COVID-19 Prioritization of Diagnostic Testing

Updated: March 17, 2020

On March 4, CDC guidance expanded testing to a wider group of symptomatic patients, dependent on the physician's judgment of need for testing, clinical course of infection, local epidemiology of COVID-19 infections and results of testing for other causes of respiratory illness (e.g., influenza). FDA has also published these Frequently Asked Questions, which provide useful information on diagnostic testing for COVID-19.

Given current limited availability of near-patient, or point-of-care, testing, IDSA has developed recommendations for diagnostic testing prioritization. These recommendations will likely change as testing becomes more widely available or as new information becomes available. IDSA continues to advocate for policies and investments to expand capacity to testing.

Tier 1:

- Critically ill patients receiving ICU level care with unexplained viral pneumonia or respiratory failure, regardless of travel history or close contact with suspected or confirmed COVID-19 patients;

- Any person, including health care workers, with fever or signs/symptoms of a lower respiratory tract illness **and** close contact with a laboratory-confirmed COVID-19 patient within 14 days of symptom onset (including all residents of an LTC facility that has a laboratory confirmed COVID-19 case);

- Any person, including health care workers, with fever or signs/symptoms of a lower respiratory tract illness **and** a history of travel within 14 days of symptom onset to geographic regions where sustained community transmission has been identified.

- Individuals with fever or signs/symptoms of a lower respiratory tract illness who are also immunosuppressed (including patients with HIV), elderly, or have underlying chronic health conditions.

- Individuals with fever or signs/symptoms of a lower respiratory tract illness who are critical to pandemic response, including health care workers, public health officials and other essential leaders.

Tier 2: Hospitalized (non-ICU) patients and long-term care residents with unexplained fever **and** signs/symptoms of a lower respiratory tract illness. The number of confirmed COVID-19 cases in the

community should be considered. As testing becomes more widely available, routine testing of hospitalized patients may be important for infection prevention and management at discharge.

Tier 3: Patients in outpatient settings who meet the criteria for influenza testing. This includes individuals with co-morbid conditions including diabetes, COPD, congestive heart failure, age >50, immunocompromised hosts among others. Given limited available data, testing of pregnant women and symptomatic children with similar risk factors for complications is encouraged. The number of confirmed COVID-19 cases in the community should be considered.

Tier 4: Community surveillance as directed by public health and/or infectious diseases authorities.

Overall, current prevalence of COVID-19 disease in the United States remains low. Thus, in interpretation of diagnostic test results, clinicians should consider that when disease prevalence is low, false-positive results of testing are increased. Typically, false positive rates of testing are increased when disease prevalence is below 15-20%. If false positive is suspected, test should be repeated (with a new specimen if possible) or a test using a second assay that targets a different gene should be performed.

Currently Available COVID-19 Diagnostic Tests and Limitations

- Send testing to CDC or state/local public health laboratories: Limitation: significant delays in deployment of testing. Delays patient care and containment measures and leads to inefficient use of scarce resources such as negative pressure rooms and personal protective equipment (PPE)
- Send testing to commercial reference laboratory. Limitations: turnaround time and cost not yet defined
- Develop local, hospital-based tests (LDTs). These tests may be based on the CDC, WHO, or manufacturer assays or created de novo. Limitation: Laboratories pursuing this route must perform an assay validation and pursue an FDA Emergency Use Authorization (EUA). The recent FDA guidance allowing laboratories to use validated tests while their EUA is under review is very helpful, yet still portends an excessive regulatory burden. Further, many reagents, primers and other components needed for LDT assays are on back-order.