

2019-NOVEL CORONAVIRUS (COVID-19) SPECIMEN COLLECTION KIT AND SHIPPING INSTRUCTIONS

Any CDC and or FDA approved SARS-Cov-2 kit can be used to collect nasopharyngeal/oropharyngeal swab specimens

Kit contents: 1 Tube of Universal Transport Media (UTM); 1 Nasopharyngeal swab (smaller swab, flexible shaft) (**CDC recommended**); 1 Ziploc specimen bag containing absorbent pad; 1 Test Requisition form and 1 Ice pack (keep in a freezer until ready to package & transport specimens)

Collection Instructions: See the current CDC guidelines for upper and lower respiratory specimen collection and

Appropriate biosafety precautions for healthcare workers found at:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html>

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/caring-for-patients.html>

1. Label tube of UTM legibly with the patient's name **and** date of birth, or medical record number (specimen tube **must** have two unique patient identifiers on it, or it will not be tested).
2. **Nasopharyngeal specimen: (CDC recommended specimen type)**
 - a. Use the flexible shaft NP swab provided to collect the specimen.
 - b. Insert the swab into the tube of UTM, making certain that the swab tip is covered by the liquid in the tube. The swab is to remain in the tube for transport.
 - c. The swab shaft extends past the top of the tube. Snap off at the break line on the shaft, allowing the end with the swab tip to remain in the liquid. The tip of the swab must be immersed in the liquid.
3. **Throat specimen (Oropharyngeal swab [OP]): If nasopharyngeal specimen can not be collected due to inability to procure np swabs, a throat swab can be sent as an alternative specimen. NOTE: Throat swab tips must be synthetic (ex: polyester, rayon, or dacron). Cotton or calcium alginate tipped, or wooden shaft swabs are unacceptable.**
 - a. Use a throat swab to collect specimen by swabbing the patient's posterior pharynx and tonsillar area (avoid the tongue).
 - b. Insert the swab into the vial of UTM. If the swab shaft extends past the top of the tube, clip it so that the top of the swab shaft it is just below the top of the tube allowing the end with the swab tip to remain in the liquid. The swab tip must be immersed in the liquid.
4. Securely tighten the cap on the tube of UTM and recheck to make certain it is labeled with two patient identifiers. Write "NP" or "OP" on the tube of UTM. Insert tube into specimen transport bag and close bag tightly.
5. Complete the test requisition form. For test requested, write "COVID-19" under Comments/Other test requests. Ensure that all information is legible, complete and accurate. Place the completed form into the outside pocket of the specimen bag. Do **not** enclose it inside the bag with the specimen tube.
6. **Shipping and Handling:** Store specimens refrigerated (2 – 8 °C) until ready to send to the laboratory. Specimens must be received refrigerated within 72 hours. Specimens must be packaged and shipped in accordance with appropriate Department of Transportation (DOT) regulations for Category B Biological Substances.
 - a. Place the securely sealed Ziploc bag containing the specimen tube **along with the frozen ice pack** into the styrofoam box that is contained within the cardboard shipping box. If using an alternate type of packaging, make certain it is compliant and labeled appropriately for Category B Biological Substances.
 - b. Ensure that the outer packing box that is supplied with the specimen kit is sealed securely with packaging tape.
 - c. Ensure shipper label information for your facility : **IGeneX, Inc., 556 Gibraltar Drive, Milpitas, CA 95035, USA** is completed in full and affixed to the outer package.
 - d. **Ship Specimen to: IGeneX, Inc., 556 Gibraltar Drive, Milpitas, CA 95035, USA**
7. **Transport:** Submitters are responsible for arranging for specimens to be transported to the Laboratory. (ex: commercial courier)
8. **For questions regarding specimen collection, packaging and shipping:** Call IGeneX and ask to speak with the person who can assist with COVID packaging and shipping questions.

