

UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

JAN 1 1 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Force Health Protection Guidance (Supplement 15) – Department of Defense Guidance for Coronavirus Disease 2019 Laboratory Testing Services

- References: (a) Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 13) Department of Defense Guidance for Coronavirus Disease 2019 Clinical Laboratory Diagnostic Testing Services," August 24, 2020 (hereby rescinded)
 - (b) Under Secretary of Defense Memorandum, "Force Health Protection Guidance (Supplement 11) Department of Defense Guidance for Coronavirus Disease 2019 Surveillance and Screening with Testing," June 11, 2020
 - (c) DoD COVID-19 Task Force Memorandum, "Optimization of COVID-19 Testing Resources," December 8, 2020
 - (d) Department of Defense Instruction (DoDI) 6440.02, "Clinical Laboratory Improvement Program (CLIP)," May 29, 2014
 - (e) DoDI 6040.45, "DoD Health Record Life Cycle Management," November 16, 2015
 - (f) DoDI 6055.01, "DoD Safety and Occupational Health (SOH) Program," October 14, 2014
 - (g) Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 8) Department of Defense Guidance for Protecting Personnel in Workplaces during the Response to the Coronavirus Disease 2019 Pandemic," April 13, 2020
 - (h) Under Secretary of Defense for Personnel and Readiness Memorandum "Force Health Protection Guidance (Supplement 14) Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic," December 29, 2020

This memorandum updates previous DoD coronavirus disease 2019 (COVID-19) laboratory testing guidance and rescinds reference (a). This force health protection (FHP) supplement provides guidance on COVID-19 testing for eligible persons suspected of having contracted COVID-19, and applies Centers for Disease Control and Prevention (CDC) testing guidance in the DoD context. DoD Components will continue to employ clinical diagnostic testing in accordance with this guidance. This guidance also supports surveillance testing and screening testing (asymptomatic individuals) conducted to decrease operational risk within DoD, consistent with applicable law and in accordance with reference (b). The Secretaries of the Military Departments, the Heads of the Office of the Secretary of Defense (OSD) or DoD

¹ Testing in this guidance refers to tests that utilize molecular, or in certain limited circumstances antigen, testing methods.

Components, and the Commanders of the Geographic Combatant Commands may implement more restrictive guidance and additional FHP measures based on mission requirements and local risk assessments in consultation with their medical staffs and appropriate public health authorities.

Testing Considerations

- Healthcare providers will use their clinical judgment and awareness of laboratory testing resource availability, and will work closely with local and installation public health authorities or Public Health Emergency officers to guide COVID-19 diagnostic testing. See the attachment for case management and disposition guidance. Providers are encouraged to test for other causes of respiratory illness as clinically indicated. The CDC testing priorities may be found at:

 https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html.
- Asymptomatic individuals may be tested based on a clinician's judgment and as deemed appropriate by public health professionals and in accordance with reference (c).
- DoD Components must ensure appropriate infection prevention and control procedures are followed throughout the entire testing process. This includes employing the appropriate biosafety precautions when collecting and handling specimens, consistent with CDC guidance.

DoD Laboratories and Tests

- Overall DoD COVID-19 testing capabilities are synchronized by the DoD COVID-19 Task Force (CVTF) Diagnostics and Testing (D&T) Line of Effort (LOE). The CVTF D&T LOE may be contacted at: dha.ncr.ha-support.mbx.cvtf-diagnostics-testing@mail.mil.
- DoD is committed to maximizing testing capability for operational needs, in accordance with reference (c), which requires standardization and synchronization across the Department. However, differences between operational environments, deployment cycles, and congregate setting limitations drive differences in testing demands to mitigate operational risk. The CVTF D&T LOE protocols should be adopted to the greatest extent practicable and, where Service-specific risk mitigation allows, in accordance with directives in this guidance. This testing includes molecular tests and, for certain limited circumstances, alternative options such as serial antigen testing.
- DoD Components will ensure that diagnostic testing and screening testing is conducted at laboratories designated by the Defense Health Agency's (DHA) Center for Laboratory Medicine Services (CLMS). CLMS manages diagnostic and

screening testing policy, certification, and exceptions in accordance with reference (d). CLMS may be contacted at: **dha.ncr.clinic-support.mbx.clms@mail.mil**.

DoD Components must comply with Food and Drug Administration (FDA) regulations for diagnostic testing and screening testing, including by complying with COVID-19 emergency use authorizations (EUAs), except when such tests are employed for risk mitigation measures as set forth in reference (c). The FDA COVID-19 EUA list is available at: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

- DoD Components may consider non-clinical, Research Use Only molecular tests² for surveillance testing using a pooled specimen testing protocol, but must coordinate such testing with the CVTF D&T LOE. Results from any positive pools will only be reported in aggregate and must not be placed into any individual's medical record. Any positive pool must be followed by testing every individual sample in that pool with an EUA-authorized molecular test, or FDA cleared or approved test (when available), and performed in a clinical laboratory registered by CLMS or an equivalent civilian laboratory in accordance with reference (d).
- EUA diagnostic and screening tests that are authorized for pooled testing for screening testing purposes may be performed at Clinical Laboratory Improvement Program-registered laboratories in accordance with the EUA.
- DoD Components must coordinate pooled testing protocols with the CVTF D&T LOE. Each Military Service will retain authority to prioritize pooled testing populations and assignments to Military Service pooled testing laboratories and resources.
- DoD Components are encouraged to employ next-generation sequencing (NGS) technology for COVID-19 surveillance testing. As with testing completed via pooled testing, testing requirements using NGS must be coordinated with the CVTF D&T LOE
- DoD Components must record COVID-19 diagnostic and screening testing results in the electronic health record or occupational health record of the individual tested in accordance with reference (e) and in accordance with applicable processes for DoD contractor personnel. DHA will assist DoD Components, as needed, to ensure this occurs.

² Research Use Only assays are products in the laboratory research phase of development, and are not approved for clinical diagnostic use (https://www.fda.gov/media/87374/download).

Eligibility of DoD Personnel, Other Beneficiaries, and Other Populations for Testing

- DoD Components may test Service members (including members of the Reserve Components when on active duty for a period of more than 30 days, or on full-time National Guard duty of more than 30 days) in accordance with this guidance.
 Reserve Component Service members on active duty for a period of 30 days or less will follow their Component's guidelines.
- DoD civilian employees (who are not otherwise DoD health care beneficiaries) may be offered testing in accordance with this guidance and reference (f) if their supervisor has determined that their presence is required in the DoD workplace.
- Eligible Military Health System beneficiaries may be offered testing in accordance with this guidance.
- DoD contractor personnel may be offered testing, subject to available funding, if such testing is necessary to support mission requirements and is consistent with applicable contracts (for example, if testing is explicitly called for under the contract, or if testing is required to access a DoD facility, the contractor personnel must access the DoD facility to perform under the contract, and the contract requires contractor personnel to abide by facility access requirements). DoD contracting officers may also modify existing contracts to require contractors to test their personnel or to permit the DoD to test their personnel as necessary to support mission requirements and subject to available funding.
- For testing of local national employees in locations outside the United States, DoD Components should refer to country-specific labor agreements or contracts and consult with supporting legal counsel for guidance and any limitations concerning such tests.

DoD FHP documents are at: https://www.defense.gov/Explore/Spotlight/Coronavirus/. My point of contact for this guidance is COL Jennifer M. Kishimori, who may be reached at (703) 681-8179 or jennifer.m.kishimori.mil@mail.mil.

Matthew P. Donovan

Attachment: As stated

Force Health Protection Supplement 15 – Attachment Clinical Testing and Case Management – COVID-19³

(Based on current Centers for Disease Control and Prevention (CDC) guidance⁴)

Testing an Individual in a Clinical Setting:

- Test based on clinical judgment and public health considerations.
 - o If laboratory positive: The individual becomes a case and must be isolated.
 - o If **laboratory negative:** The individual should be followed to ensure he/she clinically improves.
 - If **laboratory negative** and asymptomatic or **clinically improved:** The individual has no restrictions.
 - If **laboratory negative** and the individual does **NOT clinically improve or worsens**, and no other etiology is found, then consider re-testing the individual for COVID-19.

Disposition of Laboratory Confirmed or Probable Cases under Isolation:⁵

- Non-test-based criteria to discontinue isolation for symptomatic persons:⁶
 - At least one day (24 hours) has passed since the last fever without the use of feverreducing medications; and
 - o Improvement in symptoms (e.g., cough, shortness of breath); and
 - O At least 10 days have passed since symptoms first appeared for mild to moderate illness. Note: For persons with severe or critical illness or for severely immunocompromised individuals, discontinue isolation when at least 20 days have passed since symptoms first appeared, in consultation with infectious disease experts.
- Non-test-based criteria to discontinue isolation for **asymptomatic** persons not severely immunocompromised (severely immunocompromised individuals should follow the medical guidance of their provider or providers):
 - At least 10 days have passed, without the development of symptoms, since the date of the person's first positive COVID-19 diagnostic test.
 - o Follow-on negative testing does not decrease the isolation time frame.
- A **test-based** strategy is **no longer recommended to discontinue isolation**. However, providers may consider using a test-based strategy to discontinue isolation for severely immunocompromised persons, in consultation with infectious disease experts. The test-based criteria are:
 - o Resolution of fever without the use of fever-reducing medications;
 - o Improvement in symptoms (e.g., cough, shortness of breath); and
 - Negative polymerase chain reaction results from at least two **consecutive** respiratory specimens collected at least 24 hours apart.

³ This quick reference sheet applies to eligible populations as stated in this guidance.

⁴ As of January 7, 2021. DoD Components should follow the most current CDC guidance; check for updates regularly.

⁵ In locations outside of the United States, host nation policy and guidance should inform disposition of cases.

⁶ For additional information and definitions of mild, moderate, severe, and critical illness, and of severely immunocompromised, see the CDC guidance at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html.

Management of Close Contacts of a Case (as determined by contact tracing):8

- When the close contact is an eligible Service member, that Service member must be tested as soon as possible to determine if he/she is a case in accordance with guidance from healthcare personnel and/or public health authorities and based on the availability of testing resources, and must quarantine for 14 days after last contact with a confirmed case and self-monitor for symptoms of COVID-19. If symptom-free, the individual can exit quarantine after 14 days.
- The CDC recommends a quarantine period of 14 days for close contacts, but provides options to reduce this period. The Secretaries of the Military Departments, Geographic Combatant Commanders, or OSD or DoD Component Heads may exercise options to reduce the period of required quarantine if local conditions allow for reduced quarantine (e.g., low number or decreasing trend of cases in the local community), and based on a determination of acceptable risk for their respective populations, in the following manner:
 - o If local conditions allow for reduced quarantine (e.g., low number or decreasing trend of cases in the local community), test close contact eligible Service members to determine if they are a case. If negative, quarantine for 10 days without additional testing, and if symptom-free for the entire 10 days, the individual can exit quarantine at day 10. The individual will self-monitor for the full 14-day window.
 - When diagnostic testing resources are available, test close contact eligible Service members, to determine if they are a case requiring isolation. If negative, quarantine for seven days after last contact with a confirmed case. Quarantine may end at day seven if a specimen that is collected on day seven returns a negative result and the Service member remains asymptomatic through day seven. The individual must remain in quarantine until test results are obtained. A positive test result requires that the individual be managed as a confirmed case and contact tracing will be initiated. If test results are unable to be returned in a timely fashion, then revert to the 10 day no-test option for reduced quarantine.
- Exceptions to the above protocols for asymptomatic personnel whose presence is required in the workplace may be considered in accordance with reference (g).
- In all situations and for all quarantine durations, for a full 14 days after last contact with a confirmed case, Service members must continue to self-monitor, wear cloth face coverings (without an exhalation valve), and practice strict adherence to all non-pharmaceutical intervention mitigation strategies, including avoiding crowds and practicing physical distancing, hand and cough hygiene, maintaining adequate indoor ventilation, and environmental cleaning and disinfection. In addition, Service members located outside the United States identified as close contacts must follow host-nation policies, as applicable.

⁷ Close contact is defined as someone who was within six feet of a person who has contracted COVID-19 for a cumulative total of 15 minutes or more over a 24-hour period starting from 2 days before illness onset (or, for asymptomatic patients, two days prior to test specimen collection) until the time the patient is isolated and irrespective of whether the person with COVID-19 or the contact of such a person was wearing a face covering or mask or respiratory personal protective equipment. Not applicable to health care workers when following appropriate infection control precautions (https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing-plan/appendix.html#contact).

⁸ For more information on contact tracing, see: https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/contact-tracing.html

⁹ https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html

Testing Quarantined Individuals Who Develop Symptoms:

- Test eligible Service members in quarantine who develop symptoms commonly associated with COVID-19.
 - o If **laboratory positive:** The individual becomes a case and must be isolated (see above).
 - o If **laboratory negative:** The individual must be isolated and followed to ensure he/she clinically improves.
 - If **laboratory negative** and **clinically improved**: The individual **goes back** into quarantine for the remainder of the quarantine period to determine if he/she becomes symptomatic for COVID-19.
 - If **laboratory negative** and the patient does **NOT clinically improve or worsens**, and no other etiology is found, then keep the individual isolated and consider retesting for COVID-19.

Recommendations for testing during the period following initial diagnosis of COVID-19:10 For persons previously diagnosed with COVID-19 who remain asymptomatic after recovery, polymerase chain reaction retesting is not recommended within the CDC-specified time period (90 days as of January 7, 2021) from the date of initial diagnosis. Furthermore, in the event of subsequent close contact with confirmed COVID-19 positive individuals, additional quarantine (including post-travel quarantine in accordance with reference (h)) is not necessary or recommended during the CDC-specified time period as long as they remain symptom-free.

- If individuals become symptomatic during this time frame (whether or not they are a close contact of a case) they must self-isolate immediately and be evaluated by a healthcare provider to determine if they may have been re-infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or if symptoms are caused by another etiology. Isolation may be warranted during this time, particularly if symptoms developed within 14 days after close contact with an individual who has contracted COVID-19.
- If reinfection is confirmed or remains suspected, the individual concerned must remain under the recommended COVID-19 isolation until they meet the criteria for discontinuation of precautions for most persons, this would be 10 days after symptom onset and resolution of fever for at least 24 hours, without the use of fever-reducing medications, and with improvement of other symptoms. In addition, consultation with an infectious disease specialist may be warranted, on a case by case basis.

Contacts of Contacts: There is no indication to quarantine asymptomatic individuals who are contacts of contacts; they should continue to self-monitor for symptoms.

DoD family members, DoD civilian employees, and DoD contractor personnel should follow the above guidance and must follow host nation policies as applicable. DoD civilian employees and DoD contractor personnel may be restricted from workplace access at DoD facilities in accordance with reference (g).

¹⁰ For more detailed information, see: https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html. Beyond of this recovery window as determined by CDC, individuals then revert back to protocols for individuals who have never been diagnosed with COVID-19.