

Strategies to support the COVID-19 response in LMICs

A virtual seminar series

Resource Page

COVID-19 Diagnostics

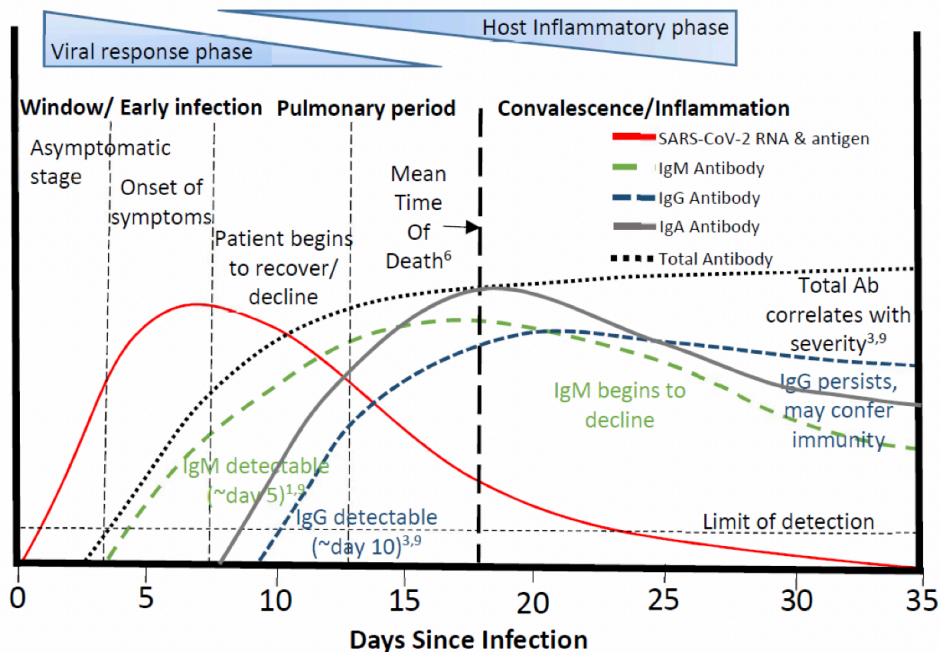
Presented by: Yukari Manabe, MD

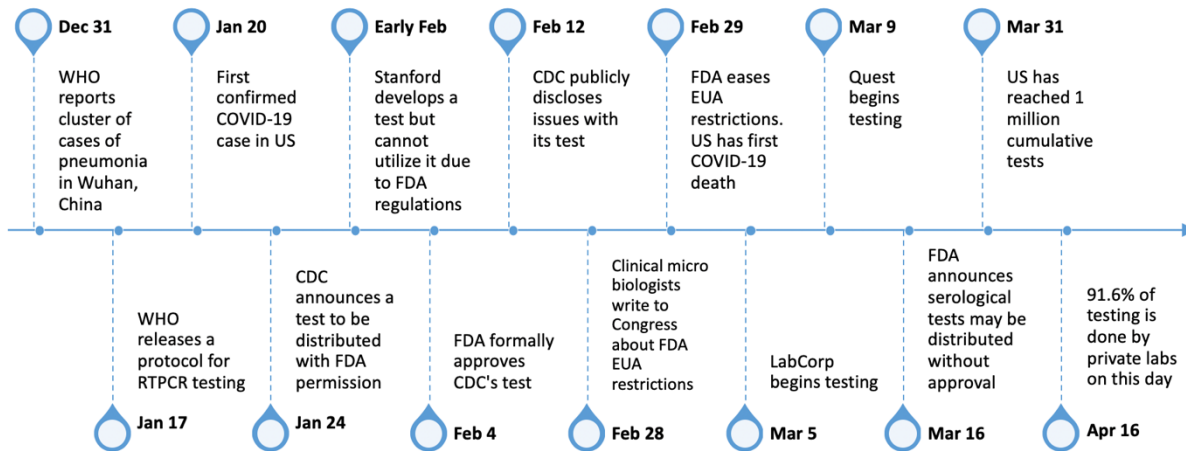
Associate Director of Global Health Research and Innovation

Summary/Key Points:

- There have been many hurdles to achieving widespread and reliable testing for diagnosing COVID-19 infection.
- The private sector has expanded to perform the vast majority of testing in the United States.
 - For example, on April 16th, 91.6% of testing was performed by the private sector.^{1,2}
- Globally, rates of testing are lower in lower income countries. This data makes it difficult to interpret lower case counts in these countries.
- There are two major types of testing: molecular testing and serologic testing.
- Molecular testing (ex. RT-PCR) is aimed at detecting various genes in the SARS-CoV2 viral genome.
- Global Issues with Molecular Testing:
 - Limited Lab Capacity - Only reference labs do RT-PCR testing
 - Countries with strong global health security programs have hub and spoke specimen transport that has been activated for COVID-19
 - Nasopharyngeal swabs rarely performed - need to validate sample types including self-collected, oropharyngeal, nasal
 - Global swab shortages
 - Biosafety concerns with getting samples
 - COVID-19 patient disposition – isolation difficult in crowded households
- Viral load is correlated with severity of disease.
 - 90% of patients with mild disease tested RT-PCR negative by day 10 after symptom onset. All patients with severe disease tested positive at or after day 10.³
- The relationship between viral load and culture positivity is still being investigated.

- Serological testing comes in three varieties: Rapid Diagnostic Tests, ELISA, and Neutralization assays.
- As of this writing, only 8 tests have been approved via FDA Emergency Use Authorization. There is variation in which antigens are detected by these assays (Spike 1, Spike 2, receptor binding domain, and nucleocapsid protein). Uncertainty remains about the preferred antigen for obtaining optimal sensitivity and specificity. Serial testing of multiple antigens, beginning with those with increased sensitivity for any coronavirus (such as nucleocapsid), followed by those with increased specificity for SARS-CoV 2 (such as Spike 1 or receptor binding domain).
- Serological Test Use Cases – Individual
 - Diagnose infection in patients who are NP swab RT-PCR negative with symptoms for more than 10-14 days.
 - Show COVID-19 exposure in a person with a plausible suspected infection in the recent past
 - Essential workers (e.g., healthcare workers, workers that interact with vulnerable populations like nursing homes)
- Correlation of serological testing with protective immunity is unknown.
- There are also studies to suggest up to 5% of people do not mount a strong serological response to COVID-19 infection.^{4,5} This would suggest that serological tests may not be a reliable measure of





Online resources:

- CDC COVID-19: <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html>
- FIND COVID Tracker: https://finddx.shinyapps.io/FIND_Cov_19_Tracker/
- Our World in Data has information on testing, cases, and mortality worldwide: <https://ourworldindata.org/grapher/three-day-daily-tests-per-thousand-since-1-per-mil-confirmed-cases>

References:

1. "Testing in the U.S." Centers for Disease Control and Prevention. Updated April 29, 2020. Accessed April 27, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html>
2. "Daily Testing per 1000 People." Our World in Data. Updated April 29, 2020. Accessed April 27, 2020. <https://ourworldindata.org/grapher/three-day-daily-tests-per-thousand-since-1-per-mil-confirmed-cases>
3. Liu Y, Yan L-M, Wan L, et al. Viral dynamics in mild and severe cases of COVID-19. *Lancet Infect Dis*. doi:10.1016/S1473-3099(20)30232-2
4. Wu F, Wang A, Liu M, et al. Neutralizing antibody responses to SARS-CoV-2 in a COVID-19 recovered patient cohort and their implications. *medRxiv*. January 2020:2020.03.30.20047365. doi:10.1101/2020.03.30.20047365
5. Zhao J, Yuan Q, Wang H, et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. *Clin Infect Dis*. 2020;(ciaa344). doi:10.1093/cid/ciaa344

Resource page created by Carolyn Reuland, Johns Hopkins University School of Medicine

