

SARS-CoV-2 Specimen Collection Kit

Cat #	Description	Qty/Unit
88-220K	SARS-CoV-2 (COVID-19) Specimen Collection Kit	50
88-220KC	Nasal Swab & Tube With 3ml 0.9% Saline Solution, Sterilized by Electron-Beam Irradiation	500



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Note to Healthcare Professionals

This nasal specimen collection kit must only be used for collection of Novel Coronavirus (SARS-CoV-2) specimens from the anterior nares. This kit is not intended for collection of other respiratory viruses that require use of an appropriate nasopharyngeal swab and specific transport media.

Specimen Collection

- During collection of the sample, take precautions and do not allow the collection swab to contact any surface other than the point of collection (anterior nares).
- Immediately following collection of the sample, place the entire swab into the provided sterile container by submerging the swab tip in the saline solution and secure the screw cap tightly.
- Label the collection tube with patient identifiers according to your SARS-CoV-2 assay provider's requirements. Common identifiers include name, date of birth and date of collection.
- Seal the tube inside the provided specimen bag and store appropriately.

Storage and Shipment of Collected Specimens

It is recommended to freeze the collected specimen; however, confirm the preferred storage and shipping temperature conditions of collected specimens with your SARS-CoV-2 assay provider prior to outbound shipment of patient specimens. Suitable options for most providers include room temperature shipment (if received within 24 hours or less after collection), refrigerated shipment (if received within 72 hours or less after collection), or frozen shipment (-20°C).

- This collection kit has received authorization by the United States Food and Drug Administration (FDA) solely for the collection and storage of nasal swab specimens to be assayed subsequently for the detection of nucleic acid from SARS-CoV-2, not for other viruses or pathogens.
- This collection kit has not been FDA cleared or approved and in combination with the authorized SARS-CoV-2 detection test, is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



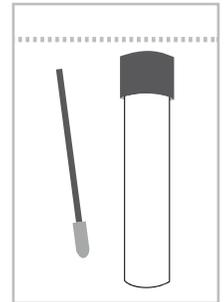
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Specimen Collection Instructions

Please read and review the following instructions carefully prior to patient sample collection.

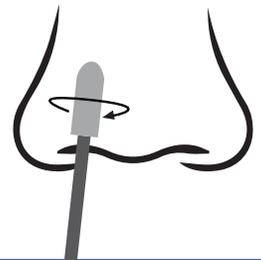
Step 1

Open the sterile pouch. Remove the collection tube and screw off its cap. Hold the tube in one hand and remove the swab from the sterile pouch with your other hand, taking care not to touch the tip of the swab to any surface, including your hands. **Do not pre-wet the swab in the saline solution before collection and take care not to spill any of the solution.**



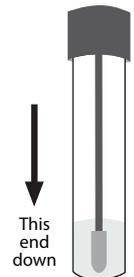
Step 2

Insert the swab into one anterior nare (nostril) **a short distance until the tip of the swab is no longer visible**, and in a circular motion, rotate the swab against the nasal mucosa of the entire inside edge of the nostril at least 3 times. **Repeat with the other anterior nare using the same swab.**



Step 3

Remove the swab from the second anterior nare and place the entire swab inside the collection tube by submerging the swab tip (the end of the swab that entered the nostrils) into the solution and secure the screw cap tightly.



Step 4

Label the collection tube with patient identifiers. Place the tube into the provided specimen bag and store appropriately before transporting to your preferred SARS-CoV-2 (COVID-19) assay provider.

