

The Tempus Nasal Sample Collection Kit

WARNINGS

Individuals exhibiting severe COVID-19 warning symptoms are not allowed to proceed with kit registration and instead directed to seek emergency medical care.

This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization for use by authorized laboratories: use by laboratories designated by Tempus Labs, Inc., which are certified under CLIA and meet the requirements to perform high complexity tests.

This product is authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Federal law restricts this device to be sold by or on the order of a licensed practitioner.

This Home Nasal Swab Collection Kit is intended for 18 years old or older individuals to self-collect anterior nares specimen unsupervised at home when determined to be appropriate by their Healthcare provider.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Intended Use

The iC SARS-CoV-2 Test is a reverse transcription, real-time polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal (NP), anterior nares (AN or anterior nasal), mid-turbinate nasal, and oropharyngeal (OP) swab specimens collected from individuals suspected of COVID-19 by their healthcare provider.

This test is also for use with AN swab specimens that are self-collected unsupervised at home by individuals 18 years of age or older using the Tempus Nasal Sample Collection Kit, when determined to be appropriate by their healthcare provider.

Testing is limited to laboratories designated by Tempus Labs, Inc. which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiologic information.

The iC SARS-CoV2 Test is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of Real-Time PCR and in vitro diagnostic procedures. The iC SARS-CoV-2 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

TEMPUS

600 West Chicago Ave, Ste 510
Chicago, IL 60654

Tempus.com | 800.739.4137

Tempus Labs, Inc. | All Content Copyright 2021 | MM.DD.21

TEMPUS

Rx Only

IVD

For Use Under Emergency Use Authorization (EUA) Only
For individuals 18 years or older

PRE-COLLECTION

1 | Visit the FedEx website at [fedex.com/labreturns](https://www.fedex.com/labreturns) to view drop box locations and pickup schedules.

- Your sample should be shipped the same day that you collect it. Make sure you are able to get to your drop box before the last pickup time on the same day you collect your sample.
- Do not deliver your sample to a drop box on the weekend.

2 | Open test kit on a clean surface.

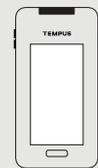
3 | Identify your sample transport tube.

- Using a permanent pen, write your date of birth (MM-DD-YY) on the enclosed label.
- Remove the adhesive backing from the label sticker and affix it to the sample transport tube.



Note: Do not write on or cover up the printed barcode or 9 digit ID number on the tube.

4 | Activate your Tempus kit at activate.tempus.com.



Follow the instructions on the website to fill out the form. Failure to write the appropriate information may result in your sample not being tested.

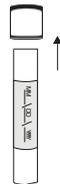
5 | Wash your hands thoroughly for 20 seconds with soap and water before collecting your sample.



COLLECTING YOUR SAMPLE

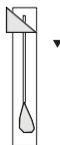
6 | Prepare the sample transport tube by tapping the tube gently and ensure the liquid is at the bottom.

- Unscrew the cap from the sample transport tube and place it on the table.



7 | Remove the swab from the package.

- Do not touch the soft tip of the swab or lay the swab down on any surface.



8 | Insert the soft tip of the swab into one nostril, until the tip of the swab is no longer visible.

- Rotate the swab four times in a circular motion around the entire inside edge of the nostril then keep it in place for 15 seconds.
- Repeat the same process in the other nostril using the same swab.



Note: Simply twirling the swab against one part of the inside of the nose, or leaving the swab in the nose for 10–15 seconds, is not proper technique and may result in an insufficient sample.

9 | Place the swab (tip first) into the sample transport tube.

- Tip of swab will be in the liquid. Leave the swab inside the tube.
- If the swab is too long to fit inside the tube, break the swab handle against the side of the tube at its perforated break point. Discard the top portion of the swab.

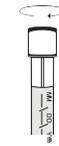


10 | Screw the cap onto the sample transport tube until it is closed tightly.



RETURNING YOUR SAMPLE

11 | Confirm that the sample transport tube is tightly closed and has your date of birth on the transport tube.



12 | Place the sample transport tube in the biohazard specimen bag and seal the bag tightly.



Make sure to leave the absorbent sheet inside the biohazard specimen bag.

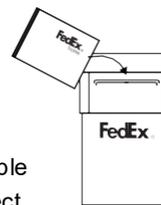
13 | Wipe the outside of the bag with the provided alcohol pad. Dispose of wipe.

14 | Place the biohazard specimen bag into the Tempus-labeled box it came in. Place the Tempus-labeled box into the FedEx UN 3373 Pak.



Remove the adhesive liner of the FedEx UN 3373 Pak and press down firmly to seal the Pak tightly.

15 | Drop off UN 3373 Pak with shipping label at the nearest FedEx Drop Box (see item 1 for locations).



- Please drop off your sample on the same day you collect it and before the last pickup time.
- Do not deliver your sample to a drop box on the weekend.

✔ YOU'RE ALL SET.

After your sample has been dropped off at FedEx, your order will be processed once received.