1. **STRATEGIES TO MAXIMIZE SENSITIVITY OF COVID-19 AND INFLUENZA TESTING**

- **Test early:** Centers for Disease Control (CDC) recommends that specimens should be collected as soon as possible once a suspect case is identified, regardless of the time of symptom onset. For maximizing the detection of influenza, respiratory specimens should be collected as close to illness onset as possible (ideally < 3-4 days after onset). For COVID-19, testing in the first 5 days of symptoms will give the best sensitivity for both antigen testing and RT-PCR. COVID-19 viral load is highest in respiratory specimens early on in the disease when symptoms tend to be mild (first five days). The median time to a negative PCR is 9 days. Studies show a patient with COVID-19 may have a negative upper respiratory PCR sample, while the virus can still be found in the lower respiratory tract in a patient with pneumonia.

- **Use anterior nares (AN) and oropharyngeal (OP), or nasopharyngeal (NP) and OP collection together if possible.** For initial diagnostic testing for COVID-19 or influenza, only one AN or NP swab is needed. The NP specimen has the best sensitivity studied; however, it is prone to a variable collection technique, and a poor specimen collection can dramatically affect the sensitivity. **Collecting both AN and OP or NP and OP further increases sensitivity.** If collecting both an AN or NP and OP swab, they can be put in the same media tube, as long as both tips are in the liquid.

- **NOTE:** Use a separate order and collect a separate specimen for each viral test being conducted (e.g., one or two swabs for influenza and one or two swabs for SARS-CoV-2 RT-PCR).

- **Test frequently (COVID-19):** Using a lower sensitivity test like the antigen Sofia 2 test for influenza or COVID-19, more often, is an excellent way to increase sensitivity. Repeat
testing as much as every 2-3 days can push the sensitivity to approximately 99%. Since the duration of influenza is much shorter than COVID-19, the utility of repeat testing will best be suited for COVID-19.

2. SPECIMEN COLLECTION

PATIENT SELF-COLLECTED SPECIMENS FOR COVID-19

Currently, guidance from the CDC and California Department of Public Health (CDPH) does not include endorsements for self-collected influenza specimens. There are multiple research papers showing accuracy. This guidance may change as more 2020-21 influenza guidance emerges.

- Anterior nares (AN), also termed “nasal”, self-collected or health care worker (HCW) collected is desirable, may lower personal protective equipment (PPE) use, is generally more acceptable to patients, and may lower refusal rates. Please see the CDC Fact Sheet on Anterior Nasal (Nasal) Collection. AN collection can be used for all types of testing, including surveillance testing.

**Anterior nares (nasal) Self Collection for COVID-19**

- **ONLY FOAM SWABS** can be used for NARES collection (e.g., Puritan 6’ Sterile Standard Foam Swab w/ Polystyrene Handle). The collection technique is the same as for the HCW collected.

- **For the antigen POC test only, use a DRY SWAB.** If the patient collection area is far from the device, put the swab in a sterile tube for transport over to the device location.

**Mid-Turbinate (MT) Self Collection for COVID-19**

- If available, **ONLY FLOCKED SWABS** can be used for MT collection (e.g., Copan® FLOQSwab or MDL® NasoSwab™).

- **MT Collection instructions:** Use a single flocked swab for collecting specimens from both mid-turbinates of a symptomatic patient.
  1. Instruct the patient to tilt their head back and look at the ceiling.
  2. Gently insert the soft tip of the swab into one nostril until the safety stopper touches the nostril’s edge.
  3. Gently twist the handle for 15 seconds.
  4. Remove the flocked swab and insert the same swab into the other nostril and repeat the same 15-second procedure.

If the HCW remains 6 feet from the patient, self-collection with MT sampling does not require an N95 respirator; a surgical mask is sufficient (provided it is not in an area where global N95 use is recommended, such as quarantine and isolation).

- **For the antigen POC test only, use a DRY SWAB.** If the patient collection area is far from the device, put the swab in a sterile tube for transport over to the device location.

**AN COLLECTION FOR COVID-19 OR INFLUENZA SPECIMENS**

- Use a single foam swab for collecting specimens from both nares of a symptomatic patient. Insert foam swab into one nostril straight back (not upwards). Once the swab is in place,
rotate it in a circular motion two times and keep it in place for 15 seconds. Repeat this step for the second nostril using the same swab. Remove the foam swab and insert the swab into an acceptable viral transport medium (PCR only), listed in this guide.

**For the antigen POC test only, use a DRY SWAB.** If the patient collection area is far from the device, put the swab in a sterile tube for transport over to the device location.

- If the HCW remains 6 feet from the patient, self-collection with AN sampling does not require an N95 respirator; a surgical mask is sufficient (provided it is not in an area where global N95 use is recommended, such as quarantine and isolation).

- **NOTE:** AN specimens can also be collected with OP to increase sensitivity. If collecting both an AN and OP swab, they can be put in the same media tube, as long as both tips are in the liquid.

**NP COLLECTION FOR COVID-19 OR INFLUENZA SPECIMENS**

- **NP Swab Technique:** Insert the swab into one nostril parallel to the palate, gently rotating the swab inward until resistance is met at the level of the turbinates; rotate against the NP wall (approximately 10 seconds) to absorb secretions. See mid-turbinate and nasal techniques below.

- **For the antigen POC test only, use a DRY SWAB.** If the patient collection area is far from the device, put the swab in a sterile tube for transport over to the device location.

**NOTE:** Sputum inductions are not recommended as a means for sample collection.

3. **ELECTRONIC HEALTH RECORD SYSTEM (EHRS) TEST ORDERING AND TEST CONSIDERATIONS FOR COVID-19 AND INFLUENZA**

**COVID-19 PCR, QUEST**

- **Ordering a COVID-19 Quest RT-PCR Test**
  - Order SARS-CoV-2 RNA (COVID-19), Qualitative Real-Time RT-PCR testing (Enter “COVID” into the order search menu, and choose: “CoV-2 RNA QUAL NAAT” in EHRS; Quest Test Code: 39448).

  - **IMPORTANT:** COVID-19 nucleic acid amplification testing (NAAT) testing should be ordered as “ASAP.” Please do not order as “routine” (delays one week) or “STAT” (will not process).

    **NOTE:** Full PPE required when obtaining specimens include an N95 mask, eye protection, gown, and gloves.

  - Please refer to the CCHCS COVID-19 Testing Fact Sheet on Lifeline (CDCR networking is required for access) and the Quest COVID-19 Specimen Collection Guidelines.

  - RT-PCR specificity is >99%, and sensitivity is >90% if done within the first five days of symptoms and with proper collection technique (see below).
Past literature and consensus have suggested that test performance for PCR is best with a NP sample, then mid-turbinate, then nasal. However, the CDC has removed the preference for NP specimens for SARS-CoV-2 testing.

Repeat testing for SARS-CoV-2 (and other respiratory pathogens if indicated) with NP and OP specimen(s) by PCR is recommended when clinical suspicion is high, but initial PCR testing is negative.

**COMBO COVID/INFLUENZA PCR and COVID/MULTI-PANEL**

A new **INFLUENZA and SARS-CoV-2 COMBINATION Qualitative NAAT** test is now available (test code 31688).

There are two other SARS-CoV-2 NAAT tests available as part of a viral multi-panel:

1. Quest Misc Test, COVID with RESP PANEL, Test Code 31686
   - SARS-CoV-2 (COVID-19), Adenovirus, Influenza A H1 and H3, Influenza B, RSV A/B, Parainfluenza 1,2,3, Rhinovirus/Enterovirus, Metapneumovirus.

2. Quest Misc Test, COVID WITH RESP PANEL, Test Code 31687
   - All in 31686 and Parainfluenza 4, Coronavirus 229E, OC43, NL63, HKU 1, Bocavirus, Chlamyドphila pneumoniae, and Mycoplasma pneumoniae.

**COVID-19 Sample Specifications from Quest**

See the Quest website for test information on the single test 39448 and combination tests 31688, 31686, and 31687.

Note: Specifications that differ between the SARS-CoV-2 tests:

- For the **31688** Combo influenza and SARS-CoV-2 (preferred specimens are NP or AN - Nasal):
  - Room temperature 7 days
  - Refrigerated 14 days

- For **31686** and **31687** (preferred specimen is NP swab in VCM transport container):
  - Room temperature unacceptable (this is different from the standalone COVID19- 39448)
  - Refrigerated 5 days
  - Frozen acceptable
  - Reject Criteria:
    - Calcium alginate swabs
    - Cotton swabs with wooden shaft
    - Amies liquid or gel transport used for bacterial cultures
    - Swab in Saline or PBS
COVID-19 and Seasonal Influenza: Interim Guidance for Health Care and Public Health Providers

- Sources other than nasopharyngeal

Single COVID test specifications for 39448:

- Dry swab submissions are unacceptable and will be rejected (use dry swabs for the Sophia 2 rapid POC testing only).

- Accepted specimen: NP (and NP with OP), MT, AN (and AN with OP) swab collected in a sterile collection tube containing 3 ml of viral transport medium. Sterile saline (2-3 ml) can also be used as a transport media. Acceptable tubes include but are not limited to phosphate-buffered saline (PBS) red top tube, diagnostic hybrid tubes (VCM) medium green-cap tube, universal transport medium (UTM), BD universal viral transport (UVT), M4, M4RT, M5, M6, or Copan ESwabs™ or BD ESwabs™ transport media.
  - Sputum (not induced) may also be collected and sent to Quest in a plastic, sterile, leak-proof container, such as a urine cup.
  - Updates on acceptable collection tubes can be found at Quest’s Specimen Collection Guidelines.

- **Important**: Leakage can be a concern. Take caution to tighten the cap properly to avoid leakage. If possible, freeze samples upright at -20°C (-68°F) before pick up. This can minimize the leakage risk.

- Storage and Transport: COVID-19 specimens are best refrigerated and transported with cold packs. Follow standard procedure for storage and transport of refrigerated samples.

- Cold packs/pouches must be utilized if samples are placed in a lockbox.

- All media: Frozen -68°F (-20°C or -4°F) specimens are stable for 7 days (freezing will mitigate potential leakage).

- All media are stable at room temperature (2-25°C or 35.6-77°F) or refrigerated (2-8°C or 35.6-46.4°F) for 5 days.

- COVID-19 is not a STAT test, and a STAT pick-up cannot be ordered.

- Turn-around time (TAT), published as 3-4 days, may be delayed in times of high demand

- Calcium alginate swabs, wooden shafted swabs, charcoal medium, anaerobic swabs, or transport medium are NOT acceptable.

- Any swab submitted in media containing guanidinium or guanidine isothiocyanate, guanidine or guanidinium thiocyanate, or like component is NOT acceptable and will be rejected.

- Examples of unacceptable swabs/transport: Ruhof kits, Abbot Multi-collect, Babio VTM, and MANTACC UTM.

**Precautions for COVID-19 Quest Specimen Collection**

- The collection of upper respiratory specimens is considered an aerosol-generating procedure (AGP). In choosing the location for specimen collection, consideration should be given for minimizing any unnecessary exposure. The preferred location for specimen collection is in a room with only the individual being sampled, the door closed, and no other individuals present.
When collecting diagnostic respiratory specimens (e.g., NP swab or HCW collected MT and AN) from a possible COVID-19 patient, all Health Care Personnel (HCP) in the room should wear an N95 respirator, eye protection, gloves, and a gown during collection. HCP present during the procedure should be limited to only those essential for that patient’s care and procedure support. Specimen collection should be performed in a location and circumstance that minimizes exposure. (See the Aerosol-Generating Procedures memo- CDCR networking is required for access).

- Clean and disinfect procedure room surfaces promptly as described in the environmental infection control section of the CDC Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings.

If individual rooms are not available, other options include:

- Large spaces (e.g., gymnasiums) where sufficient space can be maintained between swabbing stations (i.e., greater than 6 feet apart).

- An outdoor location, weather permitting, where other individuals will not come near the specimen collection activity.

Considerations for multiple persons being swabbed in succession in a single room:

- Consider using portable high-efficiency particulate air (HEPA) filters to increase air exchanges and expedite removing infectious particles.

- Minimize the amount of time each person will spend in the room.
  - People awaiting swabbing should not wait in the room where swabbing is being done.
  - Those swabbed should have a face mask or cloth cover in place for source control throughout the process and should only be removed during swabbing.
  - Those awaiting collection should physically distance as much as possible.

- Minimize the equipment kept in the specimen collection area.

**Requesting Quest COVID-19 Test Kits**

- To request COVID-19 testing kits from Headquarters (HQ), Quest, or both, submit an email to CDCRCCCHCSLabQuestions@ceder.ca.gov.

- Additionally, requests for a large number (>300) of Quest test kits need to be vetted by the HQ Public Health Branch (PHB) before distribution. Please email the HQ PHB concurrently with large-number kit requests: CDCRCCCHCSPublicHealthBranch@ceder.ca.gov. HQ PHB vetting is not needed for ongoing surveillance testing, testing to accommodate patient movement, or to maintain regular supply levels of kits.
NON-QUEST COVID-19 TEST ORDERING
- All non-Quest testing must be entered as an order in EHRS as “Misc Test Other-COVID19” to allow tracking of the pending test and for the results to later be stored as discrete reachable data. See the image below:

- The results come to CDCR through the county. CDCR staff must manually enter the results into these areas:
  1. Manual entry into the EHRS results section, which is critical for testing statistics to be captured by internal and external monitoring databases and dashboards.
  2. The PHB SharePoint website, entered by the public health nurse (PHN) or infection control nurse (ICN).

- Note: Orders for isolation or quarantine, if indicated, should be placed and will prompt the medical surveillance requirements and allow tasking and tracking by nursing and the PHB.

COVID-19 ANTIGEN TEST
Ordering a COVID-19 POC Rapid Antigen Test
Combo COVID/Influenza POC, QUEST: There are new SARS-CoV-2 and Influenza combination antigen test cassettes for the Sophia 2 POC device. Unless directed otherwise, POC testing will be charted for both the same as previously done for single SARS-CoV-2 and influenza POC tests.
- COVID-19 POC Clinical Laboratory Improvement Amendments (CLIA)-waived rapid antigen tests can be run on the Sofia 2 device provided for all institutions.
- The POC test may be ordered in the EHRS as follows:
Find the COVID-19 order options and choose the “COVID-19 Rapid Test POC.”

Then under “Type of Test,” choose the “Antigen FIA Test.”

Charting COVID-19 POC Test Results in EHRS
Chart POC COVID-19 results using: the Task List tab > Schedule Patient Care tab > double click on the Influenza-Like Illness POC Results task > the PowerForm will pop up > document and sign the PowerForm > the task and the order will complete.

There are also Webinar videos on Lifeline ECHOS/EHRS Project > ECHOS Learning Team > Nurse Webinars (tab for instructions).

Requesting Antigen COVID-19 Test Kits
- Facilities can now order their antigen test cassettes. Please follow the instructions in the 7/22/2020 memo on Ordering Sofia-2 Compatible COVID-19 POC Kits and the 8/26/20
UPDATE: Reordering Sofia-2 Compatible COVID-19 Point of Care Testing Kits (CDCR networking is required for access to both).

- The Overview of Testing for COVID-19 table compares the different types of testing for COVID-19, and Appendix 17 compares NAAT and POC antigen testing and suggested usage.

**INFLUENZA A/B PCR, QUEST**

**Influenza PCR Test Ordering**

Use the following test orders for influenza PCR:

- **Influenza A/B RNA**, Qual, PCR; Test Code 16086; the preferred specimen is NP swab
- **Influenza plus SARS-CoV-2 combination**, Qual PCR, Test Code 31688
- **Influenza A and B and RSV RNA** Qual Real-Time PCR; Test Code 91989; preferred specimen nasal or NP swab
- **Influenza as part of a multi-panel 37444** (NO SARS-CoV-2)
  - Adenovirus, Influenza A H1 and H3, Influenza B, RSV A/B, Parainfluenza 1,2,3,4, Rhinovirus/Enterovirus, Metapneumovirus, Non-COVID-19 coronaviruses 229E, OC43, NL63, and HKU1, Bocavirus, and Chlamydophila pneumoniae
- **Influenza as part of a multi-panel WITH SARS-CoV-2: 31686 and 31867**
  
  NOTE: Influenza specimen collectors usually use droplet precautions, but because all with influenza-like illness (ILI) must also be considered for COVID-19, PPE for COVID-19 should be used as above.

**Influenza Sample Specifications from Quest**

Please refer to the 2018-2019 Quest Diagnostics Specimen Collection Guide for details and the Quest test information on 16086, 37444, 31686, and 31867.

**Precautions for Influenza Quest Specimen Collection**

PPE for influenza specimen collection is a surgical mask, gown, and gloves. Collection occurring in the vicinity of COVID-19 collection should not occur. Patients with undiagnosed ILI need to be kept separate.

**RAPID INFLUENZA CLIA WAIVED DIAGNOSTIC TEST (RIDT)**

Please refer to RIDT ordering instructions and other helpful information (Appendix 14).

There are new SARS-CoV-2 (COVID-19) and influenza combination antigen test cassettes for the Sophia2 POC device. Unless directed otherwise, POC testing will be charted for both the same as previously done for single SARS-CoV-2 and influenza POC tests.

The Influenza A&B Rapid POC Test order and documentation have been placed into the EHRS production domain.

Once ordered, a task fires to the “Scheduled Patient Care” tab of the task list and is linked to the corresponding documentation for capturing results. These orders are not schedulable; therefore, staff shall complete the test at point of care or upon order by the provider.
Screenshots below reference the order that shall be placed and the task that fires as a result. Document the results of the new Influenza A&B Rapid Test POC that is being ordered by providers.

**IMPORTANT:** Use the RT-PCR for influenza testing until the 2020-2021 season has started in California, and influenza prevalence is designated as “Local” or higher.

- When influenza is prevalent (transmission designated “Regional” or “Widespread” in your region by CDPH Weekly Influenza Report or CDC Weekly Flu View), rapid test kits for POC influenza testing may be used to identify influenza infections quickly.
COVID-19 and Seasonal Influenza: Interim Guidance for Health Care and Public Health Providers

• Due to unreliable sensitivity (regardless of season), further testing is always indicated if the RIDT result is negative. Order the influenza A/B RNA Qualitative PCR (test code 16086) and COVID-19 RNA Qualitative NAAT (test code 39448).

• RIDT is only useful for ruling in influenza when prevalence is high. When the CDPH specifies that influenza transmission has downgraded to “sporadic” (typically late spring) for your institution’s geographic area, DO NOT USE the RIDT tests any longer.

• Headquarters PHB will send notification of when to stop and start RIDT use.

4. OTHER RESPIRATORY VIRUS TESTING CONSIDERATIONS

• For patients presenting with symptoms of pneumonia, test for influenza and COVID-19 concurrently. Use RT-PCR for influenza testing until the beginning of the 2020-2021 influenza season in the fall. RIDT can be used for rapid flu testing during flu season. Then clinicians should use their judgment in testing for other respiratory pathogens, including RSV and coccidioidomycosis (Valley Fever).

• The RSV season generally coincides with influenza. RSV testing is indicated if it will affect clinical management. Consider testing for RSV in vulnerable populations, including those with heart or lung disease, bone marrow and lung transplant recipients, frail older adults, and those with multiple underlying conditions. More information can be found on the California Department of Public Health’s webpage on Influenza and Other Respiratory Pathogens.

• Patients with coccidioidal infection develop symptoms and detectable antibodies within 7-21 days of exposure. Patients who demonstrate measurable anti-coccidioidal antibodies are likely to have a recent illness or one that continues to be active because antibody levels decrease over time and eventually become undetectable in most patients who resolve their infection. More information can be found in the Cocci Skin Test (CST) Education and Cocci Surveillance Training Slides (CDCR networking is required for access to both), the CCHCS Cocci Care Guide, and the CDP’s webpage on Valley Fever.

ORDERING RSV TESTS

• Use the Influenza A/B and RSV Qualitative RT-PCR (test code 91989), or as part of extensive multi-viral panels (test code 37444 does NOT have SARS-CoV-2; test code 31686 and 31687 which DO HAVE SARS-CoV-2 included), or as a standalone: Quest Misc Test, RSV (test code 16047).

• Patients with coccidioidal infection develop symptoms and detectable antibodies within 7-21 days of exposure. Patients who demonstrate measurable anti-coccidioidal antibodies are likely to have a recent illness or one that continues to be active because antibody levels decrease over time and eventually become undetectable in most patients who resolve their infection. More information can be found in the Cocci Skin Test (CST) Education and Cocci Surveillance Training Slides (CDCR networking is required for access to both), the CCHCS Cocci Care Guide, and the California Department of Public Health’s webpage on Valley Fever.