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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
    - The CDC provides clinical criteria for considering testing for COVID-19 (See Attachment 1): https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
    - Coronavirus disease (COVID-19) technical guidance: Laboratory testing for 2019-nCoV in humans: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance
- 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
    - Directory of State Health Departments: 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.[5] Additionally, there are helpful links and information posted on the CDC website for laboratories.[6] 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 SARSCoV-2 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:

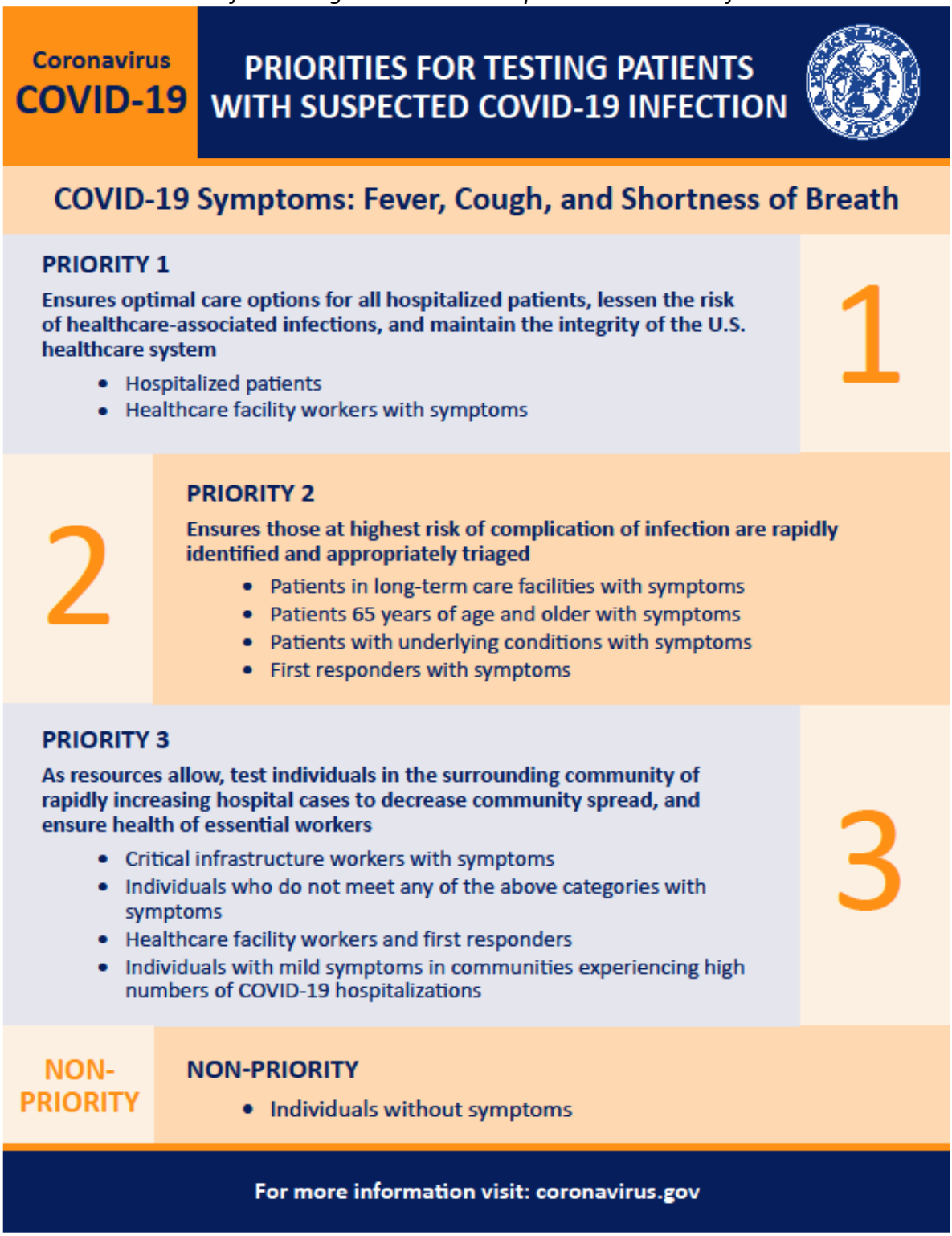
The Food and Drug Administration has released details about new policies to help approve more COVID-19 diagnostic tests to increase the amount available.[7]

- 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.[8] (AAD Guidance to donate VTM supplies)

Attachment 1. CDC's Priorities for Testing Patients with suspected COVID-19 Infection



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)

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Fact Sheet for Healthcare Providers	Fact Sheet for Patients	Package Insert
03/27/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19	Healthcare Providers	Patients	IFU
03/18/2020	Abbott Molecular	Abbott RealTime SARS-CoV-2 assay	Healthcare Providers	Patients	IFU
03/25/2020	Avellino Lab USA, Inc.	AvellinoCoV2 test	Healthcare Providers	Patients	EUA Summary
03/26/2020	BGI Genomics Co. Ltd	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV	Healthcare Providers	Patients	IFU
03/23/2020	BioFire Defense, LLC	BioFire COVID-19 Test	Healthcare Providers	Patients	IFU
02/04/2020	Centers for Disease Control and Prevention's (CDC)	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC)	Healthcare Providers	Patients	IFU
03/20/2020	Cepheid	Xpert Xpress SARS-CoV-2 test	Healthcare Providers	Patients	IFU for Labs IFU for Point-of-Care

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Fact Sheet for Healthcare Providers	Fact Sheet for Patients	Package Insert
03/19/2020	DiaSorin Molecular LLC	Simplexa COVID-19 Direct assay	Healthcare Providers	Patients	IFU
03/19/2020	GenMark Diagnostics, Inc.	ePlex SARS-CoV-2 Test	Healthcare Providers	Patients	IFU
03/16/2020	Hologic, Inc.	Panther Fusion SARS-CoV-2	Healthcare Providers	Patients	IFU
03/16/2020	Laboratory Corporation of America (LabCorp)	COVID-19 RT-PCR Test	Healthcare Providers	Patients	EUA Summary
03/27/2020	Luminex Molecular Diagnostics, Inc.	NxTAG CoV Extended Panel Assay	Healthcare Providers	Patients	IFU
03/23/2020	Mesa Biotech Inc.	Accula SARS-Cov-2 Test	Healthcare Providers	Patients	IFU
03/24/2020	PerkinElmer, Inc.	PerkinElmer New Coronavirus Nucleic Acid Detection Kit	Healthcare Providers	Patients	IFU
03/20/2020	Primerdesign Ltd.	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Healthcare Providers	Patients	IFU
03/17/2020	Quest Diagnostics Infectious Disease, Inc.	Quest SARS-CoV-2 rRT-PCR	Healthcare Providers	Patients	IFU
03/17/2020	Quidel Corporation	Lyra SARS-CoV-2 Assay	Healthcare Providers	Patients	IFU
03/12/2020	Roche Molecular Systems, Inc. (RMS)	cobas SARS-CoV-2	Healthcare Providers	Patients	IFU
03/13/2020	Thermo Fisher Scientific, Inc.	TaqPath COVID-19 Combo Kit	Healthcare Providers	Patients	IFU
02/29/2020	Wadsworth Center, New York State Department of Public Health's (CDC)	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	Healthcare Providers	Patients	IFU

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