COVID-19 Testing in the U.S.

According to the Centers for Disease Control and Prevention (CDC) as of 3/29/2020, there have been 122,653 reported cases of COVID-19 in the U.S. and its territories.\(^1\) According to the CDC, they have performed 4,750 tests compared to 125,653 performed by public health labs across 49 states.\(^2\) Due to the limit in available tests, the CDC has provided recommendations on prioritizing who should get tested.\(^3\)

Who should be tested:

- Because most people have mild illness and can recover at home and there is no treatment specifically approved for COVID-19 and care is supportive, not everyone needs to be tested for the virus.
- The CDC and World Health Organization (WHO) provide guidance on who should be tested
- However, decisions about testing are at the discretion of state and local health departments and/or individual clinicians.
  - Directory of Local Health Departments: [https://www.naccho.org/membership/lhd-directory](https://www.naccho.org/membership/lhd-directory)
  - Directory of State Health Departments: [https://www.cste.org/page/EpiOnCall](https://www.cste.org/page/EpiOnCall)

Collection of Diagnostic Respiratory Specimens:

Once the decision has been made to test for COVID-19 in symptomatic or high priority patients the CDC has the following guidelines.\(^4\)

- A nasopharyngeal specimen is the preferred choice for swab-based SARS-CoV-2 testing.
  - If it is not possible to collect a nasopharyngeal swab, then the following are acceptable alternatives.
    - An oropharyngeal (OP) specimen collected by a healthcare professional
    - A nasal mid-turbinate (NMT) swab collected by a healthcare professional or by onsite self-collection (using a flocked tapered swab)
    - An anterior nares specimen collected by a healthcare professional or by onsite self-collection (using a round foam swab)
- CDC also recommends testing lower respiratory tract specimens, if available. For patients who develop a productive cough, sputum should be collected and tested for SARS-CoV-2. The induction of sputum is not recommended. When it is clinically indicated (e.g., those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage sample should be collected and tested as a lower respiratory tract specimen.
The CDC website has additional guidelines depending on the method used to obtain the test specimen. These guidelines are related to how much specimen should be collected and how to properly store and ship specimens to the lab for testing.

**How to interpret existing COVID-19 test: results**
The CDC fact sheet includes information related to the suggestions for addressing positive, negative, false positive, or false-negative COVID-19 results. Additionally, there are helpful links and information posted on the CDC website for laboratories. For a picture of the CDC test kit see Attachment 2.

- A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

- A negative test result for this test means that SARS-CoV RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.

**Food and Drug Administration Approved COVID-19 Test:**
The Food and Drug Administration has released details about new policies to help approve more COVID-19 diagnostic tests to increase the amount available.

- Following the Emergency Use Authorization (EUA) to enable broader emergency use of the CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel on February 4th, 2020, the FDA has issued 20 diagnostic EUAs and the list of all FDA approved diagnostic EAU as of March 30th, 2020 are listed in Attachment 3).

- Most test kits can be used to test direct nasal, nasopharyngeal, or throat swabs and nasal, nasopharyngeal or throat swabs eluted in viral transport media. Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website.

**Bottleneck in getting faster results:**

- As new avenues on conducting a rapid test evolves, one of the major bottlenecks slowing down test results is availability of the supplies. As more testing labs ramp up, we could expect more shortage of the supplies and reagents to conduct these tests. As a reminder, the Academy encourages Dermatologist to donate their viral transport medium (VTM) or nasal swaps. (AAD Guidance to donate VTM supplies)
Attachment 1. CDC’s Priorities for Testing Patients with suspected COVID-19 Infection

Priorities for Testing Patients with Suspected COVID-19 Infection

COVID-19 Symptoms: Fever, Cough, and Shortness of Breath

**Priority 1**
Ensures optimal care options for all hospitalized patients, lessen the risk of healthcare-associated infections, and maintain the integrity of the U.S. healthcare system
- Hospitalized patients
- Healthcare facility workers with symptoms

**Priority 2**
Ensures those at highest risk of complication of infection are rapidly identified and appropriately triaged
- Patients in long-term care facilities with symptoms
- Patients 65 years of age and older with symptoms
- Patients with underlying conditions with symptoms
- First responders with symptoms

**Priority 3**
As resources allow, test individuals in the surrounding community of rapidly increasing hospital cases to decrease community spread, and ensure health of essential workers
- Critical infrastructure workers with symptoms
- Individuals who do not meet any of the above categories with symptoms
- Healthcare facility workers and first responders
- Individuals with mild symptoms in communities experiencing high numbers of COVID-19 hospitalizations

**Non-Priority**
- Individuals without symptoms

For more information visit: coronavirus.gov
Attachment 2. This is a picture of the CDC’s laboratory test kit for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Attachment 3. In Vitro Diagnostics EUAs Approved by the FDA (Updated March 30, 2020)

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<thead>
<tr>
<th>Date EUA Issued</th>
<th>Manufacturer</th>
<th>Diagnostic (Letter of Authorization)</th>
<th>Fact Sheet for Healthcare Providers</th>
<th>Fact Sheet for Patients</th>
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References