

COVID-19 Testing for First Responders

Product (EMS42) Purpose

This document provides a brief overview of COVID-19 testing to inform decision-making for first responders including emergency medical service (EMS), Fire & Rescue, Law Enforcement and 911 telecommunicators.

Developed By

The Federal Healthcare Resilience Task Force (HRTF) is leading the development of a comprehensive strategy for the U.S. healthcare system to facilitate resiliency and responsiveness to the threats posed by COVID-19. The Task Force's EMS/Pre-Hospital Team is comprised of public and private-sector EMS and 911 experts from a wide variety of agencies and focuses on responding to the needs of the pre-hospital community. This team is composed of subject matter experts from the National Highway Traffic Safety Administration (NHTSA) Office of Emergency Medical Services (OEMS), National 911 Program, Federal Emergency Management Agency (FEMA), U.S. Fire Administration (USFA), U.S. Army, U.S. Coast Guard (USCG), Department of Homeland Security (DHS) Cybersecurity and Infrastructure Security Agency (CISA) and non-federal partners representing stakeholder groups. Through collaboration with experts in related fields, the team develops practical resources for field providers, supervisors, administrators, medical directors, and associations to better respond to the COVID-19 pandemic.

Intended Audience

State, Local, Tribal, and Territorial Governments (SLTTs), First Responders (Law Enforcement, Fire & Rescue, Emergency Medical Services (EMS) and 911 communication personnel).

Expected Distribution Mechanism

EMS.gov, Stakeholder Calls, EMS stakeholder organization's membership distribution Email mechanisms, USFA website, Social Media posts. Request assistance distributing to FEMA/HHS RECs

Internal Routing Review

NRCC (for approval), All ESFs and HCRTF Teams & Threads (for SA only)

Primary Point of Contact

NHTSA Office of EMS, nhtsa.ems@dot.gov, 202-366-5440

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Federal Healthcare Resilience Task Force

EMS/Prehospital Team

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Purpose: This document provides a brief overview of COVID-19 testing to inform decision-making for first responders including emergency medical service (EMS), Fire & Rescue, Law Enforcement and 911 telecommunicators.

1. Overview of testing for SARS-CoV-2 (the virus that causes the disease COVID-19): The Food and Drug Administration (FDA) is the U.S. government entity responsible for regulating medical devices, including tests and devices like those being used to detect SARS-CoV-2. Because of the public health emergency caused by a previously unknown novel coronavirus, the FDA has issued multiple Emergency Use Authorizations (EUA) for various types of medical devices, including tests. Final validation of these tests still need to be completed through all of the normal FDA clearance criteria and received approval or clearance by the FDA under the traditional marketing pathways approval processes at this time. A list of tests which have been issued EUAs is available at [EUA Information: FDA.gov](#).
2. Types of Testing:
 - **Molecular:** The molecular diagnostic tests look for evidence of an active infection by detecting either the genetic material of the pathogen or a unique marker of it. This type of test detects signs of the virus's genetic material. One type of molecular testing uses is called a reverse transcriptase – polymerase chain reaction (RT-PCR) for pathogen detection. This approach requires only a small sample size of the pathogen (ex. from blood or saliva) and amplifies segments of the virus' genetic code and replicates it in order to be show it is present more easily detected. A positive result indicates the presence of actual infectious viral material in the body. However, these results cannot alone determine if the pathogen remains viable (e.g., infective) or is dead and no longer infective. The presence of such material does not necessarily indicate if the patient is infectious (although for provider safety, patients with a positive test should be presumed infectious) but simply that such material is there. Test samples are usually obtained from humans using a special nasal swab designed for this purpose.
 - **Antigen:** The antigen diagnostic tests quickly detect fragments of pathogen proteins found on or within the virus from testing samples collected from humans, often from a swab of the nasopharyngeal cavity using swabs. However, antigen tests may not detect all active infections. Antigen tests are very specific for the virus but are often not as sensitive as molecular RT-PCR tests because of the certainty of positive samples used to develop the actual test. This means that while positive results from antigen tests are generally highly quite accurate, but there is also a higher chance of false negatives – which means falsely claiming absence of infection, thus negative results do not rule out infection. Until well-

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validated antigen testing is available, negative results from this approach may warrant confirmatory testing using a molecular test (i.e. an antigen test may need to be confirmed with a RT-PCR test prior to making treatment decisions or to help prevent the possible spread of the virus due to a false negative).

- Serological: The serology tests look for the presence of antibodies, which are specific proteins made in response to an infection as part of the body's attempt to fight that infection. It does not specifically indicate current (active) disease. It is important to remember that development of antibodies takes some time to develop after exposure to the infection, usually weeks. There are also different types of antibodies that are developed and can be tested for individually (ie. IgG, IgM). Depending on when someone was infected and the timing of the test, antibodies may not have developed in sufficient quantities to be detected by the test. We currently don't know if detection of antibodies, and at what level, indicates immunity, and/or protection, from a future exposure. Similarly, there is also, another concern that any detected antibodies may instead reflect other strains of a more commonly occurring coronaviruses, such as those causing which causes some variations of the common cold.

3. Testing Limitations: No test is 100% accurate 100% of the time.

- a. **Specificity:** Specificity is a measures of a test's ability to correctly generate a *negative* result for people who *don't* have the condition that's being tested for (also known as the "true negative" rate). A high-specificity test will correctly rule out almost everyone who *doesn't* have the disease when the test is negative and won't generate a high percentage of false-positive results. (Example: a test with 90% specificity will correctly return a negative result for 90% of people who don't have the disease but will return a positive result — a false-positive — for 10% of the people who don't have the disease and should have tested negative – which is termed a false positive result.)
- b. **Sensitivity:** Sensitivity is a measures of how often a test correctly generates a positive result for people who have the condition that's being tested for (also known as the "true positive" rate). A test that's highly sensitive will identify almost everyone who has the disease and not generate many false-negative results. (Example: a test with 90% sensitivity will correctly return a positive result for 90% of people who have the disease but will return a negative result — a false-negative — for 10% of the people who have the disease and should have tested positive, or a false negative.)
- c. There are currently a variety of tests which have not been reviewed by FDA but may be purchased to test for COVID-19. The concern with false negatives relates to the higher potential for future transmission whereas the concern for a false positive relates to unnecessary additional diagnostic or medical procedures for the patient and wasted unnecessary PPE use for the provider and a false negative result could lead to

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additional exposure to contacts of the patient, including first responders and EMS personnel.

4. Testing Evaluation Tips:

- a. Testing for first responders and EMS clinicians should be coordinated with the EMS Medical Director and other local/state public health agencies.
- b. Check the FDA site ([COVID-19 Testing EUA Recipients](#)) to determine whether the test you are considering purchasing has received an EUA by the FDA.
- c. Work with the EMS Medical Director to identify the test error rate to determine whether the results can be relied upon and if actions can be made with the data obtained.
- d. Purchase tests only through verified suppliers to ensure authenticity. There have been reports of counterfeit tests being sold to unsuspecting clients.
- e. Follow the test instructions exactly to avoid increasing the error rate and to achieve full test performance. Use Clinical Laboratory Improvement Amendments (CLIA)-certified labs for test processing, if required based on the specific test.

5. Research References:

CDC Serology Testing: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

Emergency Use Authorizations: <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices>

FAQs on Diagnostic Testing for SARS-CoV-2: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>

FDA Contact Information on Testing:

- Toll-free line 24 hours a day: 1-888-INFO-FDA option *;
- Email to report shortages: deviceshortages@fda.hhs.gov;

Email applicable diagnostic tests: COVID19DX@FDA.HHS.GOV

FDA Statement Regarding COVID-19 Antigen Testing: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-antigen-test-help-rapid-detection-virus-causes>

Serology Test FAQs: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#serology>

CDC recommendations for the Testing of COVID 19: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html>

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Infectious Disease Society of America (IDSA) primer on serological testing :

<https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf>*

Guidance on Interpreting COVID-19 Test Results: <https://www.whitehouse.gov/wp-content/uploads/2020/05/Testing-Guidance.pdf>

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