

LetsGetChecked Coronavirus (COVID-19) Home Collection Kit – Nasal Sample

This collection kit is suitable for the following individuals:

- | | | |
|---|--|--|
| ✓ Adults aged 18+:
Self-collect (unless
unable to do so) | ✓ Teenagers aged 12-17:
Self-collect with
adult (18+) supervision | ✓ Children aged 2-11:
Adult (18+) to collect |
|---|--|--|

Please read these instructions carefully and follow the steps below before you start to collect the sample

If you are collecting a sample from yourself and from a child, please collect your own sample first and then collect the sample from the child.

What to do if you are collecting the sample from a child

- A Position the child for the sample collection.** Remain calm and confident. This will help the child to stay calm too. If possible, have the child sit on someone's lap or have someone hold their hand. Decide before starting who will comfort the child and who will collect the sample.
- B Communicate with the child.** Talk through the steps together. If the child enough, explain the sample collection process in terms they can understand. It may be helpful to give them a distraction or to make the sample collection process into a game.
- C Follow the instructions to collect the sample.** Please see the instructions below. Do not continue if the child has any pain or asks to stop.

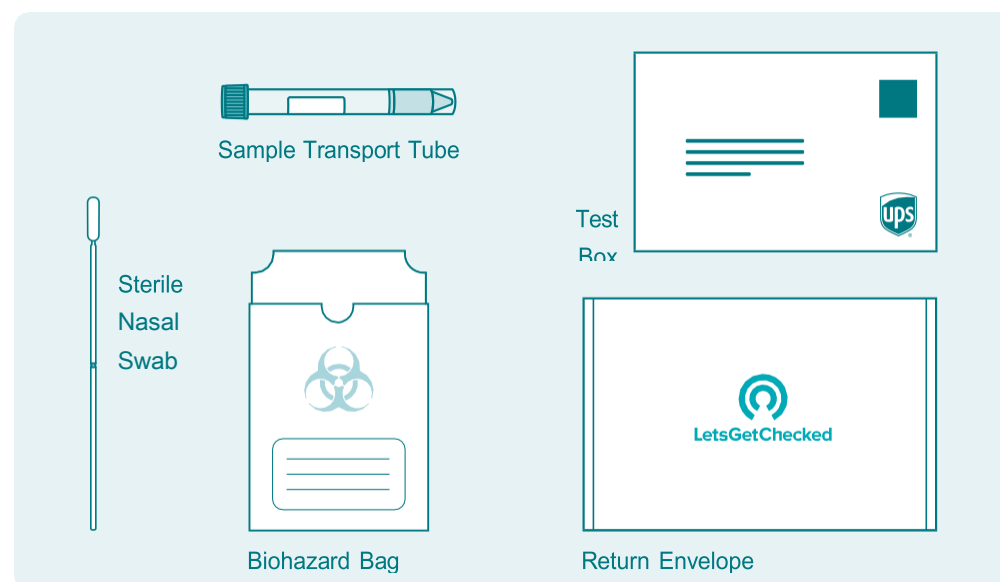
⚠ WARNING:

- You must be over the age of 18 to collect a sample from a child.
- Do not drink or breathe in the liquid in the sample tube
- Avoid contact with eyes and
- If irritation persists, seek
- been placed into the sample
- Keep out of reach of children.

For Use Under Emergency Use Authorization Only.

Nasal Sample Collection Kit Contents

Before you start, make sure you have received the following items:




LetsGetChecked Checklist

Before you return the sample, please ensure you have completed the following steps:


- 1 Before you start, please read all of the warnings.
- 2 Please contact UPS to arrange a pickup, or find a UPS drop off point, before you collect the sample.
- 3 Activate the kit on the LetsGetChecked app or online at LetsGetChecked.com/activate. **Failure to activate the kit means that your sample cannot be processed by the laboratory.**
- 4 Fill in the label on the outside of the biohazard bag with the sample collection date, date of birth and gender.
- 5 Collect the sample following the instructions. Close and seal the sample transport tube in the biohazard bag.
- 6 Place the biohazard bag in the kit box. **Return immediately** using the return envelope provided.

If you have any questions, you can find our contact details on [LetsGetChecked.com](https://www.LetsGetChecked.com)

LetsGetChecked Coronavirus (COVID-19) Home Collection Kit – Nasal Sample: Step-By-Step Instructions.

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Step 1: Before you start



Before you start you must read all of the instructions including the warnings in relation to the liquid in the sample transport tube.
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Step 2: Arrange a UPS return or drop off

Please contact UPS to arrange a pickup, or find a UPS drop off point before you collect your sample. Visit wwwapps.ups.com/pickup/schedule or call 1-800-742-5877 to schedule a pickup. Visit www.ups.com/dropoff to find a drop off point.

You should collect the sample on the same day as the pickup is scheduled for.

Please note that UPS does not operate on Sundays. Do not collect sample on Sundays.

- 3**
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- Step 3: Activate the kit**
- Before collecting your sample, activate the kit on the LetsGetChecked app or online at [LetsGetChecked.com/activate](https://www.letsgetchecked.com/activate).
- If the sample is from a person under the age of 18, please follow the steps to create a guardian account to activate on behalf of the child.
- It is important to note the numerical code on the label on the outside of the biohazard bag. This will be required to activate the kit and to ensure the sample is returned in the correct kit box.
- 4**
- 
- Step 4: Complete the details on the label**
- It is important to fill in the label located on the biohazard bag with the date of collection and the date of birth and gender of the person that the sample was collected from.
- This is essential for the lab to process the sample. Please do not remove any labels from the kit components as they are required for sample identification.
- Please turn this page over to continue.**



Home Collection Kit

Coronavirus (COVID-19)

Nasal Sample Instructions

For Use Under Emergency Use Authorization Only.

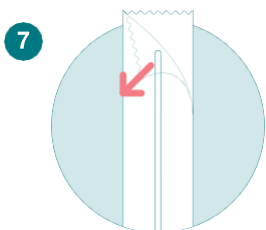
In vitro diagnostic medical device.



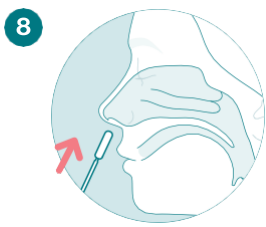
Step 5: Wash hands
Wash your hands in warm, soapy water and dry thoroughly.



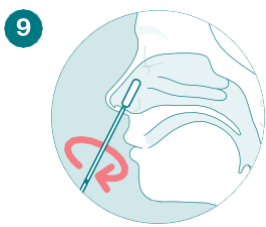
Step 6: Remove the sample transport tube from kit
Remove the sample transport tube from the kit. Screw off the lid and place the tube on a flat surface. Do not spill the contents of the tube.
If you spill the liquid from the sample transport tube, and it makes contact with the skin or eyes, rinse with water. If irritation persists, seek medical advice.



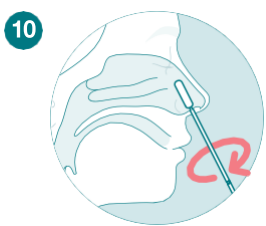
Step 7: Remove the nasal swab from packaging
Partially peel open the nasal swab package. Remove the swab from the packet. Do not touch the soft tip or lay the swab down on any surface. You will need to use this swab on both nostrils.



Step 8: Insert the swab into the nostril
Place the swab into the nostril until the cotton end of the swab is no longer visible. Do not continue if there is any pain.
Do not reinsert the swab into the nostril after it has been placed into the sample transport tube.



Step 9: Collect the nasal sample
Keep the swab in place and rotate it for 10 seconds, then gently remove from the nose. Do not force the swab any further up and into the nose at any point.
You must collect the sample from both nostrils before placing the swab into the sample transport tube.



Step 10: Repeat in the other nostril
Gently insert the swab in the vertical position into the other nostril until the cotton end of the swab is no longer visible. Keep the swab in place and rotate it for 10 seconds, then gently remove from the nose. Do not force the swab any further up and into the nose at any point.



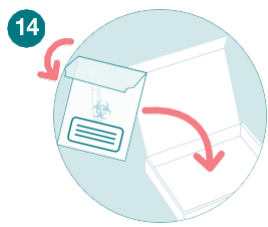
Step 11: Place the swab into the sample transport tube
Place the swab into the sample transport tube immediately. Make sure the swab tip is covered by the liquid in the sample transport tube. Carefully break the swab at the marked/scored line against the side of the tube. Note that breaking the swab above the marked line may result in rejection of the sample.
Discard the top portion of the swab – do not put it into the tube with the sample.



Step 12: Screw the lid of the sample transport tube closed
Screw the lid of the sample transport tube tightly to close it.
This will ensure that the lid does not come off during shipping which would prevent the sample from being processed in the lab.



Step 13: Seal the sample transport tube in the biohazard bag
Place the sample transport tube in the biohazard bag. Do not remove the absorbent pad from the biohazard bag.
To seal the biohazard bag, remove the strip of plastic and fold down the flap.



Step 14: Place the biohazard bag into the kit box
Place the biohazard bag back into the LetsGetCheckedkit box. Ensure you have folded the biohazard bag flap to seal it. Wash your hands in warm, soapy water and dry thoroughly.
Ensure you have completed the label which is located on the biohazard bag.



Step 15: Return the sample
Place the kit box in the return envelope provided. Send the sample back on the same day with UPS. Follow the instructions on the return card in the kit box.
Please note that UPS does not operate on Sundays. Do not collect sample on Sundays.

PLEASE READ:

Visit the CDC website and follow the advice provided in the up to date guidelines here:

www.cdc.gov/coronavirus/2019-ncov

Most people who contract coronavirus are unlikely to have severe symptoms, if you feel very unwell, are experiencing breathing difficulties or feel that

you should NOT wait for the results of this test and you should immediately call your healthcare provider, or in a medical emergency, call the emergency services.

If you require further advice related to this kit, please see LetsGetChecked.com or the LetsGetChecked app.

CAUTION: You should collect this sample yourself unless

PURPOSE/INTENDED USE OF DEVICE:

The LetsGetChecked Coronavirus (COVID-19) Test is a direct to consumer product for testing of anterior nasal swab specimens collected at home using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit by any individuals, 18 years and older (self-collected), 12 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) including individuals without symptoms or other reasons to suspect COVID-19. Specimens collected using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit can be transported at ambient temperature for testing. Testing is limited to the LetsGetChecked, Inc. laboratory (PrivaPath Labs d.b.a.LetsGetChecked Labs) which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, and meets the requirements to perform high complexity tests.

The LetsGetChecked Coronavirus (COVID-19) Test is also indicated for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 anterior nasal swab specimens per pool that were collected in individual vials containing transport media using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit from any individual (age 2 and older), including individuals without symptoms or other reasons to suspect COVID-19.

FOR USE UNDER EMERGENCY USE AUTHORIZATION ONLY.

LetsGetChecked, Inc offers this product with an FDA Emergency Use Authorization (EUA). This means that this product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of nucleic acid from SARSCoV-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.

PrivaPath Diagnostics Ltd., Unit 32, Lavery Avenue, Park West Industrial Park, Park West, Dublin 12, D12 A611, Ireland.

Do not use if the kit or any items included within it, are damaged/faulty, or if any items are absent from the kit.

In vitro diagnostic medical device. Storage temperature: 15°C — 25°C

Keep away from sunlight. Keep dry.

See outside of kit box for lot number. See outside of kit box for expiry date.

Consult instructions for use.

Caution when using. Do not re-use.

For more information visit: www.letsgetchecked.com/ie/en/instructions/nasal-swab-collection



For use under Emergency Use Authorization (EUA) only.

This sample collection kit is suitable for the following individuals:

- ✓ 18 years and older (self-collected)
- ✓ 12 years and older (self-collected under adult supervision)
- ✓ 2 years and older (collected with adult assistance)

It's good to know.™



**LetsGet
Checked®**

- ✓ **Adults aged 18+:** Self-collect (unless unable to do so)
- ✓ **Teenagers aged 12-17:** Self-collect with adult (18+) supervision
- ✓ **Children aged 2-11:** Adult (18+) to collect

3 Return your sample to our accredited laboratory using the prepaid shipping envelope.

All results are reviewed by a board certified physician. If you receive a positive or invalid test result a registered nurse will contact you to provide 1-on-1 support.

Let'sGetChecked, Inc offers this product with an FDA Emergency Use Authorization (EUA). This means that this product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA. This product has been 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.

Kit contents include:

- 1 x Nasal Swab
- 1 x Sample Transport Tube
- 1 x Biohazard Bag
- 1 x Test Box
- 1 x Return Label

Nasal Swab

Contains one single use collection kit.
Access to internet/computer/smartphone and email account are required to use kit.

It's good to know.™ — consult your pharmacist or visit [LetsGetChecked.com/activate](https://www.LetsGetChecked.com/activate)

If you have any symptoms concerning for COVID-19 and any of the following conditions or risk factors, which may put you at increased risk of severe illness from COVID-19, you should consult with your healthcare provider before using this test:

- Chronic kidney disease
- COPD (chronic obstructive pulmonary disease)
- Immunocompromised state (weakened immune system) from solid organ transplant or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other immune weakening medicines
- Obesity (body mass index [BMI] of 30 or higher)
- Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
- Sickie cell disease
- Type 2 diabetes mellitus
- Asthma (moderate-to-severe)
- Cerebrovascular disease (affects blood vessels and blood supply to the brain)

Regardless of your risk status, if you are experiencing any of the following emergency warning signs for COVID-19, it is recommended that you immediately seek emergency care:

- Cystic fibrosis
- Hypertension or high blood pressure
- Neurologic conditions, such as dementia
- Liver disease
- Pregnancy
- Pulmonary fibrosis (having damaged or scarred lung tissues)
- Smoking
- Thalassemia (a type of blood disorder)
- Type 1 diabetes mellitus