

Document ID: Pearl - 103	Pearl Medical Practice Standard of Procedure for Collection of SARS-CoV-2 Specimens	Print Date:
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This protocol is established in respect to specimen integrity, patient safety, and employee safety.

Inventory Processes to begin each day

1. Personal Protective Equipment

Ensure at the beginning of each day that all necessary PPE materials are stocked and available at a capacity required for the work load expectations. Insufficiencies in inventories of these materials should be identified in enough time in order to allow for receipt of orders placed for supplies. These supplies include the following materials: gloves, face shield, face mask, and lab coat.

2. Collection Materials

Prior to the day's workload check all necessary supplies required for the collection of a swab specimen. Supplies that are less than sufficient volume should be identified in enough time in order to allow for receipt of orders placed for collection supplies from Pearl Medical. Please evaluate and re-stock these supplies throughout your work day as patient volume necessitates. Materials needed are as follows:

- a. PPE
- b. Collection Supplies
 - a. Nasopharyngeal swab w/ Collection Tube OR
 - b. Nasal Swab w/ Collection Tube
- c. Biohazard Disposal Box

Filling Out Requisition

1. Fill out all fields of the Pearl Medical requisition including the questions at the bottom of the page.
2. Have patient and/or ordering provider sign the requisition.
3. Place two unique patient identifiers on the sample. Types of patient identifiers are below. Patient name and date of birth are preferred.
 - a. Date of birth
 - b. First and Last name of patient
 - c. Social Security Number
 - d. Medical Record Number

Patient Acknowledgement

One of the most important steps in the process of collecting a swab specimen is the interaction with the patient. Not only for the comfort of the patient but also in the capacity that it allows Pearl Medical to gain specific information necessary to the collection of a swab specimen. Important information can be shared as well that is essential to patient safety.

1. Introduction

Please state your name for the patient and explain that Pearl Medical has obtained that requires a collection of a swab specimen.

2. Patient Confirmation

Have the patient confirm the two unique identifiers provided in the orders given to Pearl Medical. The questions asked in this process should not have the expected responses of “Yes or No”.

Example: “Please tell me your date of birth and your last and first name”

Preparation for collection

1. Review the requisition form and make sure all fields are filled out.
2. Arrange collection materials that are needed for the collection of the swab specimen.
3. Hygiene and PPE - Wash your hands and apply all PPE that is necessary. Change gloves with every patient encounter.

Collection of the Specimen

1. Labeling
 - a. Label all tubes with two unique patient identifiers
2. Swabbing
 - a. Nasal Swab
 - i. Use the nasal swab included in the sampling kit. Tilt patient’s head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at turbinates). Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.
 - b. Nasopharyngeal swab
 - i. NP swab: Insert minitip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

- c. Oropharyngeal
 - i. Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.
 - d. When patients are self-collecting their swabs under clinical supervision:
 - i. Hand a swab to the patient only while wearing a clean set of protective gloves.
 - ii. The patient can then self-swab and place the swab in transport media or sterile transport device and seal.
 - iii. If the patient needs assistance, you can help the patient place the swab into transport media or a transport device and seal it.
3. Packaging
- a. Place swab in a dry transport tube and fold over or break swab stem to fit into tube. Cap the tube.
 - b. Place samples in individual biohazard bags before shipping with an absorbent pad in each bag.
 - c. Label biohazard bag with two patient identifiers.
 - d. Fold and place requisition in bag with sample.
4. Handling and Storage of Collected specimen
- a. Store specimens at room temperature until ready to ship. If not shipped within 24 hours, store at 2–8°C.
5. Dismissal of Patient
- a. Make sure that the patient no further concerns and make them aware that all results will be rendered to the Medical Provider.
 - b. Sanitize the collection area prior to the receipt of another patient for collection of blood.

Shipping of Collected specimen

1. Ship samples in a cooler between 2–8° within 8 hours of collection. If shipment is expected to exceed 2 days, ship specimens frozen.
2. Place packed samples in a FedEx® UN 3373 Pak.
3. Ship to:
Pearl Medical Practice
c/o Laboratory
2202 Buechel Avenue
Louisville, KY 40218



Lyra Direct SARS-CoV-2 ASSAY

Emergency Use Only Oropharyngeal Specimen Collection Procedure Card

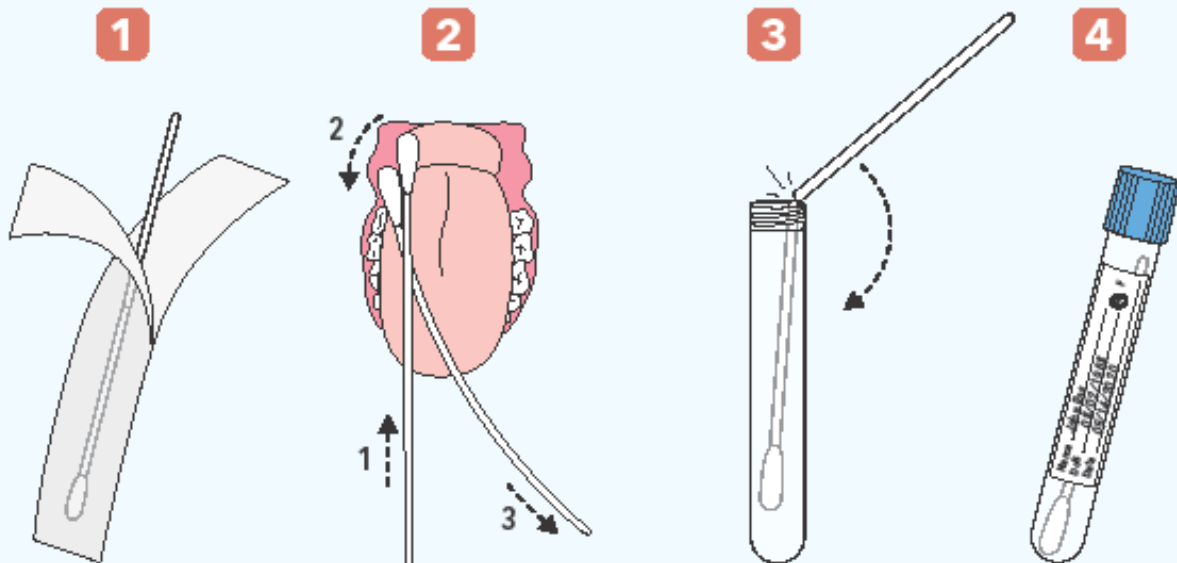


Study the Package Insert thoroughly before using this Procedure Card. This is not a complete Package Insert.

NOTE: For nasal swab specimens use flocked or polyester spun swab.



Dry transport tubes can be received in 1 of the 3 different tubes. One of these tubes will be provided.



Peel open sterile pouch and remove swab.

Touch the swab tip to the tonsil area.
Rub the swab tip quickly and firmly over this area to obtain a good sample.
Remove swab from mouth (without touching any surface).
A gag reflex reaction is very common when a good sample is obtained.

While holding the swab, remove cap from the tube.
Insert the swab into the tube until the breakpoint is level with the tube opening then break the swab stem at that breakpoint.

Record specimen information on tube.
Store patient swab(s) at room temperature for 24 hours or up to 72 hours at 2°C to 8°C until testing.



Lyra^{Direct} SARS-CoV-2 ASSAY

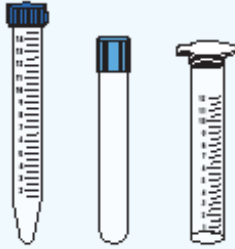
Emergency Use Only

Nasal Specimen Collection Procedure Card

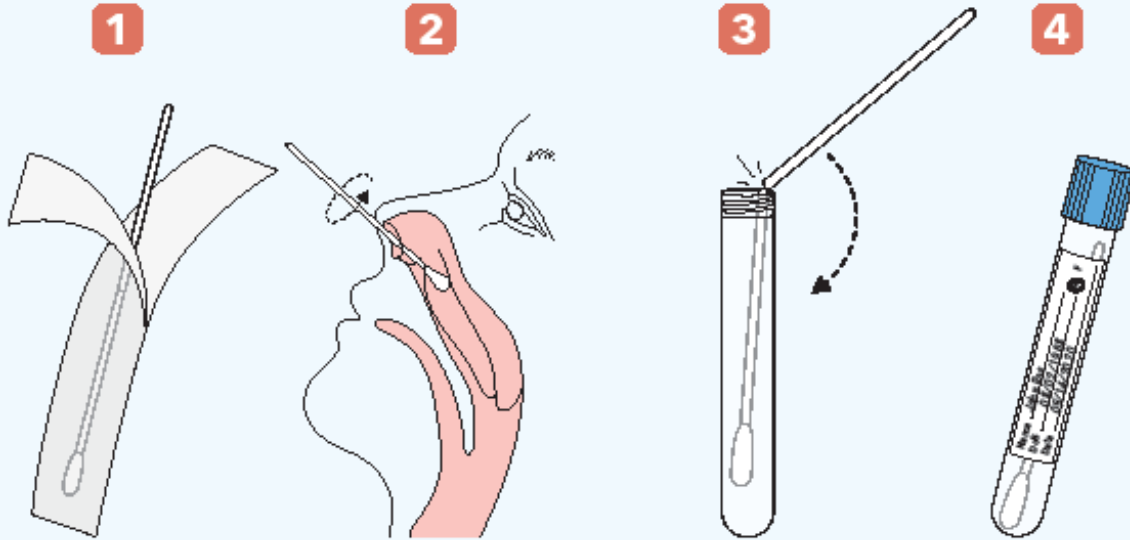


Study the Package Insert thoroughly before using this Procedure Card. This is not a complete Package Insert.

NOTE: For nasal swab specimens use flocked or polyester spun swab.



Dry transport tubes can be received in 1 of the 3 different tubes. One of these tubes will be provided.



1 Peel open sterile pouch and remove swab.

2 Gently insert the sterile swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab a few times against the nasal wall and remove from nostril.

3 While holding the swab, remove cap from the tube. Insert the swab into the tube until the breakpoint is level with the tube opening then break the swab stem at that breakpoint.

4 Record specimen information on tube. Store patient swab(s) at room temperature for 24 hours or up to 72 hours at 2°C to 8°C until testing.



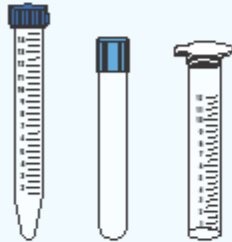
Lyra Direct SARS-CoV-2 ASSAY

Emergency Use Only Nasopharyngeal Specimen Collection Procedure Card



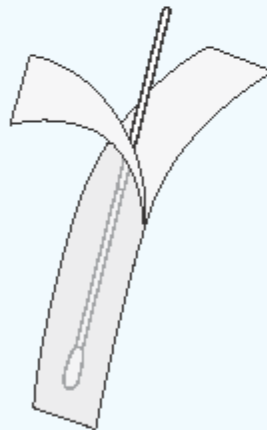
Study the Package Insert thoroughly before using this Procedure Card. This is not a complete Package Insert.

NOTE: For nasopharyngeal swabs use only flocked swabs with flexible plastic shafts.



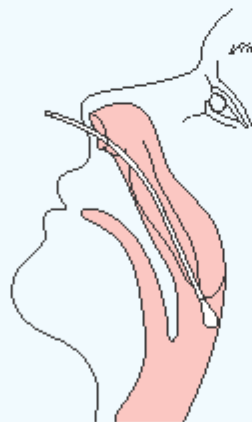
Dry transport tubes can be received in 1 of the 3 different tubes. One of these tubes will be provided.

1



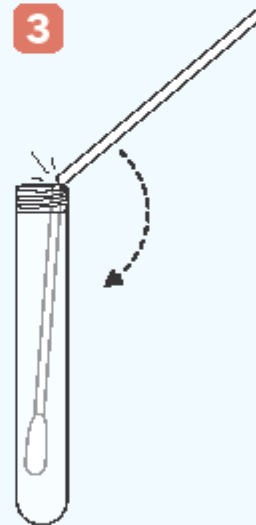
Peel open sterile pouch and remove swab.

2



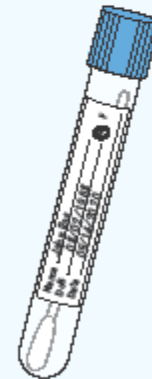
Obtain nasopharyngeal swab by gently inserting the sterile swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times and remove from nostril.

3



While holding the swab, remove cap from the tube. Insert the swab into the tube until the breakpoint is level with the tube opening then break the swab stem at that breakpoint.

4



Record specimen information on tube. Store patient swab(s) at room temperature for 24 hours or up to 72 hours at 2°C to 8°C until testing.