

Instructions for use of medical device for medical sample collection and transport for SARS-CoV-2 and other respiratory viruses.

► Required materials:

- GenoSur SARS-CoV-2 Sample Collection Kit.
- Disposable Personal Protective Equipment (PPE):
 - Disposable gown.
 - Gloves.
 - Surgical face mask or face shield.
 - Eye protection: safety glasses, goggles, or face shield.
 - Disposable headcover.
- Tissues.
- Biohazard bag.
- Soap and water or alcohol gel to clean hands.
- Permanent marker to label the sample.
- A gauze or wipes with 70% isopropyl or ethyl alcohol.

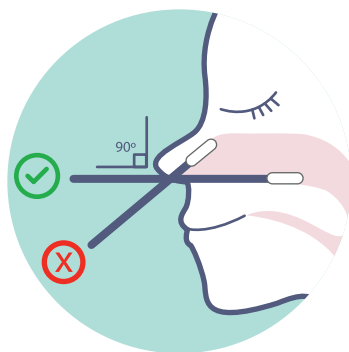
► Steps:

1. Before coming into contact with the patient:

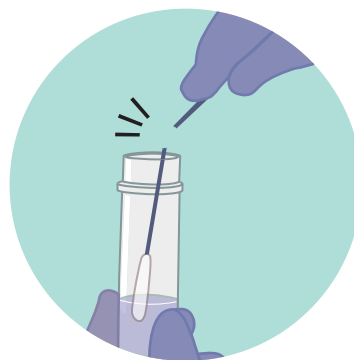
1. Gather all the required materials.
2. Put on the facial PPE: surgical face mask, safety glasses, and headcover.
3. Perform a surgical scrub of hands with soap and water or alcohol gel.
4. Put on the rest of the PPE: gown, and finally the gloves.
5. Open the kit.
6. Write the date and time of the sample collection and the patient ID on both labels.
7. Attach one of the labels to the sample collection tube and the other to the airtight storage bag.
8. Fill out the Security Checklist Part 1. Do not take it to the area in contact with the patient.

2. When in contact with the patient:

9. Take all the required materials with you when entering the patient's room.
10. Greet the patient and explain to them the procedure you will perform.
11. Ask the patient to blow his/her nose and to discard the tissue in the biohazard bag.
12. Place the patient in a comfortable position with his/her head slightly tilted back and hopefully supported by a wall or pillow. Hold it in that position.
13. Insert the swab through the nostrils parallel to the palate, not upward, until contacting the nasopharynx, indicated by encountering resistance, or a distance equivalent to that from the ear to the nostril of the patient.



14. Gently rotate the swab in that position, trying to obtain as much mucus as possible.
15. Slowly remove swab.
16. Place the swab into the kit tube. Be sure that the swab is submerged in the liquid, but not touching the bottom.
17. Break off the swab shaft using the breakpoint on it. Hold the tube firmly to avoid dropping it. While breaking off the swab shaft, be sure that the tip of the swab is not touching the bottom of the tube. The remaining swab shaft may be too long to close in the tube otherwise.



18. Screw the cap back onto the tube with the swab inside.
19. Gently shake the tube up and down at least 5 times.
20. Clean the entire tube surface using the gauze and alcohol, or the 70% alcohol wipes.
21. Place the tube inside the airtight bag and close it.
22. Place the airtight bag inside the transportation bag (white bubble mailer bag).
23. Discard all the leftover items in the biohazard bag.
24. Exit the patient's room.

3. After coming into contact with the patient:

25. Remove the PPE: first, remove the gown by holding one shoulder area using the opposite hand and pulling down toward the hand. Remove the glove from that hand when removing that sleeve. With the hand that has no glove, hold the gown touching the inside that is in contact with you, and repeat the previous maneuver to remove the other sleeve and glove. Discard the gown and gloves in the biohazard bag. Remove the head cover, the security glasses, and the face mask in that order.
26. Discard the PPE in the biohazard bag.
27. Close the biohazard bag.
28. Perform a surgical hand scrub.
29. Prepare the sample to be sent to a lab.
30. Complete Security Checklist Part 2.

► Security Checklist:

Before coming into contact with patient:

- I placed all the materials in order and prepared them.
- I put on the facial PPE.
- I washed my hands.
- I put on the PPE gown and gloves.
- I labeled the kit labels with date, name, and Patient ID/Code (identification).
- I attached the kit labels to the tube and the airtight bag.

After coming into contact with patient:

- The patient blew his/her nose and discarded the tissue in the biohazard bag.
- I took the nasopharynx sample correctly. I felt the resistance, and I gently rolled the swab
- I placed the swab inside the tube.
- I carefully cut off the swab shaft. I did not spill the tube content or shake it roughly.
- I placed the cap on the tube.
- I cleaned the tube outside with 70% alcohol or alcohol gel.
- I placed the tube inside the transport bag.
- I closed the transport bag.
- I placed the transport bag inside the white bubble mailer.
- I discarded all leftovers in the biohazard bag.
- I removed the PPEs according to the established protocol.
- I did not touch my skin or my face when I took off the PPEs.
- I discarded the PPEs in the biohazard bag.
- I closed the biohazard bag.
- I washed my hands.