

#### UNDER SECRETARY OF DEFENSE 4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

### DEC 3 0 2021

#### MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP COMMANDERS OF THE COMBATANT COMMANDS DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

## SUBJECT: Force Health Protection Guidance (Supplement 15) Revision 3 – Department of Defense Guidance for Coronavirus Disease 2019 Laboratory Testing Services

This memorandum updates previous DoD coronavirus disease 2019 (COVID-19) laboratory testing guidance and rescinds and replaces reference (a).<sup>1</sup> 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<sup>2</sup> in accordance with this guidance. This guidance also supports the DoD surveillance strategy for the COVID-19 pandemic response with complementary health surveillance activities, screening, asymptomatic testing, and sentinel screening testing surveillance consistent with applicable law and in accordance with reference (b).

#### **Testing Considerations**

- Health care 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 1 for case management and disposition guidance. Providers are encouraged to test for other causes of respiratory illness as clinically indicated.
- 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 Under Secretary of Defense for Personnel and Readiness, in accordance with reference (d), through the Assistant Secretary of Defense for Health Affairs (ASD(HA)).

<sup>&</sup>lt;sup>1</sup> References are listed in Attachment 2.

<sup>&</sup>lt;sup>2</sup> Testing in this guidance refers to tests that utilize molecular, or when clinically indicated, antigen testing methods.

- DoD is committed to maximizing testing capability for operational needs and to increasing standardization and synchronization across the Department. However, differences among operational environments, deployment cycles, and congregate setting limitations drive differences in testing demands to mitigate operational risk. 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 are 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 (c). 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 compliance with COVID-19 emergency use authorizations (EUAs), and 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 tests<sup>3</sup> for surveillance testing using a pooled specimen testing protocol, consistent with applicable law and regulations. 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 FDA EUA-authorized molecular test, or an 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 (c).
- FDA EUA-authorized 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 terms of the applicable EUA.
- DoD Components must coordinate planned updates to pooled testing protocols with the ASD(HA). Each Military Department will retain authority to prioritize pooled testing populations and assignments to Military Department 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 ASD(HA).
- 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

<sup>&</sup>lt;sup>3</sup> 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).

contractor personnel. DHA will assist DoD Components, as needed, to ensure this occurs.

#### 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 eligible DoD health care beneficiaries) may be offered testing in accordance with this guidance and reference (f) if they would otherwise be restricted from the workplace under reference (g) and their supervisor has determined that their presence is required in the DoD workplace or testing is required for official travel
- Eligible DoD 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 DoD to test their personnel, as necessary to support mission requirements and subject to available funding.
- For testing of foreign 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 available at:

https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/Latest-DOD-Guidance/. Please direct any questions or comments to the following email address: dha.ncr.ha-support.list.policy-hrpo-kmc-owners@mail.mil.

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Gilbert R. Cisneros, Jr.

Attachments: As stated

#### ATTACHMENT 1 Clinical Testing and Case Management – COVID-19

The guidance below is applicable to Service members. It is recommended for DoD family members, DoD civilian employees, and DoD contractor personnel. DoD civilian employees and DoD contractor personnel may be restricted from workplace access at DoD facilities in accordance with current workplace safety guidance and reference (g). DoD family members, DoD civilian employees, and DoD contractor personnel may be subject to pre-travel testing as required by reference (h) and must follow applicable host nation requirements.

#### Testing an Individual in a Clinical Setting:

- Test based on clinical judgment and public health considerations.
  - If **laboratory positive:** Regardless of vaccination status, the individual becomes a COVID-19 case and must be isolated.
    - The individual will stay isolated for 5 days (day 0 is the day of specimen collection).
    - The individual may leave isolation after 5 days, if no symptoms are present or if they are afebrile for more than 24 hours and any remaining symptoms are resolving. Mask wearing must continue for 5 days after leaving isolation when around others, even if mask wearing is not otherwise required by DoD guidance.
    - If fever, shortness of breath, or severe fatigue start or persist, the individual will stay isolated until these symptoms resolve.
    - A negative test is not required to discontinue isolation due to difficulty interpreting persistent positive results. This is consistent with CDC's recommendation to NOT test during the 90-day period following initial diagnosis. This applies to all viral testing methodologies, including antigen testing.
  - 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.

### Management of Close Contacts<sup>4</sup> of a Case (as determined by contact tracing):<sup>5</sup>

• When the close contact is an individual vaccinated with an FDA licensed or authorized COVID-19 vaccine, quarantine is required unless the individual has: (1) received an FDA licensed or authorized COVID-19 booster dose; or (2) it has been less than 6 months since completion of the primary series with an mRNA vaccine (i.e., Pfizer-BioNTech/Comirnaty or Moderna); or (3) it has been less than 2 months since receiving a Johnson and Johnson COVID-19 vaccine dose as a primary vaccination. Regardless of vaccination status, close

<sup>&</sup>lt;sup>4</sup> Close contact is defined as someone who was within 6 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, 2 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.

<sup>&</sup>lt;sup>5</sup> For more information on contact tracing, see: https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing.html.

contacts must wear a mask around others for 10 days, even if mask wearing is not otherwise required by DoD guidance, and if *practical*, *test on day 3-5 following exposure*. *If symptoms develop, then the individual* must get tested and isolate until test results are complete.

- Close contact individuals who are not fully vaccinated must quarantine for 5 days. The individual should wear a mask at all times when around other individuals, regardless of those individuals' vaccination status, and even if mask wearing is not otherwise required by DoD guidance. Testing should occur on day 3-5 after exposure, if practical. If no symptoms develop, quarantine may end after 5 days, but the individual must continue to wear a mask around others for an additional 5 days (i.e., masks must be worn for a total of 10 days after exposure, to include the time in quarantine). If any symptoms develop at any time, the individual should be tested for COVID-19 and advised to isolate.
- Exceptions to the above protocols for asymptomatic unvaccinated personnel whose presence is required in the workplace may be considered in accordance with reference (g).
- In all situations, for a full 10 days after last contact with a confirmed case, Service members must continue to self-monitor, and practice strict adherence to all non-pharmaceutical intervention mitigation strategies, and, if not fully vaccinated, wear masks that meet specifications in DoD guidance<sup>6</sup>, avoid crowds and practice physical distancing, hand and cough hygiene, maintain adequate indoor ventilation, and perform environmental cleaning and disinfection. In addition, Service members located outside the United States identified as close contacts must follow host-nation policies, as applicable.

#### **Testing Quarantined Individuals Who Develop Symptoms:**

- Test eligible Service members in quarantine who develop symptoms commonly associated with COVID-19.
  - If **laboratory positive:** The individual becomes a case and must be isolated (see above).
  - If **laboratory negative:** The individual must continue to follow procedures for quarantine as outlined above.

# **Recommendations for Testing During the Period Following Initial Diagnosis of COVID-**19:<sup>7</sup>

For persons previously diagnosed with COVID-19 who remain asymptomatic after recovery, polymerase chain reaction retesting is not recommended within 90 days 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 health care 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 10 days after close contact with an individual who has contracted COVID-19.

<sup>&</sup>lt;sup>6</sup> https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html

<sup>&</sup>lt;sup>7</sup> For more detailed information, see: https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html. Beyond of this recovery window as determined by the CDC, individuals revert back to protocols for individuals who have never been diagnosed with COVID-19.

• If reinfection is confirmed or remains suspected, the individual concerned must remain under the recommended COVID-19 isolation until he or she meets the criteria for discontinuation of precautions – for most persons, this would be 5 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. Following isolation, the individual must continue to wear a mask when around others for an additional 5 days.

**Aircrew Notification:** In situations where an individual is identified as a case within 72 hours after medical transport in the en-route care system, local public health authorities at the receiving military medical treatment facility (MTF), or at the closest MTF if the case is transferred to a civilian medical facility, must notify the regional Theater Patient Movement Requirements Center to initiate contact tracing and air crew exposure procedures.

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

#### ATTACHMENT 2 References

- (a) Acting Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 15) Revision 2 – Department of Defense Guidance for Coronavirus Disease 2019 Laboratory Testing Services," July 2, 2021 (hereby rescinded)
- (b) Acting Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 22) – Department of Defense Guidance for Coronavirus Disease 2019 Surveillance and Screening Testing," July 21, 2021
- (c) Department of Defense Instruction (DoDI) 6440.02, "Clinical Laboratory Improvement Program (CLIP)," May 29, 2014
- (d) Deputy Secretary of Defense Memorandum, "Coronavirus Task Force Diagnostics and Testing Line of Effort Transition of Functions," May 3, 2021
- (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) Acting Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 18) – Department of Defense Guidance for Protecting All Personnel in Department of Defense Workplaces During the Coronavirus Disease 2019 Pandemic," March 17, 2021
- (h) Acting Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 20) – Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic," April 12, 2021