PERSONNEL AND
READINESS

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

APR - 7 2020

MEMORANDUM FOR CHIEF MANAGEMENT OFFICER OF THE DEPARTMENT OF DEFENSE
SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
CHIEF OF THE NATIONAL GUARD BUREAU
GENERAL COUNSEL OF THE DEPARTMENT OF DEFENSE
ASSISTANT SECRETARY OF DEFENSE FOR LEGISLATIVE AFFAIRS
ASSISTANT TO THE SECRETARY OF DEFENSE FOR PUBLIC AFFAIRS
DIRECTORS OF DEFENSE AGENCIES
DIRECTORS OF DOD FIELD ACTIVITIES

SUBJECT: Force Health Protection (Supplement 6) – Department of Defense Guidance for Coronavirus Disease 2019 Laboratory Diagnostic Testing Services

This memorandum provides DoD laboratory testing guidance to supplement force health protection (FHP) guidance for the coronavirus disease 2019 (COVID-19) pandemic response. The Centers for Disease Control and Prevention (CDC) continues to update laboratory testing guidance found at: **https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html**. This FHP supplement incorporates aspects of the CDC testing guidance for DoD use. Effective immediately, DoD Components will comply with this guidance to protect at-risk populations, maximize critical testing capability, and enable optimal public health decision-making. Diagnostic testing will be used in support of patient care.

Testing Determinations:

Asymptomatic individuals and mildly symptomatic **should generally not be tested** with the currently available diagnostic tests as this usually will not provide actionable information and may deprive tests from those symptomatic individuals who have the urgent need for testing. However, the guiding principle is that a negative test result in an asymptomatic individual does not rule out exposure to the virus, and **must not** be used to clear that individual for duty (see Attachment 1 for case management and disposition).

Healthcare providers, in consultation with military and local public health authorities, will determine whether a patient should be tested based on having signs and symptoms compatible with COVID-19, along with level of local community transmission, and an increased exposure risk or potential for severe outcomes. Many confirmed COVID-19 individuals have developed

fever (either subjective or confirmed) and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing, or shortness of breath). Providers should use the following guidelines to determine testing applicability:

- Hospitalized patients with signs and symptoms compatible with COVID-19 should be tested to inform patient care, as well as infection prevention and control decisions.

- Other symptomatic individuals who may be tested include those who may be at higher risk or have potential for poor outcomes such as older adults and those with underlying medical conditions, e.g., conditions such as diabetes, heart disease, immunosuppression, chronic lung disease, or other conditions.

- Testing of other symptomatic, mission essential individuals or those in high risk settings (e.g., training commands, shipboard settings, etc.) may be conducted at command direction, in consultation with medical staff.

- Individuals with mild symptoms who can recover at home or other comparable settings should not be tested. However, if during home isolation, mild symptoms progress into severity, individuals should be re-evaluated for potential testing.

- 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, per CDC guidance.

Case Management and Return to Duty:

- Clinical management of hospitalized patients may be guided by the "DoD COVID-19 Practice Management Guide," found at: **https://health.mil/Reference-Center/Technical-Documents/2020/03/24/DoD-COVID-19-Practice-Management-Guide**.

- **Attachment 1** is a recommended algorithm for testing and management that outlines 1) defining/testing a person or patient under investigation; 2) management and disposition of cases (those in isolation); 3) management of close contacts (those in isolation); 4) testing in isolation; and 5) guidance for contacts of contacts.

Approved Diagnostic Laboratories and Tests:

- DoD Components will conduct diagnostic testing at approved DoD laboratories, or at state, territorial, and local public health laboratories and commercial laboratories, as available. For DoD Component activities outside the United States, partner host-nation test results from tests approved by host nation regulatory authorities may also

be used pursuant to DoD Component approval or host nation agreements, as applicable.

- DoD Components must comply with Food and Drug Administration (FDA) regulations for diagnostic testing, to include compliance with COVID-19 emergency use authorization (EUA) requirements consistent with and not to exceed the terms of the EUA. Specifically, deviating from the manufacturer's instructions, (e.g., combining samples from different individuals) is prohibited by this guidance, unless otherwise authorized by the FDA. The FDA COVID-19 EUA list is at: **https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd**.

- The Defense Health Agency Center for Laboratory Medicine Services (CLMS) collaborates with the DoD Laboratory Network Gatekeeper and works with the Office of the Assistant Secretary of Defense for Health Affairs and the Military Departments to advise and approve expanding capability where needed. The CLMS may be contacted at: **https://www.milsuite.mil/book/groups/dod-clinical-lab-services**.

COVID-19 Laboratory Tests Not Under FDA EUA for Public Health Decision-Making:

- Use of COVID-19 laboratory assays that have not received EUA status will not be used to diagnose individuals. Such assays include research use only (RUO) molecular surveillance assays and laboratory developed tests (LDT) that are not being submitted for EUA. However, DoD Components can use such assays to inform public health decision-making to protect their personnel and preserve mission execution.

- Laboratories able to perform RUO tests, LDT, or environmental or surveillance tests may apply for certification to conduct clinical diagnostic testing in accordance with DoD Manual 6440.02, "Clinical Laboratory Improvement Program (CLIP) Procedures," dated May 29, 2014, and FDA guidance, "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency – Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff."

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

- DoD Components may test Service members who meet the criteria described in the "Testing Determinations" section of this guidance. Civilian employees (who are not otherwise DoD health care beneficiaries) who meet this criteria may also be tested if their supervisor has determined that their presence is urgently required in the DoD workplace.

- Subject to availability, DoD Components may test DoD family members who are Military Health System beneficiaries who meet the "Testing Determinations" criteria in this guidance to meet the mission of delivering care to eligible beneficiaries.

- Other individuals with limited eligibility for DoD health care services, such as DoD contractor personnel in deployed locations, will use established processes for medical care to access testing.

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

ATTACHMENT 1

Force Health Protection Guidance Supplement 6 - Attachment 1
Testing and Management - COVID-19
(Based on current CDC published guidance[1])

Defining and Testing a Patient Under Investigation[2]:

- Isolate and test based on clinical judgment of patient with **signs and symptoms** of COVID-19, along with level of local community transmission and an increased exposure risk or potential for severe outcomes.
  - **If lab positive**: they become a case and must be isolated.
  - If **lab negative**: they should be clinically followed to ensure they improve clinically.
    - If **lab negative** and **clinically improved**: they have no restrictions.
    - If **lab negative** and they do **NOT clinically improve or worsen,** and no other etiology is found, then you can consider re-testing the patient for COVID-19.

Management and Disposition of Laboratory Confirmed Cases and Clinically Diagnosed Cases in Isolation:

- Isolate either at home or in a hospital (if required) until below criteria met:
- Criteria to discontinue isolation (**Non-test** based):
  - At least 3 days (72 hours) have passed since recovery (defined as resolution of fever without the use of fever-reducing medications) **and**
  - improvement in respiratory symptoms (e.g., cough, shortness of breath); **and**
  - At least 7 days have passed since symptoms first appeared.
- Criteria to discontinue isolation (**Test** based):
  - Resolution of fever without the use of fever-reducing medications **and**
  - Improvement in respiratory symptoms (e.g., cough, shortness of breath) **and**
  - Negative results from at least two **consecutive** nasopharyngeal swab specimens collected ≥24 hours apart (total of two negative specimens).

Management of Close Contacts[3] of a Laboratory Confirmed or Clinically Diagnosed Case:

- Isolation for 14 days and monitor for symptoms of COVID-19.
- Individuals **cannot test-out** of isolation; individuals must remain in isolation for the full 14 day incubation period.
  - The lab test is a diagnostic test; it is NOT a screening test; this means:
    - A positive result **IS** meaningful: they are infected and become a lab confirmed case.
    - A negative test is **NOT** meaningful. A negative could mean the individual does not yet have a high enough virus circulating to trigger a positive test; that result could change (i.e., become positive) with more time. Therefore they must remain in isolation for the 14 days.
- Do NOT test persons at the end of their isolation period. They may be released if they are asymptomatic.

Testing in Isolation:

- Only test persons in isolation who develop symptoms commonly associated with COVID-19 infections
  - If **lab positive**: they become a case (See above)
  - If **lab negative**: they should be clinically followed to ensure they improve clinically
    - If **lab negative** and **clinically improved**: they **go back** into isolation for the remainder of the 14 days to see if they become symptomatic for COVID-19
    - If **lab negative** and they do **NOT clinically improve or worsen,** and no other etiology is found, then consider re-testing the patient for COVID-19

Contacts of Contacts:

- There is no indication to isolate these individuals

---

[1] As of 27 MAR: https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html

[2] Patient under investigation (PUI) is defined as an individual with sign and symptoms of COVID-19 who either have a test pending or would have been tested had a test been available.

[3] Close contact is defined as a) being within approximately 6 feet (2 meters) of a COVID-19 case for a prolonged period of time (>10 minutes); close contact can occur while caring for, living with, visiting, or sharing a health care waiting area or room with a COVID-19 case; or, b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on).