Shasta County Health & Human Services Agency | Public Health Branch

COVID-19 Health Advisory #15

August 19, 2020

Please distribute to all providers in the facility

Go to: https://tinyurl.com/ShastaCOVID-19 for an electronic version of this Health Alert

COVID-19 Testing Updates

The purpose of this health advisory is to provide healthcare providers with information on the following topics:

- Provider reimbursement available for counseling patients at time of COVID-19 testing
- Anterior nares supervised specimen collection
- Updated public health laboratory testing criteria
- Antigen testing
- Updates to Title 17 CCR section 2500 and 2505

Provider reimbursement available for counseling patients to self-isolate at time of COVID-19 testing

On July 30, the Centers for Medicare and Medicaid Services (CMS) and the CDC announced that payment is available to physicians and health care providers to counsel patients, at the time of COVID-19 testing, about the importance of self-isolation after they are tested and prior to the onset of symptoms.[1]

Provider counseling to patients at the time of their COVID-19 testing should include:

- Discussion of immediate need for isolation, even before results are available
- The importance to inform their immediate household that they too should be tested for COVID-19
- The review of signs and symptoms and services available to them to aid in isolating at home.
- Actions to take should they test positive - wear a mask at all times, respond to SCPH when contacted to provide information for contact tracing, and tell their immediate household and recent contacts in case it is appropriate for these individuals to be tested for the virus and to self-quarantine.

CMS will use existing evaluation and management (E/M) payment codes to reimburse providers who are eligible to bill CMS for counseling services no matter where a test is administered, including doctor's offices, urgent care clinics, hospitals and community drive-thru or pharmacy testing sites.

For self-isolation and quarantine instructions, please visit https://www.co.shasta.ca.us/covid-19/instructions (**instructions coming soon**). To link patients to resources during their isolation or quarantine period, visit www.shastaready.org or https://211norcal.org/covid-19-shasta/.

[1] https://www.cms.gov/newsroom/press-releases/cms-and-cdc-announce-provider-reimbursement-available-counseling-patients-self-isolate-time-covid-19

Anterior nares supervised self-collection
The CDC has changed its specimen-collection guidance to indicate all five methods are equally acceptable.[3] SCPH recommends providers consider supervised self-collection in order to increase outpatient healthcare provider capacity for specimen collection.

Anterior nares supervised-self collection is one method that can be done with greater comfort and convenience to the patient than an NP swab. It requires less Personal Protective Equipment (PPE) for the provider and can be done at a physical distance of 6 feet during self-collection by the patient. If remaining at a distance of 6 feet, supervised anterior nares self-collection requires only gloves and mask for the supervising healthcare provider. This method has similar percent positive agreement to NP swab for coronavirus detection. It requires a flocked or spun polyester swab to perform. Please refer to attached instructional materials for implementing this type of specimen collection in your office. For assistance with specimen collection supplies, please email DOC45@co.shasta.ca.us.

Updated public health laboratory testing criteria
Ongoing challenges with testing capacity and changing demands requires periodic updates to prioritization for specimens tested in the Public Health Lab.

Symptomatic. SCPH continues to recommend that patients with symptoms consistent with COVID-19[2] be tested, with certain priority populations tested at the Public Health Lab.

- ✓ SCPH is expanding its priority criteria for testing in the Public Health Lab to include symptomatic students or staff in a K-12 **in-person** instructional setting.

Asymptomatic. With evidence supporting the potential for asymptomatic transmission of SARS-CoV-2 and the routine detection of asymptomatic cases in Shasta County, SCPH is continuing to urge testing of asymptomatic individuals via the OptumServe site or Rite Aid Drive-Thru sites or the Public Health Lab if they are known to be exposed to a COVID-19 case.

Please note: Tier 1 Priority referred to in this advisory is for the Shasta County Public Health Lab only. Refer to California Department of Public Health Testing Guidance for additional prioritization criteria using commercial labs. https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Updated-COVID-19-Testing-Guidance.aspx

Actions requested of all clinicians with patients testing for COVID-19 infection:

1. **Collect and submit** upper respiratory specimens.[3] Supplies: Shasta County has received allotments of specimen collection supplies for health care facilities to test for COVID-19. If your facility needs VTM, saline, swabs, or testing kits you can email the DOC45@co.shasta.ca.us.
2. **Remind** patients with symptoms consistent with COVID-19 to self-isolate pending test results.

[2] COVID-19 symptoms include fever (objective or subjective), cough, shortness of breath or difficulty breathing, fatigue, chills, muscle aches, headache, sore throat, congestion or runny nose, nausea or vomiting, diarrhea, and new loss of taste or smell.

[3]Acceptable specimens include NP or OP collected by a healthcare provider, nasopharyngeal wash/aspirate or nasal wash/aspirate (NW) collected by a healthcare provider, or mid-turbinate or anterior nares by either supervised onsite self-collection or HCP collection. Multiple specimens may be taken with a single swab and swabs from two anatomic locations may be placed in the same vial. See FDA FAQ on Diagnostic Testing for SARS-CoV-2 and CDC Interim Guidelines for Collecting, Handling and Testing Clinical Specimens for COVID-19.

3. **Tier 1:**
    a. **Send** specimens along with a completed Lab Requisition Form to Shasta County Public Health Lab (SCPHL); see address on form.
    b. Specimens may be **delivered** directly or by courier Monday-Friday 8am-5pm and weekends 9am-10am. To arrange for delivery times outside of these hours call 530-395-0132. For questions about specimen collection supplies or packaging, call the SCPHL at 530-225-5072.
    c. **Complete** the **COVID-19 Tier 1 Criteria Form** on pg. 5 and fax to 530-229-8301 by 10 AM daily. **Specimens received without this corresponding form will be delayed. The form will be reviewed for Tier 1 criteria and specimens returned if criteria not met.**
    d. Results are typically available within 2 business days.
4. **Tier 2:** Send specimens to commercial laboratories (LabCorp, Quest, etc.).
5. **Report** all positive cases to SCPH by phone at (530) 225-5591 AND confidential fax at (530) 229-8301.[4]

Who to test:

Priority		*Criteria*
Tier 1	Shasta County Public Health Laboratory	**Patients with signs/symptoms compatible with COVID-19 AND one of the priority criteria below:** • Patients who are hospitalized, regardless of age or comorbidities • Health care workers, including emergency medical services (EMS) and other first responders • Individuals residing or working in congregate living facilities (e.g. jails, shelters, long-term care facilities) • Students or staff in K-12 **in-person** instructional setting - ***New*** **Any patient, regardless of symptom status, as capacity allows:** • Individuals with known exposure to a suspected or confirmed COVID-19 case • Investigation and management of outbreaks (includes contact tracing)
Commercial Lab		All other patients – refer to California Department of Public Health testing guidance for additional prioritization criteria when using commercial labs. https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Updated-COVID-19-Testing-Guidance.aspx

Antigen testing

While RT-PCR tests remain the preferred tests for diagnosing COVID-19 in individual patients, SARS-CoV-2 Antigen (Ag) testing has useful applications as a point-of-care diagnostic test with rapid results in ***symptomatic*** patients. There are currently two Ag tests available through FDA Emergency Use Authorization (EUA): 1) the Quidel Sofia SARS Antigen FIA assay, and 2) the BD Veritor System for Rapid Detection of SARS-CoV-2. Both assays are approved as CLIA-waived tests (point of care).

These antigen tests are lateral flow assays designed to detect the nucleocapsid of SARS-CoV-2 virus, if present, from a patient's nasal swab and can provide results in about 15 minutes.
The Sofia Ag assay also allows for the collection of NP specimen using a nylon flocked NP swab (not supplied).

[4]The California Department of Public Health has updated Title 17 Sections 2500 and 2505 of the California Code of Regulations to include COVID-19 on the lists of reportable conditions.

- Both tests require dry swab collection with NO transport media
- Both tests recommend testing as soon as possible once the specimen is collected
- Antigen tests are not as sensitive as nucleic acid amplification assays such as PCR. Thus, positive results tend to be accurate, but a negative result should be interpreted with caution, and should be considered in the context of clinical suspicion of disease and risk status of the patient.
    - Negative results for the BD Veritor antigen test should be treated as presumptive negative
    - Negative results for the Sofia Ag test should be treated as presumptive if the specimen is collected beyond five days from symptom onset.

NOTE: detailed information is contained within the Instructions for Use (IFU) brochure and on the FDA EUA website for each test[5]

	BD Veritor	Sofia Ag FIA
PPA	84% (C.I. 67%–93%)	96.7% (C.I. 83.3% - 99.4%)
NPA	100% (CI 98%–100%)	100.0% (C.I. 97.9% - 100.0%)
OPA	98% (C.I. 95%–99%)	99.5% (C.I. not provided)
PPV	100% (C.I. 89% -100%)	100% (C.I. not provided)
NPV	97.5% (C.I. 95% - 99%)	99.4% (C.I. not provided)

PPA: positive percent agreement; **NPA:** negative percent agreement; **OPA:** overall percent agreement; **PPV:** positive predictive value; **NPV:** negative predictive value

Updates to Title 17 CCR section 2500 and 2505

On July 28, the California Department of Public Health updated the Title 17 California Code of Regulations section 2500 reporting requirements for medical providers to require reporting of data that will improve our ability to accurately assess disparities in reportable conditions related to race, ethnicity, sexual orientation and gender identity. Additionally, section 2505 was changed to shorten the laboratory reporting timeframe for SARS-CoV-2. The changes go into effect immediately and are described below.

2500 (Provider reporting to public health) changes (use COVID-19 Confidential Morbidity Report at https://tinyurl.com/ShastaCOVIDCMR)

- Requirement to report sexual orientation and gender identity data elements including current gender identity, sex assigned at birth, and sexual orientation.
- Clean-up of race/ethnic group to separate data elements: race and ethnicity.

2505 (Laboratory reporting to public health) changes (use lab requisition form at https://tinyurl.com/ShastaLabForm)

- Requirement to include Race and Ethnicity on test requisition and lab report
- Change in SARS-CoV-2 reporting timeframe requirements to within eight hours rather than immediate by phone

SCPH sincerely appreciates your partnership in working together to address health disparities.

[5] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev

SHASTA COUNTY PUBLIC HEALTH LABORATORY
COVID-19 Tier 1 Criteria Form

Fax this page along with face sheet/demographics to Shasta County Public Health Communicable Disease Program:
530-229-8301

Patient Last Name	Patient First Name	Patient Date of Birth
Provider/Clinic Name	Clinic Contact Name and Direct Phone Number	

Please check all criteria below that apply for Tier 1 testing.

Symptomatic individuals[6] AND one of the criteria below.

□ Hospitalized
Hospital: _____ MRN:_____

□ Health care worker, emergency medical services (EMS), or other first responder
Hospital or agency: _____ City: _____

□ Congregate living facility
Facility Name: _____ City: _____

□ Students or staff in K-12 **in-person** instructional setting
School name: _____

Symptomatic or asymptomatic individuals meeting criteria below.

□ Known exposure to a suspected or confirmed COVID-19 case

□ Exposed in an outbreak
Outbreak setting (specify details): _____

If none of the above, send to commercial lab (LabCorp, Quest, etc.) for testing.

[6]COVID-19 symptoms include fever (objective or subjective), cough, shortness of breath or difficulty breathing, fatigue, chills, muscle aches, headache, sore throat, congestion or runny nose, nausea or vomiting, diarrhea, and new loss of taste or smell.