

COVID-19 - IDPH Laboratories
Testing Priorities, Definitions, and Immediate Reporting
ED Testing Availability Survey
Antibody Testing Update Interim Guidance 4/04/2020

- 1) Updated guidance for COVID-19 testing at IDPH is attached, including considerations when testing health care and public safety workers.**
- 2) Other patients can be tested via an increasing number of commercial, hospital, and academic laboratories.**
- 3) Immediate reporting is required for some cases of COVID-19 infection (see page 3).**
- 4) Concerns with New SARS-CoV-2 Antibody Testing**

IDPH is alerting providers and clinical laboratories to the unusual manner in which SARS-CoV-2 antibody testing is entering the marketplace. Under a new policy, the Food and Drug Administration (FDA) is allowing manufacturers to distribute diagnostic serology test kits as long as the manufacturers state that the assays have been validated.

One manufacturer ([Cellex](#)) [has received an Emergency Use Authorization \(EUA\) from the FDA](#) for an IgM/IgG rapid test. The test is not FDA approved. The package insert contains [limited information](#) regarding test performance. Because the FDA has not reviewed validation data for any other assays, they have not been assessed for reliability, sensitivity or specificity by a nonpartial regulatory agency.

The FDA is requiring serology testing reports to include the following messages:

- This test has not been reviewed by the FDA and may not reliably determine whether a person has been exposed to SARS-CoV-2.
- Negative results do not rule out SARS-CoV-2 infection, particularly in people for whom prior SARS-CoV-2 exposure is suspected. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus species, such as coronavirus HKU1, NL63, OC43, or 229E.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

Testing at IDPH (High Priority)

<ul style="list-style-type: none"> Hospitalized (inpatients) with suspect COVID-19
<ul style="list-style-type: none"> Individuals with suspect COVID-19 who are residents of a congregate setting that serves a vulnerable population¹ and are part of a potential cluster of COVID-19
<ul style="list-style-type: none"> Outpatients with suspect COVID-19 who are involved in front-line COVID-19 response (Health care and public safety workers (EMS, law enforcement, firefighters))
<ul style="list-style-type: none"> Outpatients with suspect COVID-19 who are employees in residential congregate settings serving vulnerable populations

Note: 1) Testing for other viruses is not required prior to ordering COVID-19 testing via IDPH
 2) IDPH or LHD approval is not necessary for COVID-19 testing at commercial, hospital, or academic laboratories.

Definitions for SUSPECT COVID-19 by Setting

Setting	Suspect COVID-19 Illness Definition
Hospitalized patients	Severe respiratory illness (e.g. pneumonia or ARDS) of unclear etiology after initial evaluation.
Health care and public safety workers Staff in residential congregate care settings	Fever (≥ 100.4 F/38 C) AND new onset respiratory symptom(s) (e.g. cough, or SOB, or sore throat) that cannot be attributed to an underlying or previously recognized condition
Residents in congregate care settings that serve vulnerable populations that are part of a cluster in that setting	Fever ≥ 100.0 F/37.8C OR cough OR shortness of breath OR sore throat that cannot be attributed to an underlying or previously recognized condition Cluster: 2 or more suspect or lab confirmed COVID illnesses occurring among residents within a 7-day period. If suspect cases test negative for COVID-19 and either have an alternative diagnosis or do not have progressive respiratory illness, they are no longer considered to have suspect COVID-19 illness.

¹ Congregate setting that serves vulnerable populations: e.g. a skilled nursing facility, an assisted living facility, group home, homeless shelter, or correctional setting. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus species, such as coronavirus HKU1, NL63, OC43, or 229E.

Additional considerations regarding COVID-19 testing of ill HCW and PSW

1. Frontline health care and public safety workers critical to COVID-19 response and maintaining critical infrastructure should be prioritized.
2. Lab capacity at IDPH is limited, and entities employing HCW and PSW should make arrangements now for testing at an alternate laboratory, so that necessary testing can be performed on a timely basis if testing at IDPH is not available.
3. An alternative to a testing strategy if for ill HCW and PSW is to stay home/self- isolate for 7 days after symptom onset, or 72 hours after symptoms are improving and fever has resolved.
4. Co-infections as well as false negative test results for patients with COVID-19 have been reported. If HCW and PSW return to work with respiratory symptoms, wearing a mask for 7 days after symptom onset, or 72 hours after symptoms are improving should strongly be considered. HCW and PSW with fever should not return to work.

Immediate Reporting, by Telephone

Providers should **immediately (within 3 hours)** report to the local health department by telephone:

- 1) A cluster of **2** or more suspect cases of COVID-19 among residents of congregate settings that serves vulnerable populations* with onset \leq 7 days apart.
- 2) Outpatients with **suspect COVID-19** who are employees in residential congregate settings that serve vulnerable populations*
- 3) Any person hospitalized with pneumonia of unclear etiology who lives in or works at a residential congregate setting that serves vulnerable populations *
- 4) Any resident or staff member from a residential congregate setting that serves vulnerable populations, who has laboratory confirmed COVID-19, and whose illness has not been previously reported to the local health department.

* e.g. skilled nursing facility, an assisted living facility, group home, homeless shelter, or correctional setting.