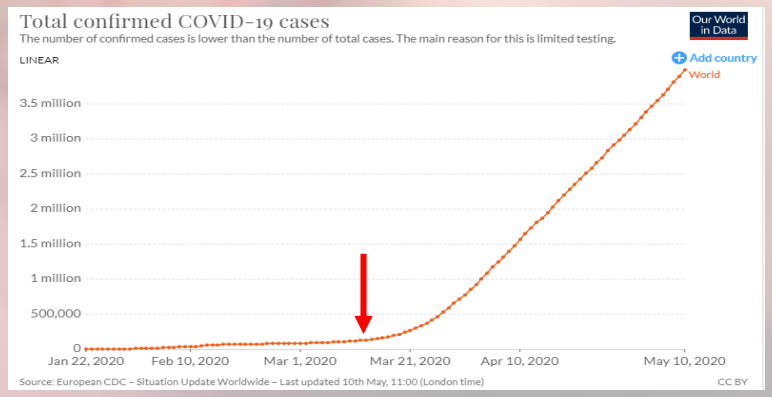
April

Widespread community-level transmission acknowledged

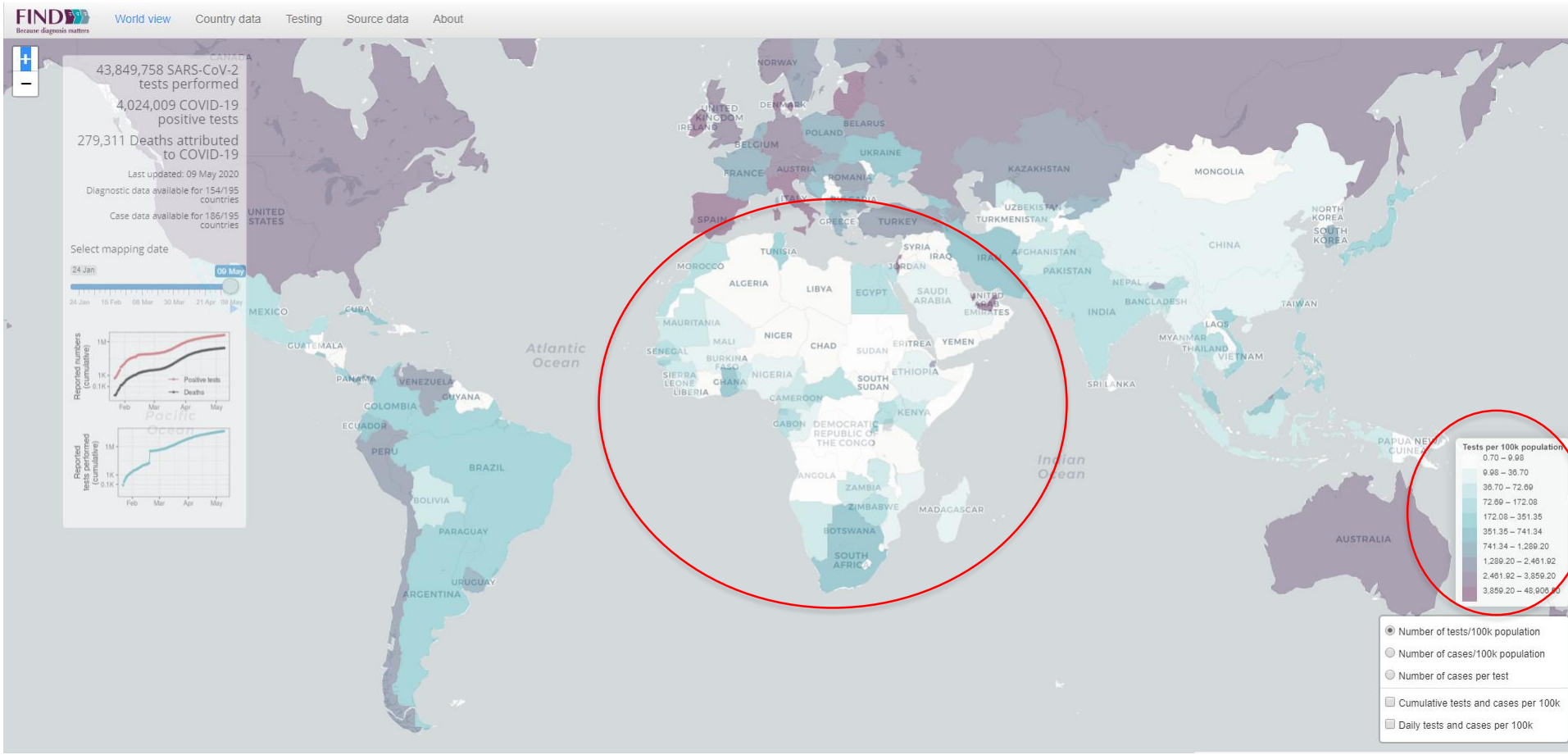


"You don't want to wait until the last minute to start to prepare." –Dr. Keith Jerome. NY Times, March 13, 2020



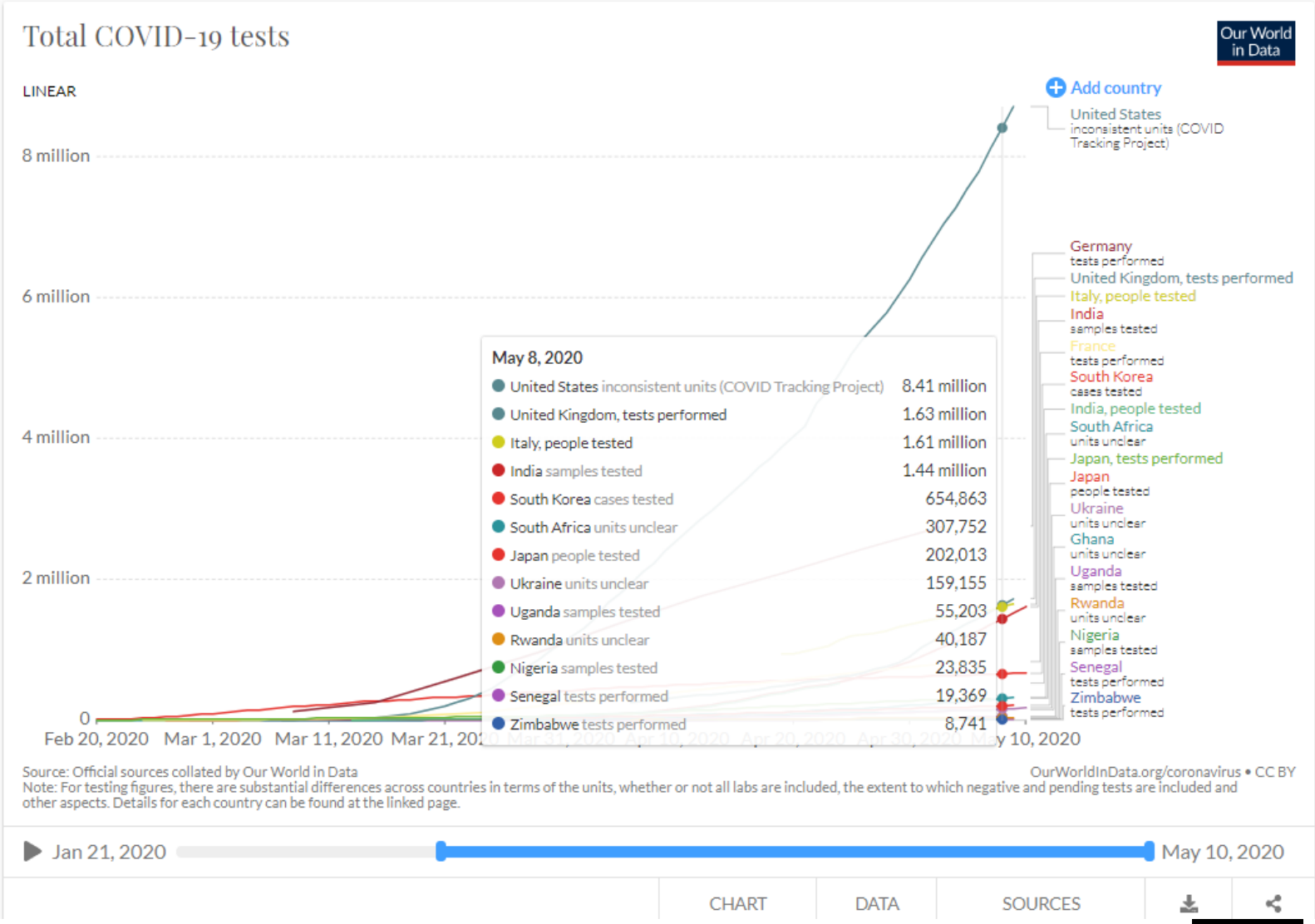


Worldwide testing rates per 100k



https://ourworldindata.org/covid-testing
https://finddx.shinyapps.io/FIND_Cov_19_Tracker
//

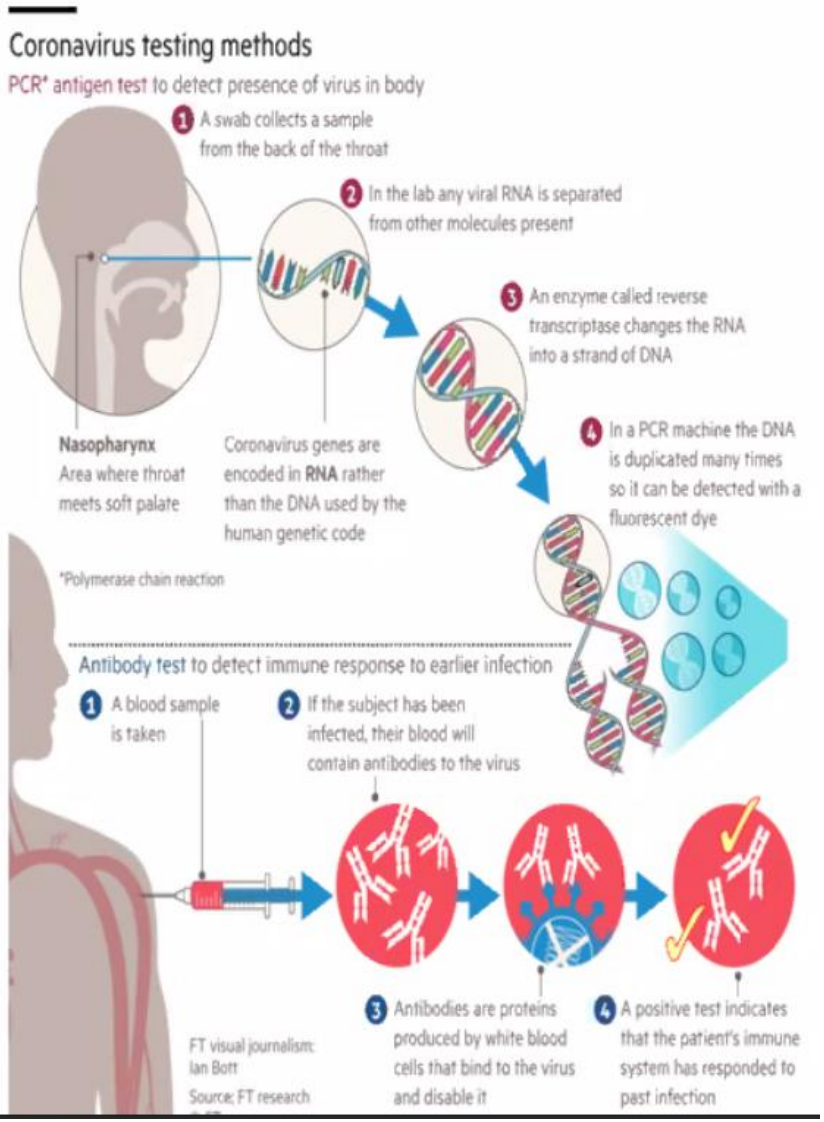
Testing data from African countries is not sufficient



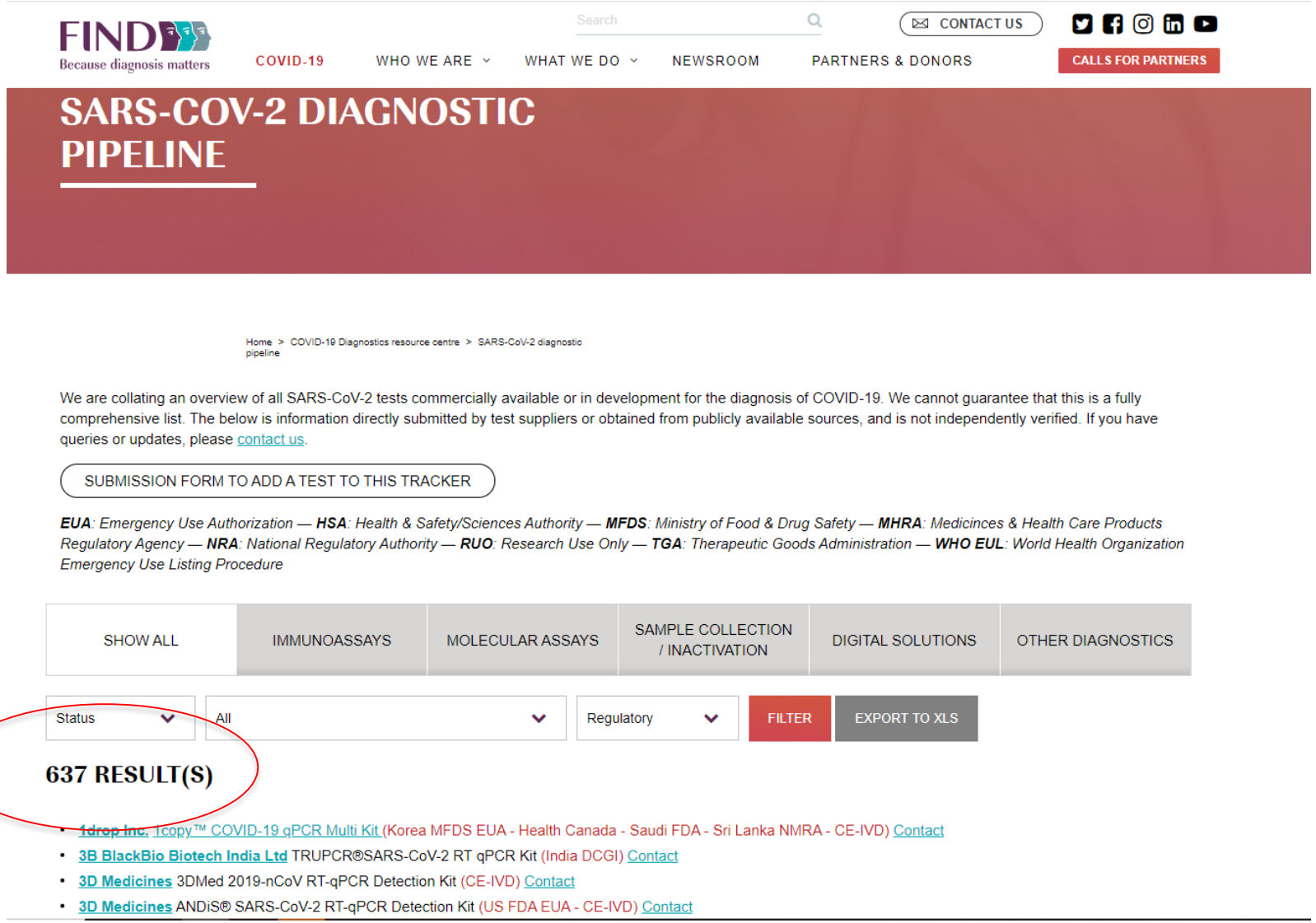
"Blood test" AKA Serology

PCR tests detect the presence of COVID-19 virus RNA – i.e. do you have it now?

Serology tests detect the immune response to COVID-19 infection – i.e. have you ever had it?



Slide courtesy University of British Columbia, Department of Pathology and Laboratory Medicine



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SARS-COV-2 DIAGNOSTIC PIPELINE

Home > COVID-19 Diagnostics resource centre > SARS-CoV-2 diagnostic pipeline

We are collating an overview of all SARS-CoV-2 tests commercially available or in development for the diagnosis of COVID-19. We cannot guarantee that this is a fully comprehensive list. The below is information directly submitted by test suppliers or obtained from publicly available sources, and is not independently verified. If you have queries or updates, please contact us.

SUBMISSION FORM TO ADD A TEST TO THIS TRACKER

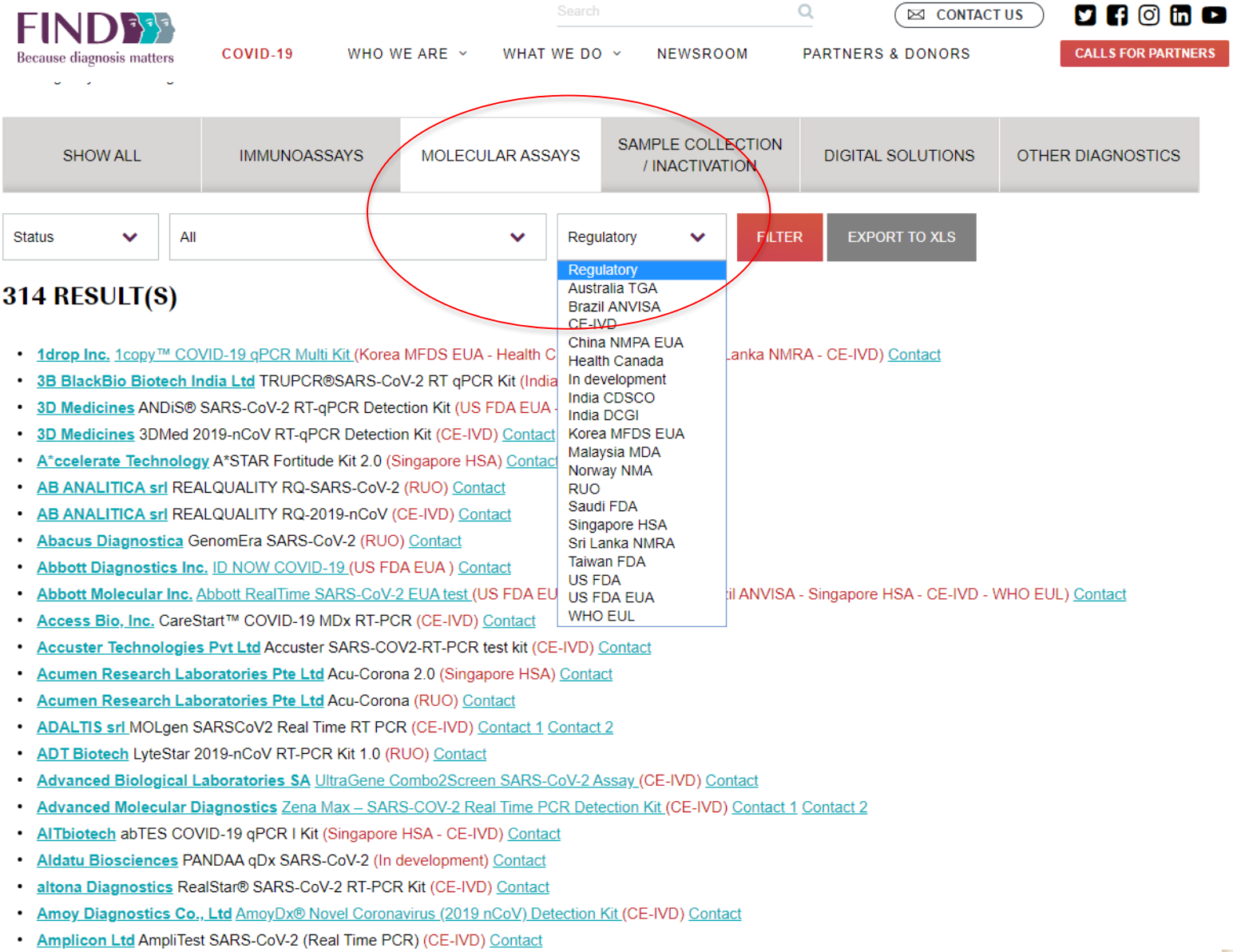
***EUA**: Emergency Use Authorization — **HSA**: Health & Safety/Sciences Authority — **MFDS**: Ministry of Food & Drug Safety — **MHRA**: Medicinces & Health Care Products Regulatory Agency — **NRA**: National Regulatory Authority — **RUO**: Research Use Only — **TGA**: Therapeutic Goods Administration — **WHO EUL**: World Health Organization Emergency Use Listing Procedure*

SHOW ALL | IMMUNOASSAYS | MOLECULAR ASSAYS | SAMPLE COLLECTION / INACTIVATION | DIGITAL SOLUTIONS | OTHER DIAGNOSTICS

Status | All | Regulatory | FILTER | EXPORT TO XLS

637 RESULT(S)

- 1drop Inc. 1copy™ COVID-19 qPCR Multi Kit (Korea MFDS EUA - Health Canada - Saudi FDA - Sri Lanka NMRA - CE-IVD) Contact
- 3B BlackBio Biotech India Ltd TRUPCR®SARS-CoV-2 RT qPCR Kit (India DCGI) Contact
- 3D Medicines 3DMed 2019-nCoV RT-qPCR Detection Kit (CE-IVD) Contact
- 3D Medicines ANDiS® SARS-CoV-2 RT-qPCR Detection Kit (US FDA EUA - CE-IVD) Contact



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Regulatory
Australia TGA
Brazil ANVISA
CE-IVD
China NMPA EUA
Health Canada
In development
India CDSCO
India DCGI
Korea MFDS EUA
Malaysia MDA
Norway NMA
RUO
Saudi FDA
Singapore HSA
Sri Lanka NMRA
Taiwan FDA
US FDA
US FDA EUA
WHO EUL

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- 3D Medicines 3DMed 2019-nCoV RT-qPCR Detection Kit (CE-IVD) Contact
- A*ccelerate Technology A*STAR Fortitude Kit 2.0 (Singapore HSA) Contact
- AB ANALITICA srl REALQUALITY RQ-SARS-CoV-2 (RUO) Contact
- AB ANALITICA srl REALQUALITY RQ-2019-nCoV (CE-IVD) Contact
- Abacus Diagnostica GenomEra SARS-CoV-2 (RUO) Contact
- Abbott Diagnostics Inc. ID NOW COVID-19 (US FDA EUA) Contact
- Abbott Molecular Inc. Abbott RealTime SARS-CoV-2 EUA test (US FDA EU ...il ANVISA - Singapore HSA - CE-IVD - WHO EUL) Contact
- Access Bio, Inc. CareStart™ COVID-19 MDx RT-PCR (CE-IVD) Contact
- Accuster Technologies Pvt Ltd Accuster SARS-COV2-RT-PCR test kit (CE-IVD) Contact
- Acumen Research Laboratories Pte Ltd Acu-Corona 2.0 (Singapore HSA) Contact
- Acumen Research Laboratories Pte Ltd Acu-Corona (RUO) Contact
- ADALTIS srl MOLgen SARSCoV2 Real Time RT PCR (CE-IVD) Contact 1 Contact 2
- ADT Biotech LyteStar 2019-nCoV RT-PCR Kit 1.0 (RUO) Contact
- Advanced Biological Laboratories SA UltraGene Combo2Screen SARS-CoV-2 Assay (CE-IVD) Contact
- Advanced Molecular Diagnostics Zena Max – SARS-COV-2 Real Time PCR Detection Kit (CE-IVD) Contact 1 Contact 2
- AITbiotech abTES COVID-19 qPCR I Kit (Singapore HSA - CE-IVD) Contact
- Aldatu Biosciences PANDAA qDx SARS-CoV-2 (In development) Contact
- altona Diagnostics RealStar® SARS-CoV-2 RT-PCR Kit (CE-IVD) Contact
- Amoy Diagnostics Co., Ltd AmoyDx® Novel Coronavirus (2019 nCoV) Detection Kit (CE-IVD) Contact
- Amplicon Ltd AmpliTest SARS-CoV-2 (Real Time PCR) (CE-IVD) Contact

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23 RESULT(S)

- 3D Medicines ANDiS® SARS-CoV-2 RT-qPCR Detection Kit (US FDA EUA - CE-IVD) Contact
- Abbott Diagnostics Inc. ID NOW COVID-19 (US FDA EUA) Contact
- Abbott Molecular Inc. Abbott RealTime SARS-CoV-2 EUA test (US FDA EUA - Health Canada - Brazil ANVISA - Singapore HSA - CE-IVD - WHO EUL) Contact
- Atila BioSystems, Inc. Atila iAMP COVID-2019 Detection Kit (US FDA EUA) Contact
- Becton Dickinson BioGX SARS-CoV-2 Reagents for BD MAX™ System (US FDA EUA - Health Canada - Australia TGA - Brazil ANVISA - Singapore HSA)
- BioFire Defense, LLC BioFire COVID-19 Test (US FDA EUA) Contact
- Cepheid Xpert Xpress SARS-CoV-2 (US FDA EUA - Health Canada - Australia TGA - Singapore HSA) Contact
- DiaSorin Molecular, LLC Simplexa™ COVID-19 Direct RT-PCR Kit (US FDA EUA - CE-IVD)
- Fast Track Diagnostics Luxembourg S.à r.l., a Siemens Healthineers Company FTD-114 SARS-CoV-2 (manual & lab-based NAT) (US FDA EUA - CE-IVD) Contact
- GenMark Diagnostics ePlex® SARS-CoV-2 Test (US FDA EUA) Contact
- Hologic Panther Fusion SARS-CoV-2 assay (US FDA EUA - Health Canada - Australia TGA)
- LabGenomics Co., Ltd LabGun™ COVID 19 Assay PCR Kit (US FDA EUA - CE-IVD) Contact
- LGC Biosearch technology Molecular assays, RNA extraction kit, rt-PCR reagents (China NMPA EUA - US FDA EUA) Contact
- Luminex Corp. ARIES SARS-CoV-2 Assay (US FDA EUA) Contact
- Next Pharma Inc. DiaCarta's QuantiVirus™SARS-CoV-2 Test (US FDA EUA - CE-IVD) Contact
- Novacyt/primerdesign genesig Real-Time PCR COVID-19 (US FDA EUA - CE-IVD - WHO EUL)
- QIAGEN GmbH QIAstat-Dx Respiratory Panel 2019-nCoV (US FDA EUA - CE-IVD) Contact 1 Contact 2
- Quidel Lyra SARS-CoV-2 Assay (US FDA EUA - Health Canada - CE-IVD) Contact
- Roche Molecular Diagnostics cobas® SARS-CoV-2 (for use on the cobas® 6800/8800 Systems) (US FDA EUA - WHO EUL) Contact
- Saladax Biomedical Inc. Fosun COVID-19 RT-PCR Detection Kit (US FDA EUA - CE-IVD) Contact
- SEASUN BIOMATERIALS U-TOP™ COVID-19 Detection Kit (Korea MFDS EUA - US FDA EUA - CE-IVD) Contact
- Seegene, Inc. Allplex 2019-nCoV assay (US FDA EUA - Health Canada - Australia TGA - Korea MFDS EUA - Singapore HSA - CE-IVD) Contact
- Thermo Fisher Scientific TaqPath™ COVID-19 Combo Kit (US FDA EUA - Health Canada - Australia TGA - Singapore HSA) Contact

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Home / Emergencies / Diseases / Coronavirus disease 2019 / Technical guidance / National laboratories

Coronavirus disease (COVID-19) technical guidance: Laboratory testing for 2019-nCoV in humans

Coronavirus disease 2019

Technical guidance

National laboratories

Unity Studies: Early Investigation Protocols

Case management

Surveillance, rapid response teams, and case investigation

Infection prevention and control

Points of entry and mass gatherings

Overview

On this page you will find information about:

1. WHO interim guidance for laboratory testing
2. WHO interim guidance for laboratory biosafety related to COVID-19 virus
3. Molecular assays to diagnose COVID-19 virus
4. WHO refence laboratories providing confirmatory testing for COVID-19
5. Guidance for laboratories shipping specimens to WHO reference laboratories that provide confirmatory testing for COVID-19 virus
6. Laboratory Assessment Tool for laboratories implementing COVID-19 testing
7. Scientific brief: Advice on the use of point-of-care immunodiagnostic tests for COVID-19

1. WHO interim guidance for laboratory testing

The purpose of this document is to provide interim guidance to laboratories and stakeholders involved in laboratory testing of COVID-19 virus.

- Read the document (updated 2 March 2020)

Diagnostic testing for COVID-19 is critical to tracking the virus, understanding epidemiology, informing case management, and to suppressing transmission. This document describes the strategic use of diagnostic testing in different transmission scenarios of the COVID-19 outbreak, from no cases to community transmission, including how testing might be rationalized when lack of reagents or

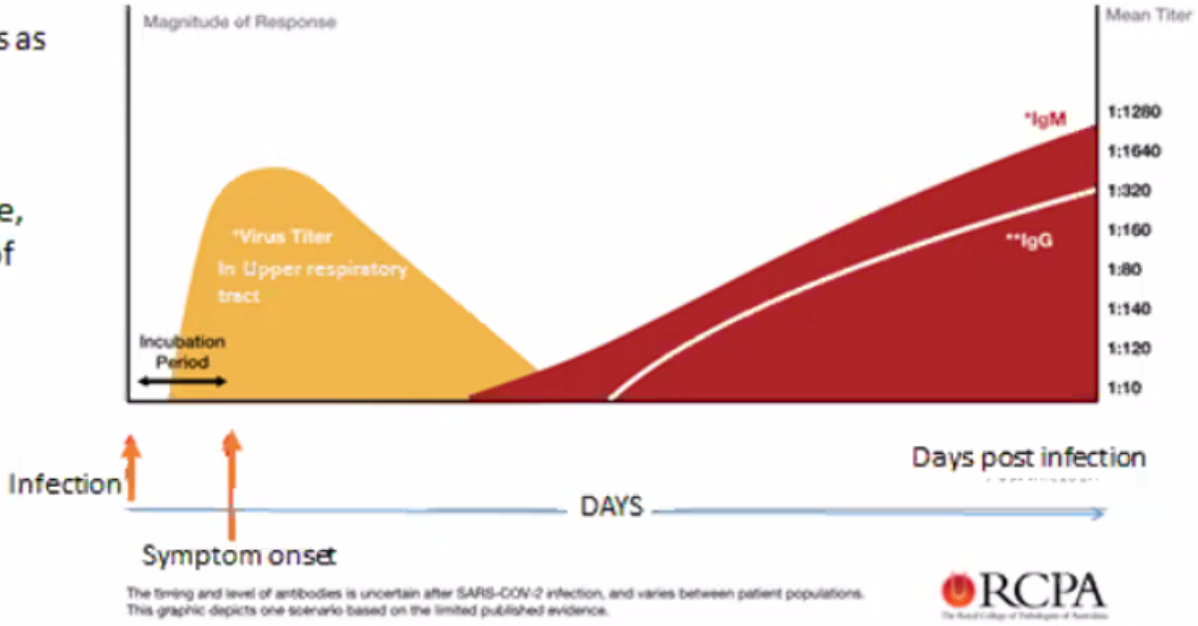
here to search

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance

Serology is not part of acute diagnostic testing at this time

Serology of limited use for diagnostic testing

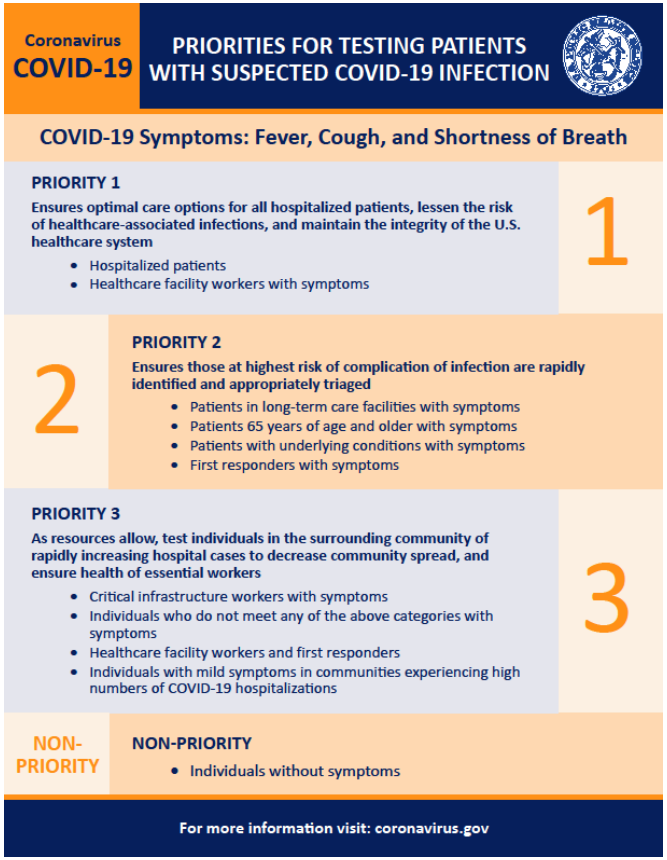
- Specific scenarios as per clinical judgement
- e.g., NAT negative, longer duration of symptoms



Data courtesy The Royal College of Pathologists of Australasia

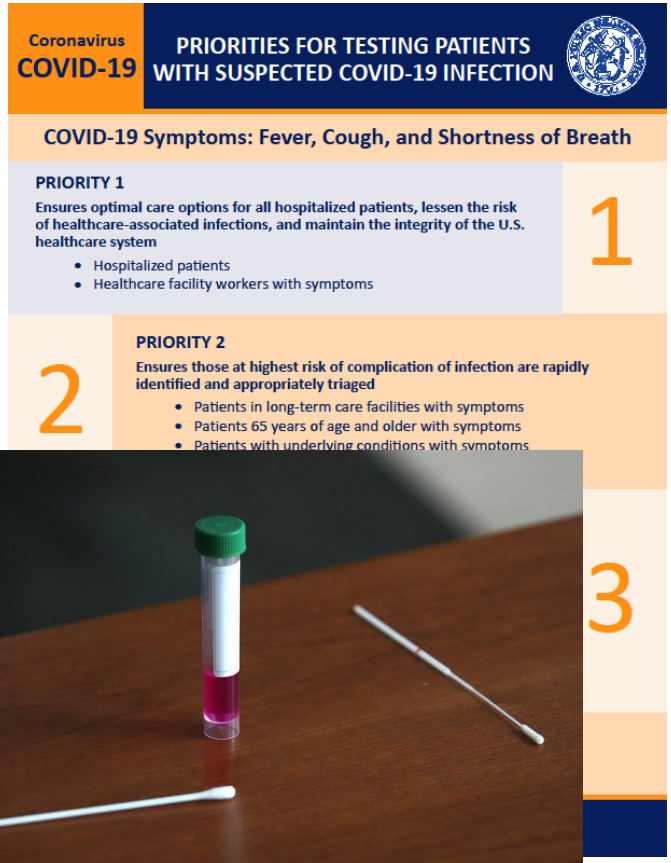
What have been the major challenges so far?

1. Access to Testing-
   - Tiered testing approach
   - Who to test
   - Lab Capacity/referral



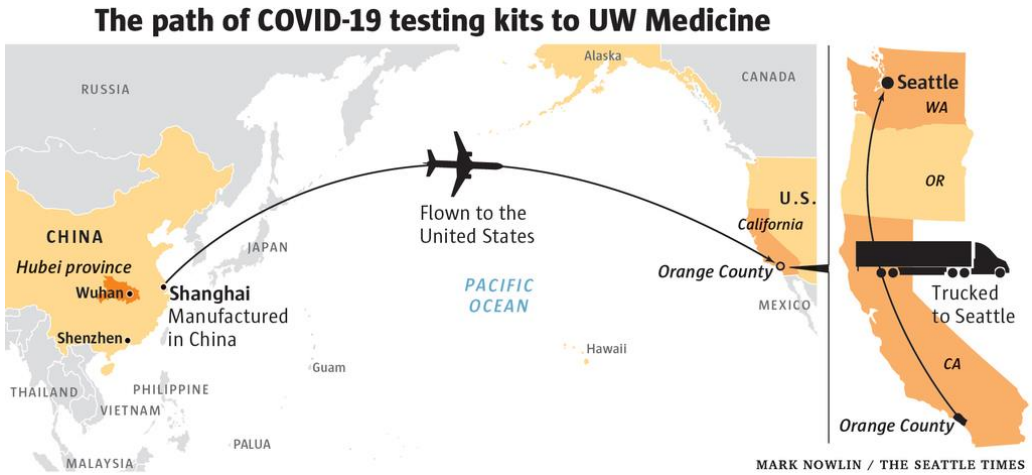
What have been the major challenges so far?

1. Access to Testing-
   - Tiered testing approach
   - Who to test
   - Lab Capacity/referral
2. Lost time
   - Test failure
   - Slow expansion of testing
   - Regulatory process



What have been the major challenges so far?

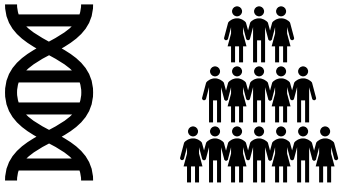
1. Access to Testing-
   - Tiered testing approach
   - Who to test
   - Lab Capacity/referral
2. Lost time
   - Test failure
   - Slow expansion of testing
   - Regulatory process
3. Supply Chain Problems
   - PPE
   - sampling kits
   - lab reagents (positive control material, extraction reagents)



Courtesy University of British Columbia, Department of Pathology and Laboratory Medicine

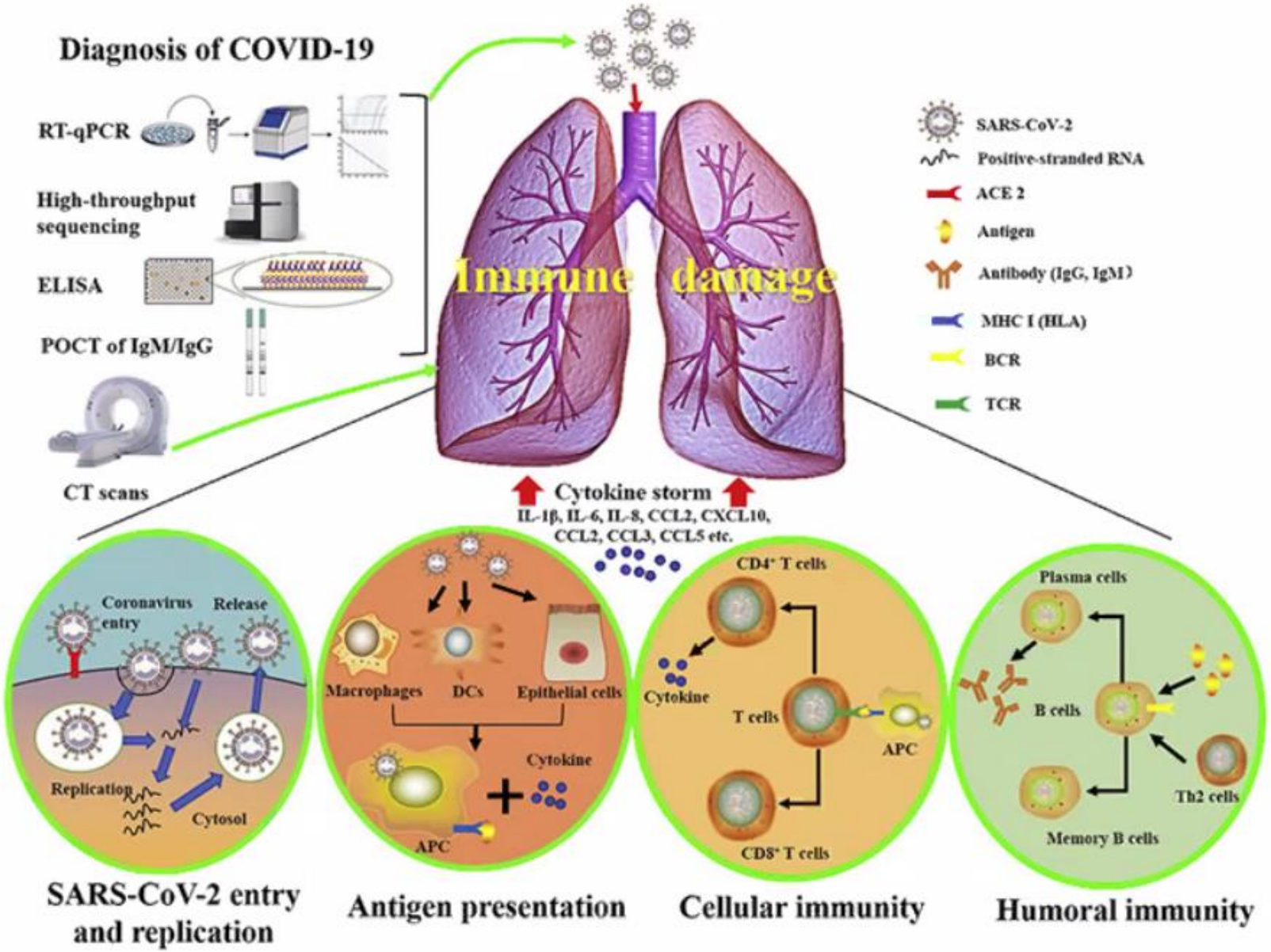
The Road to Opening

Better data



Improvements in clinical and public health system capabilities

Effective therapeutic, prophylactic, and preventive treatments

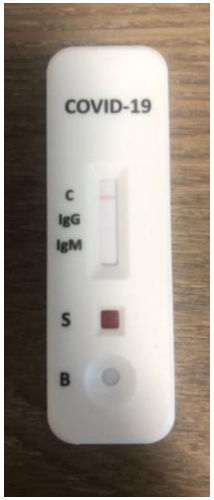


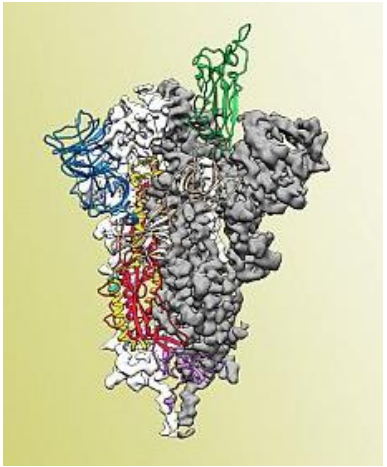
Xiaowei Li et al; Journal of Pharmaceutical Analysis Volume 10, Issue 2, April 2020, Pages 102-108

UNIVERSITY of WASHINGTON

Serology-based tests for COVID-19

Type of test	Time to results	What it tells us	What it cannot tell us	Approved for use in USA?
Rapid diagnostic test (RDT)	10-30 minutes	The presence or absence (qualitative) of antibodies against the virus present in patient serum.	The quantifiable amount of antibodies in the patient serum, or if these antibodies are able to protect against future infection	2
Enzyme linked immunosorbent assay (ELISA)	1-5 hours	The presence or absence (quantitative) of antibodies against the virus present in patient serum.	If the antibodies are able to protect against future infection.	1 + 1 modified ELISA
Neutralization assay	3-5 days	The presence of active antibodies in patient serum that are able to inhibit virus growth ex vivo, in a cell culture system. Indicates if the patient is protected against future infection.	It may miss antibodies to viral proteins that are not involved in replication.	O



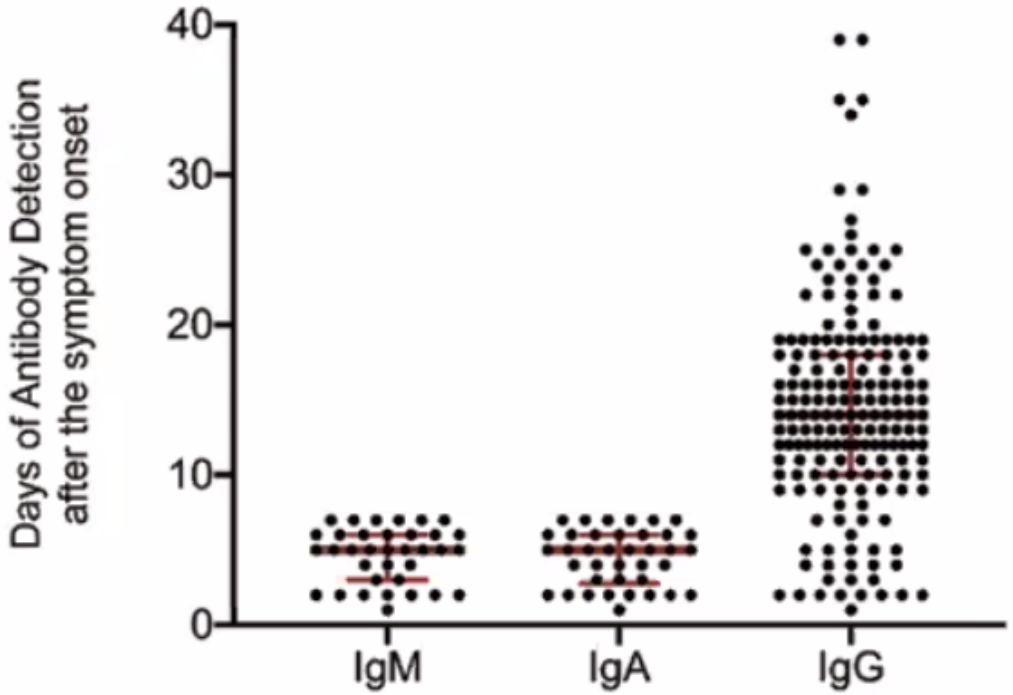


Wrapp D, et al. Science. 2020 Feb 19.

A current list of available tests is being compiled here: https://www.centerforhealthsecurity.org/resources/COVID-19/serology/Serology-based-tests-for-COVID-19.html

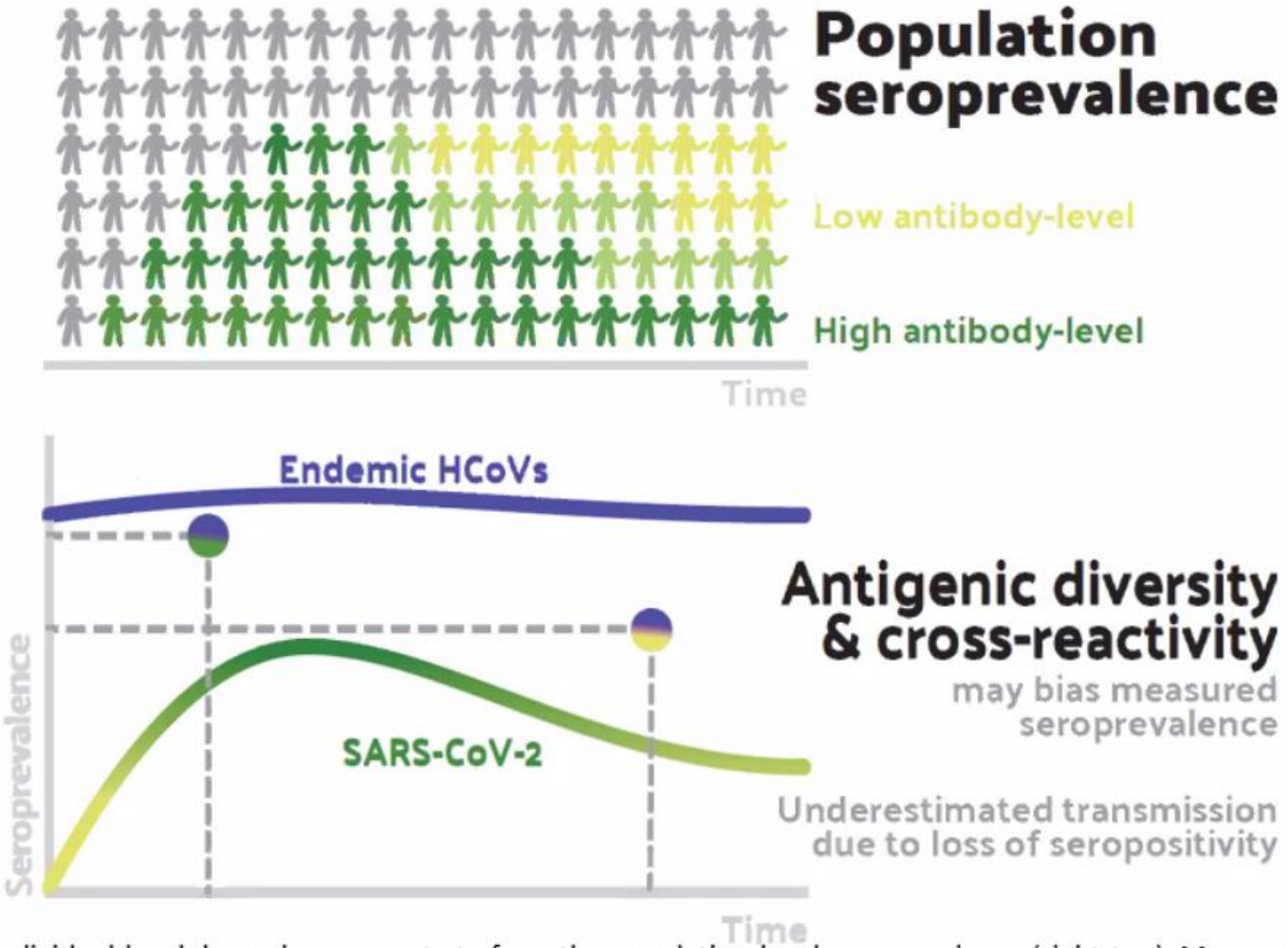
UW GLOBAL HEALTH

Early Humoral Response to SARS-CoV-2



Characteristics of plasma antibodies in patients infected with SARSCoV-2. *A*, Time of appearance of IgM, IgA, and IgG antibodies to SARS-CoV-2, determined by ELISA of plasma samples obtained from inpatients with SARS-CoV-2 infection.

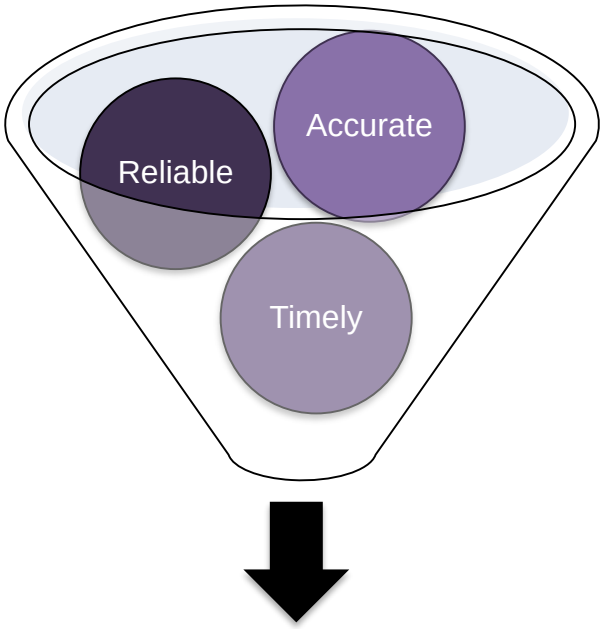
Guo et al; Clinical Infectious Diseases, March 20, 2020; https://doi.org/10.1093/cid/ciaa310



These individual-level dynamics aggregate to form the population-level seroprevalence (right-top). Measures of seroprevalence may imperfectly measure past exposure to infection due to antigenic diversity of future SARS-CoV-2 viruses and cross-reactivity of endemic human coronaviruses (HCoVs) with SARS-CoV-2. Measures of seroprevalence may also be inconsistent across times as antibody levels within individuals wane.

Slide courtesy University of British Columbia, Department of Pathology and Laboratory Medicine

A Word About Self Testing



Effective diagnosis

Test Performance and Use Matters

- Sensitivity
- Specificity
- Predictive value
- Likelihood ratio

Calculations

Sensitivity = 95%
Specificity = 98%

Disease prevalence	PPV	NPV
70%	99.08%	89.63%
50%	97.88%	95.28%
20%	92.02%	98.78%
5%	70.83%	99.74%
1%	31.79%	99.95%

→ For low disease prevalence, test specificity is paramount!