COVID-19 Diagnostics
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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
  o Diagnose infection in patients who are NP swab RT-PCR negative with symptoms for more than 10-14 days.
  o Show COVID-19 exposure in a person with a plausible suspected infection in the recent past
  o 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. This would suggest that serological tests may not be a reliable measure of

![Image of viral response phase and host inflammatory phase with a timeline of days since infection showing the detection of IgM and IgG antibodies.]
Online resources:

- FIND COVID Tracker: [https://finddx.shinyapps.io/FIND_Cov_19_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](https://ourworldindata.org/grapher/three-day-daily-tests-per-thousand-since-1-per-mil-confirmed-cases)

References:


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