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Laboratory Testing for the SARS-CoV-2 Pandemic

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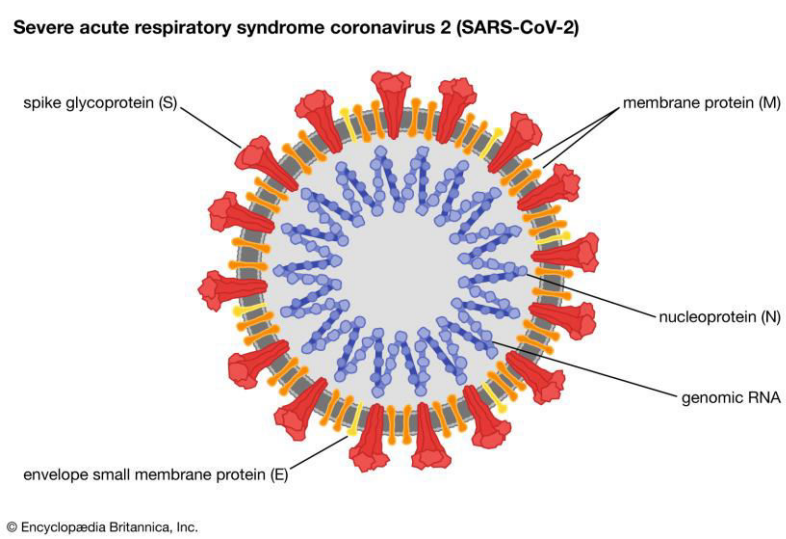
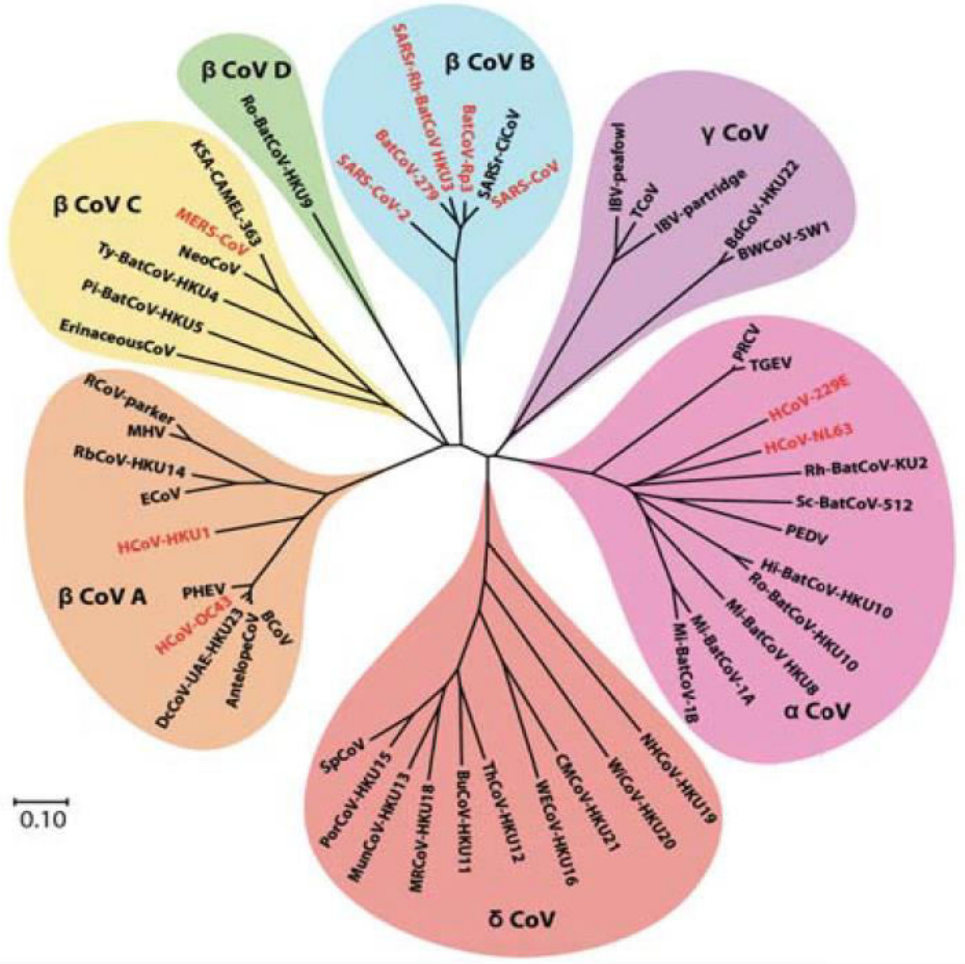
October 6, 2020

Types of Assays

- Tests for viral detection
  - RT-PCR
  - Antigen
- Tests for viral exposure
  - IgA, IgM, IgG
- Molecular epidemiology





Shrock E et al. Science 2020

Methods for Detection of SARS-CoV-2

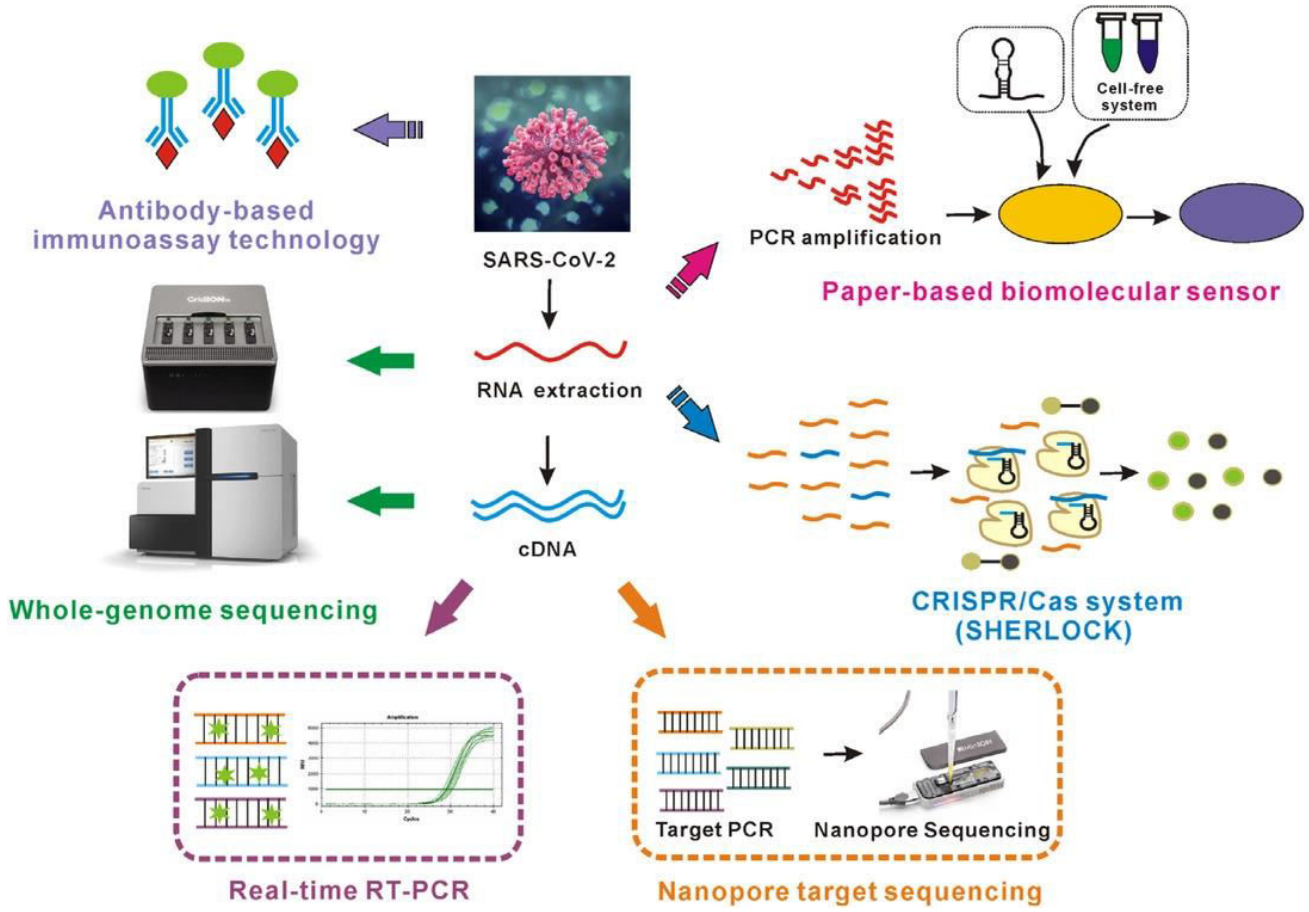
Sample types

Swabs
- Nasopharyngeal
- Oral pharyngeal

Saliva

Passive drool

Stool

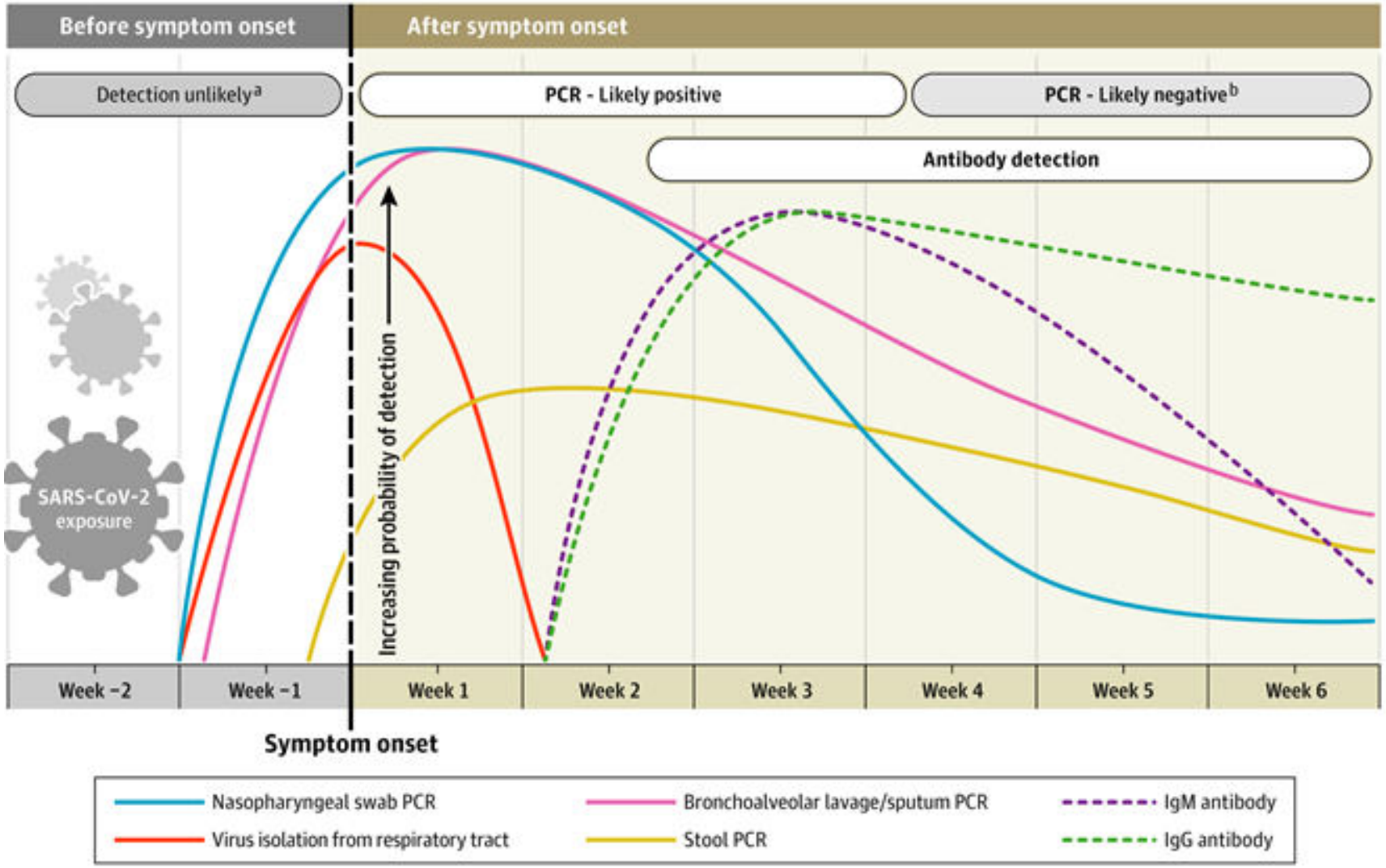


Liu R, Fu A, Deng Z, Li, Liu T, VIEW 2020

Evaluation of SARS-CoV-2 Assays

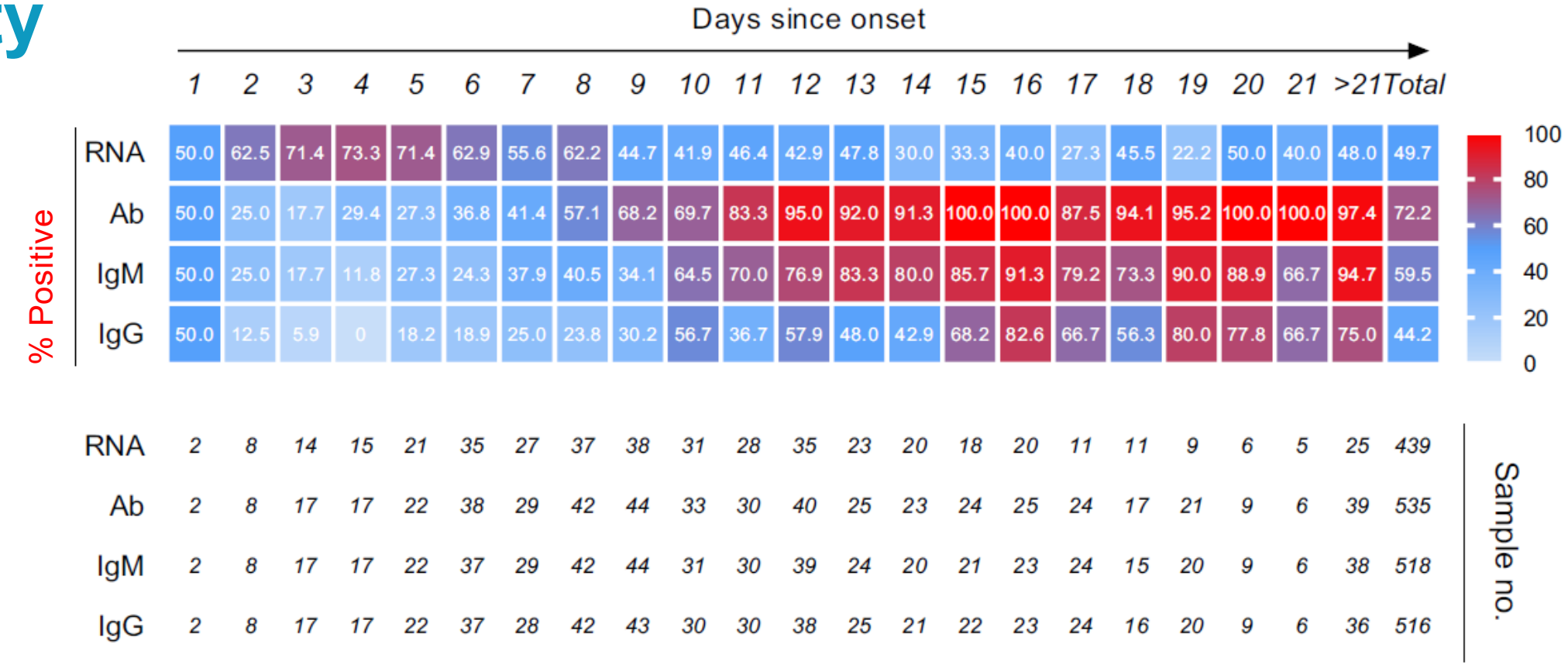
- https://www.cdc.gov/coronavirus/2019-ncov/lab/resources.html
- https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices
- https://www.finddx.org/covid-19/dx-data/
- https://www.who.int/diagnostics_laboratory/EUL/en/

Timing of Detection of Diagnostic Test by Symptom Onset



Sethuraman, Jeremiah and Ryo JAMA 2020

Sensitivity of Tests by Days Since Disease Onset



Technology used by WANTAI

Zhao CID 2020

Serologic Tests for Antibodies to SARS-CoV-2

- Almost all hospitalized patients seroconvert by 14 days after symptom onset
- 5-10% of non-hospitalized patients do not seroconvert
- IgM and IgG responses occur over similar periods
  - This may reflect previous exposure to other common coronaviruses

Long Q-X et al Nature Med 2020

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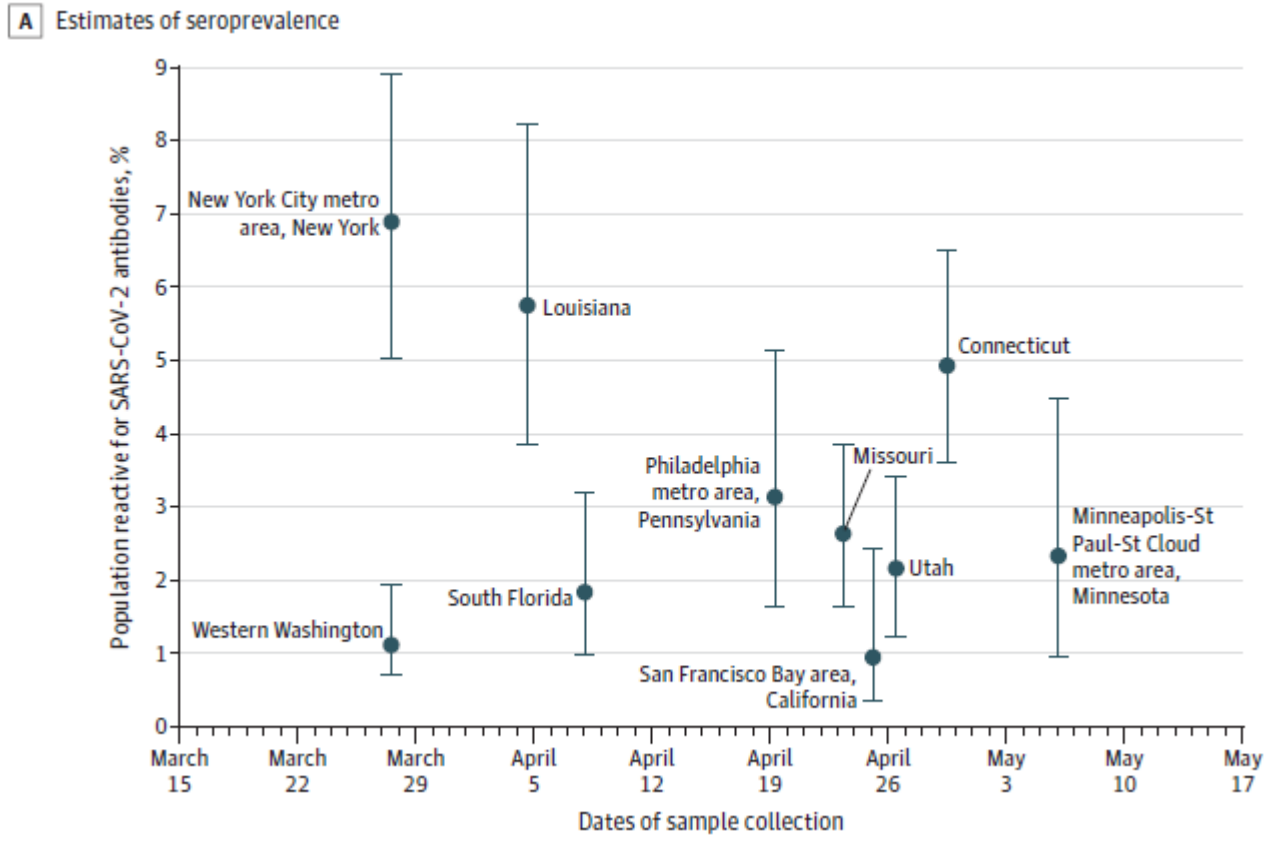
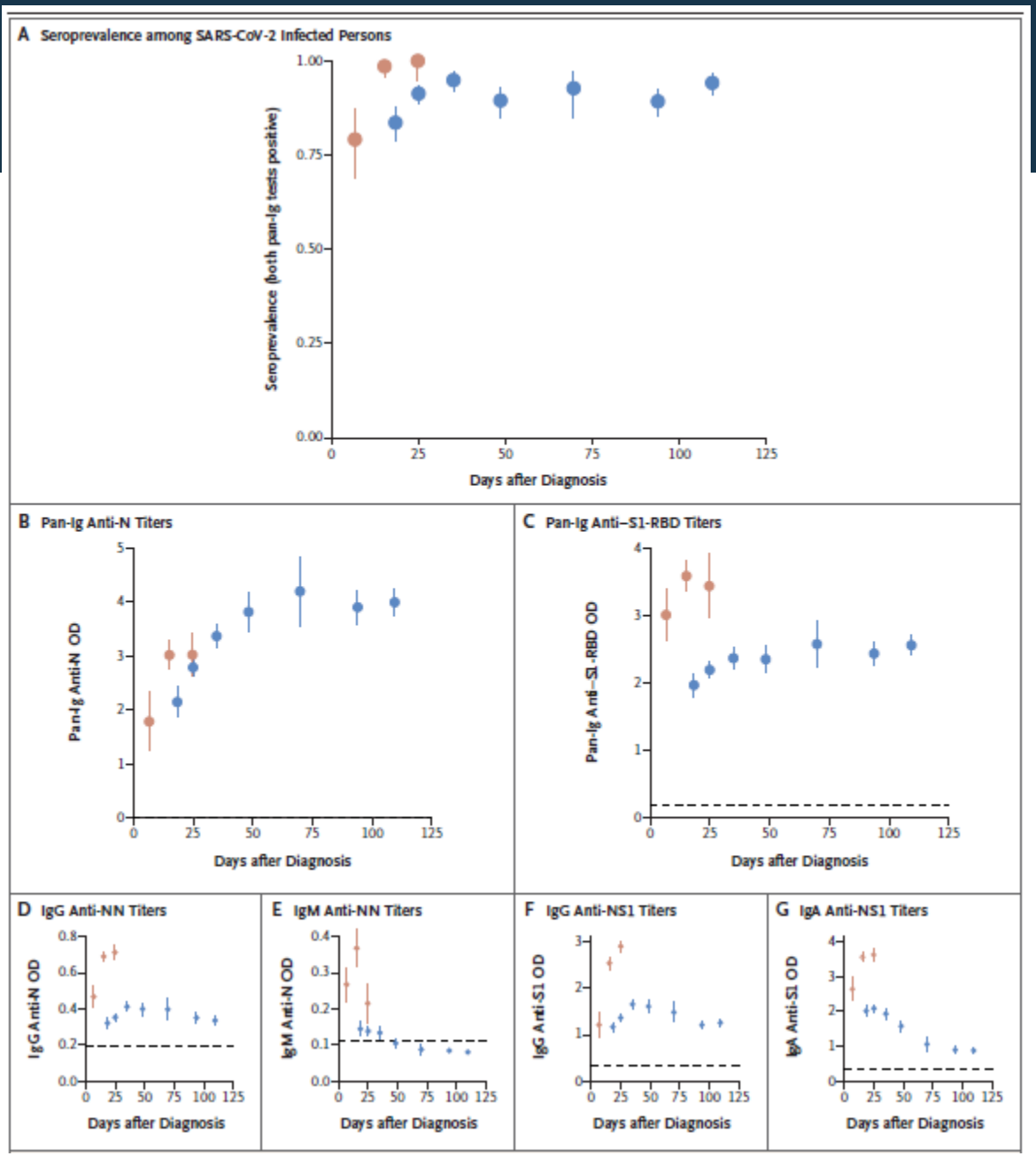
Applications of Validated Serologic Assays





Havers FP et al JAMA Int Med 2020

Gudbjartsson DF et al NEJM 2020

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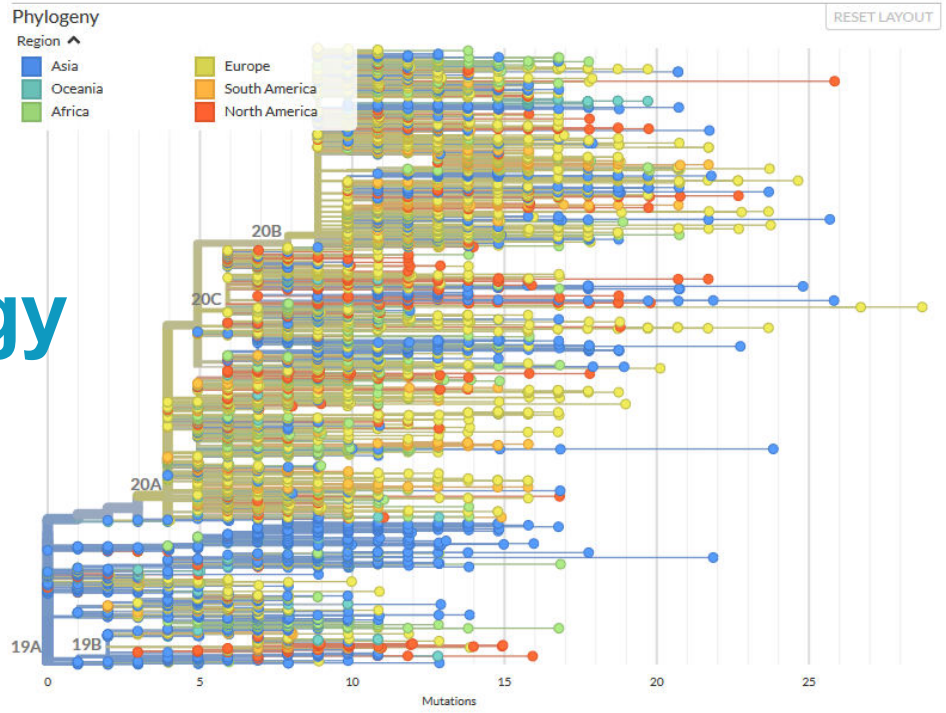
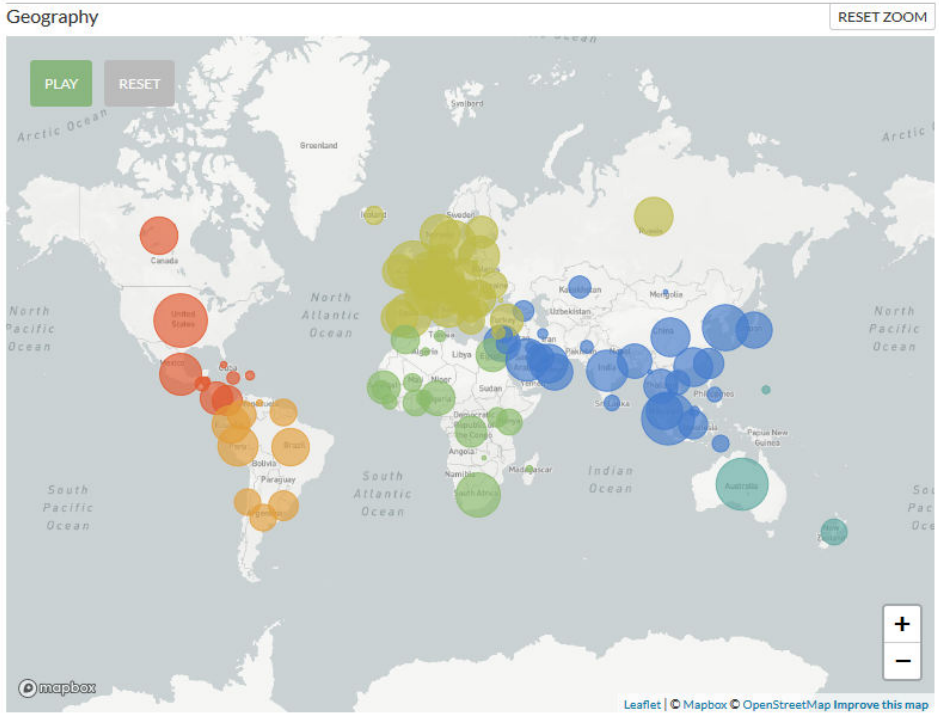
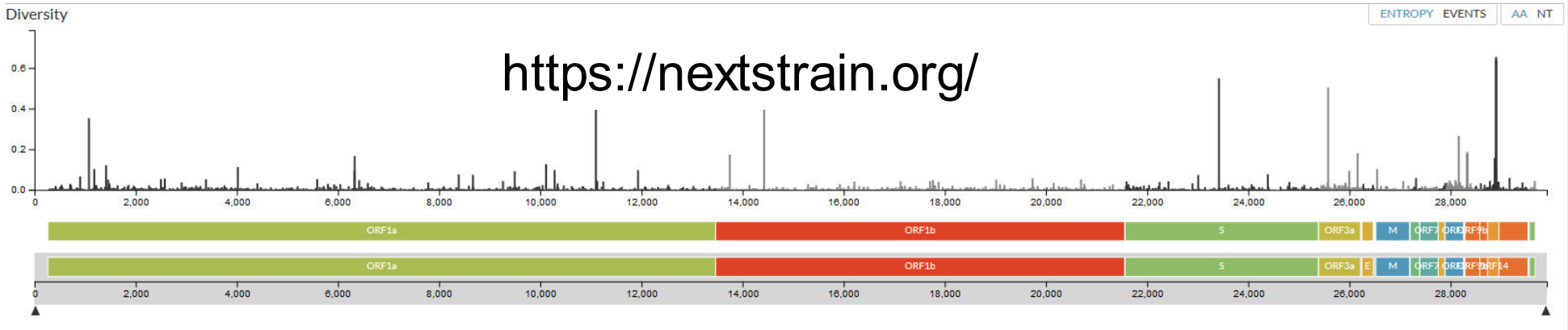
Molecular Epidemiology of SARS-CoV-2







https://nextstrain.org/

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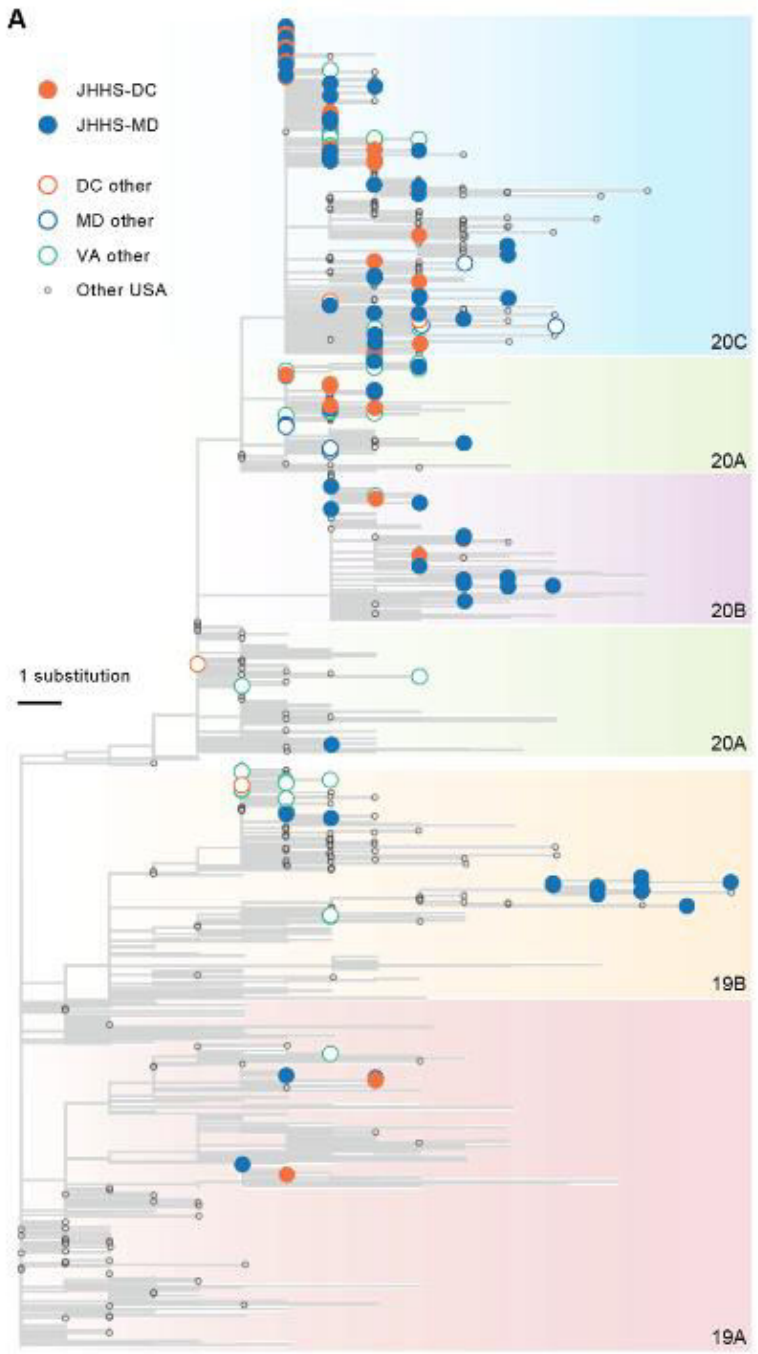
Sequence Analysis: National Capital Region of the United States

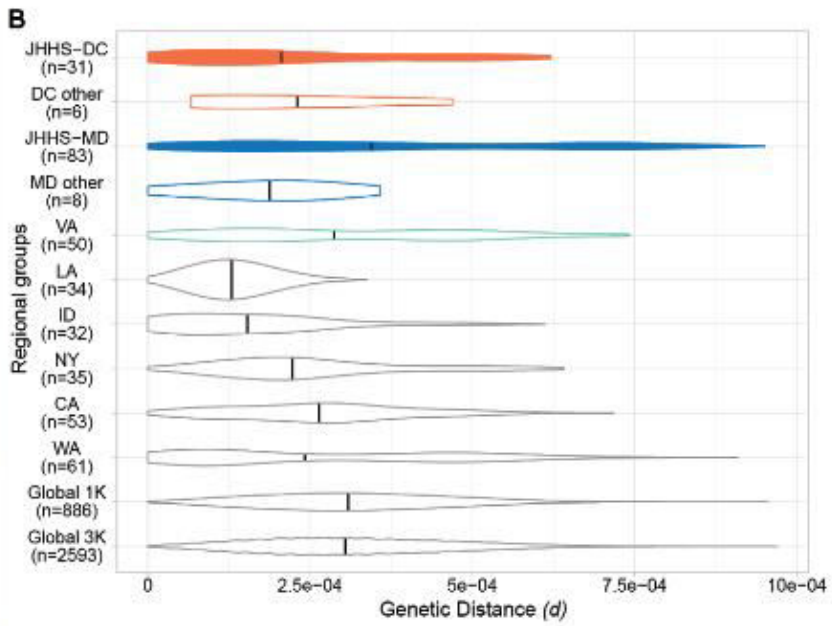
620 samples from the Johns Hopkins Health System collected between March 11–31, 2020

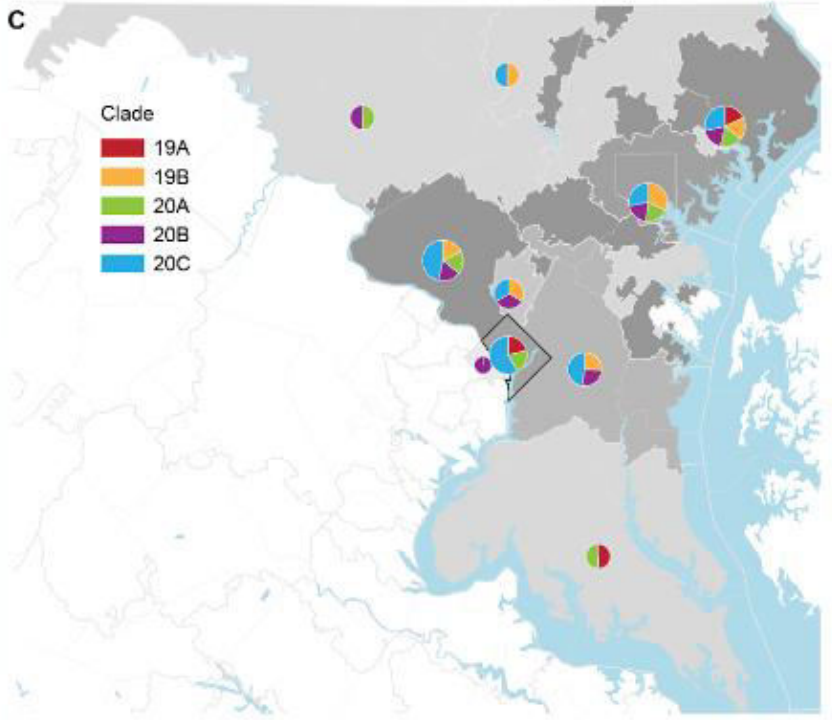
Genetic variation in the Baltimore-Washington DC area was as varied as the worldwide variation of SARS-CoV-2

This suggests that many different introductions of SARS-CoV-2 occurred early in the epidemic

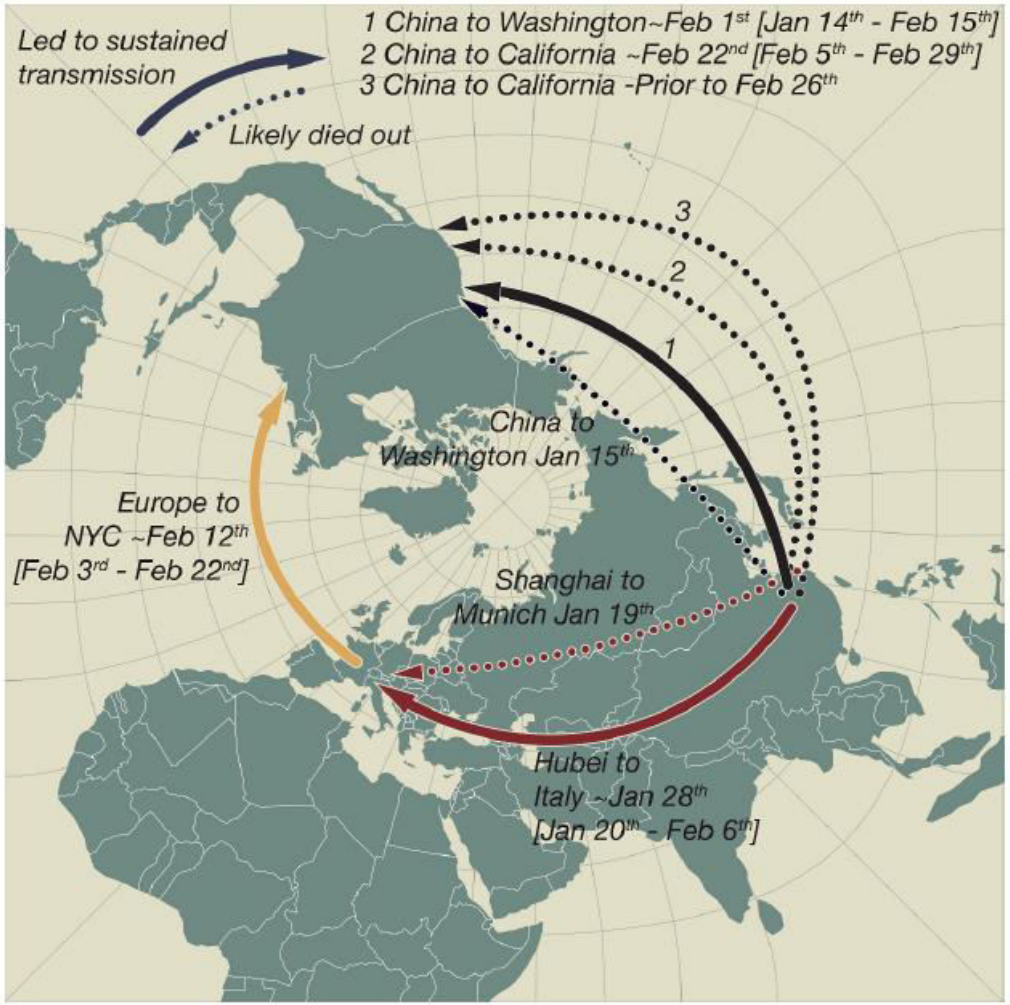
Thielen PM et al medRxiv

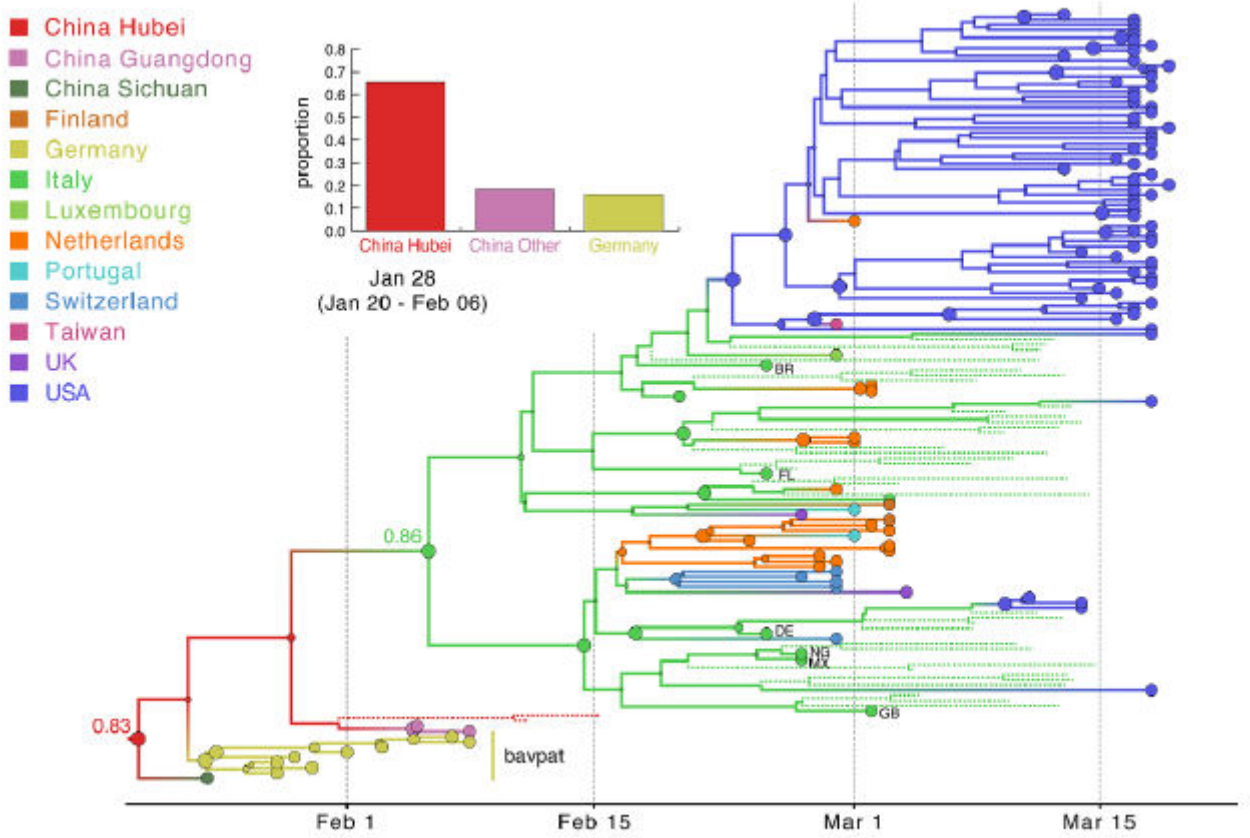






SARS-CoV-2 Emergence in Europe and North America





Worobey M et al Science 2020

Conclusions

- Nucleic acid and serologic assays for SARS-CoV-2 are good, but have limitations
  - ➢ Assays are imprecise
    - Timing of sample collection effects assay performance
    - Sample collection – COVID-19 is primarily a pulmonary disease; oral/nasal samples may not detect infection
      - This impacts sensitivity of RNA and antigen assays
    - Asymptomatic individuals infected people never seroconvert
    - Antibodies fade over time in many infected persons
  - ➢ Further evaluation of assay performance is needed in low- and middle-income countries
  - ➢ Supply chain problems limit the availability of tests for diagnosis, contract tracing, and surveillance
- Molecular epidemiologic studies provide critical information for understanding the evolution and spread of the COVID-19 pandemic

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ACKNOWLEDGEMENTS

Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH) under Award Numbers UM1AI068619 (HPTN Leadership and Operations Center), UM1AI068617 (HPTN Statistical and Data Management Center), and UM1AI068613 (HPTN Laboratory Center).

Additional support was provided by the Division of Intramural Research, NIAID, NIH.