



COVID-19 Diagnostic Testing Policy Recommendations

IIDSA appreciates that HHS (including CDC and FDA), Congress, and laboratories (i.e. public health, commercial and academic) are working hard to expand testing capacity for COVID-19. Testing capacity, however, remains insufficient. IIDSA recommends the following policies and investments to guarantee sufficient capacity for rapid, broad deployment of near-patient testing for this and future outbreaks. Inadequate access to testing (including delayed deployment of tests and slow turnaround time) severely limits our understanding of the prevalence, severity, mortality and transmission of respiratory viruses and negatively impacts patients, limits our ability to provide for their care and contain the spread of infection, and may cause unnecessary use of scarce resources such as negative pressure rooms and personal protective equipment (PPE).

- Enable testing venues that will limit exposure of individuals seeking testing to other patients (e.g. external tents, drive-through testing).
- Prices of testing must be transparent and public and private insurers or governmental resources must cover testing. CMS recently developed new codes for reimbursement of COVID-19 tests (CDC test and non-CDC test). Several private insurance companies have agreed to waive copays coronavirus testing. These are critical steps forward. Cost must not be a barrier to testing for patients, including the uninsured and underinsured. Pre-approval requirement for testing by insurers should not be allowed. Reduce other barriers to testing where appropriate, including requirements for face-to-face visits.
- Reduce regulatory barriers to test development by academic clinical laboratories that have demonstrated experience developing, validating and performing laboratory developed tests (LDTs). High complexity academic clinical laboratories that already offer LDTs should be designated as “overflow laboratories” by public health authorities, pre-qualified and permitted to develop and use LDTs within their local communities for COVID-19 (and future public health emergencies), either without FDA review or with a more streamlined, inexpensive, and rapid FDA review. This system can allow CDC to emphasize quality control while reducing the burden on CDC and public health laboratories to conduct all testing in house. Recent improvements to the FDA EUA process are an important step forward, and the following steps would further increase testing capacity:
 - Such laboratories that utilize CDC protocol’s primers should be given flexibility on nucleic acid extraction methods, and amplification instruments;
 - Regulatory paperwork requirements must be reduced and streamlined; and
 - CDC (or other appropriate federal agency) should prioritize making materials (e.g., inactivated virus, sequences, synthetic targets, spiked samples) easily and quickly available to such laboratories for test development.
 - FDA should review Emergency Use Authorization submissions within 1-2 business days when such submissions are required.

- Standardized validation materials (e.g. quantitated, inactivated virus) should be made available to clinical laboratories and diagnostic test manufacturers to assess analytical test performance. It may be necessary to update these materials if the virus changes over time.
- Ensure long-term capacity of academic clinical laboratories to rapidly develop tests in response to emerging threats, particularly to fill gaps that public health laboratories cannot fill and to ensure widespread access to near-patient testing capable of producing rapid results. Legislation to reform diagnostics regulation must not limit patient access to testing and should include the flexibility described above for academic clinical laboratories.
- Funding allocated in the emergency supplemental appropriations bill should be rapidly distributed to academic clinical laboratories to assist with rapid scale up in testing capacity (e.g. to hire support to navigate regulatory processes and additional staff to perform the increased numbers of tests, to purchase new equipment, etc.)
- The FDA should expedite review of COVID-19 assays adapted to existing molecular diagnostic testing platforms, including those that are near-to-care and low complexity with short (20 min - 1hr) turnaround times.
- CDC should publicly disclose the number of cases tested in order to better gauge the significance of the number of positives and help determine whether states that have few or no reported cases truly have low or no prevalence or whether low reporting is due to undertesting. This will in turn inform how aggressive testing needs to be in specific areas. In areas with community transmission, testing should be more aggressive, less restrictive.
- The FDA should address rapid pathways for incorporating new targets into established NAAT testing platforms, since those platforms may offer near point of care testing, reduced complexity and risk of contamination or high throughput.

Critical Questions Needing Rapid Answers for Clinicians:

- Determine COVID-19 transmission process (e.g. airborne, droplet or contact). Airborne isolation requires significantly more resources and infrastructure than droplet or contact precautions. Requiring only droplet or contact isolation will reduce the burden associated with COVID-19 infected patient diagnosis and management and will have significant implications for outpatient care as well. One opportunity to inform this decision may be for CDC to conduct air sampling on the cruise ship quarantined off the coast of California.
- If it is determined that only droplet or contact precautions are required, clarify whether N-95 masks or PAPR (powered, air purifying respirators) would be need for specimen collection.
- Define best sampling approach for diagnostic accuracy. Comparative diagnostic accuracy (i.e. sensitivity, specificity) of throat or nasal/naso-pharyngeal swabs, naso-pharyngeal aspirates and/or lower respiratory samples (if bronchoscopy conducted) should be rapidly addressed. Pooling of samples to conserve testing resources should be rapidly explored. Establishing whether a single test (at one timepoint) is sufficient for ruling out infection in an asymptomatic adult vs child is needed.
- Define the kinetics and sites of viral replication in adults and children. Understanding the timing, site and quantity of virus in the body will help determine if and how molecular tests can

be used to screen asymptomatic patients for infection. This information is critical when triaging potentially exposed patients, determining optimal duration of quarantine.

- Determine the shedding period and transmission potential before symptom onset and after resolution of symptoms.
- Determine the analytic performance of the CDC COVID-19 assays. Defining the sensitivity/specificity of the CDC COVID-19 assay is necessary to inform public health officials, clinicians, and clinical laboratories on prevention and management of COVID-19.
- Determine appropriate guidance on return-to-work testing for healthcare workers who have been exposed to COVID-19 or infected, particularly individuals with minor or moderate symptoms who may not meet criteria for testing.