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 is old 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.
- Follow directions for use.
- Use of gloves is recommended.
- Do not drink or breathe in the liquid in the sample tube or let it touch your skin.
- Avoid contact with eyes and respiratory tract.
- If contact with the body occurs, rinse with water.
- If irritation persists, seek medical advice.
- Do not reinsert the swab into the nostril after it has been placed into the sample transport tube.
- Keep out of reach of children.

For Use Under Emergency Use Authorization Only.
**PURPOSE/INTENDED USE OF DEVICE:**

The LetsGetChecked Coronavirus (COVID-19) Test is a direct-to-consumer product for testing in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360ii(a)-(b) or (f), unless the declaration is further up and into the nose at any point.

**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 LetsGetChecked kit box. Ensure you have folded the biohazard bag flap to seal it. Wash your hands in warm, soapy water and dry thoroughly.

**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 need treatment from a medical professional, 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 you are collecting from a child.

For more information visit: www.letsgetchecked.com/en/instructions/nasal-swab-collection
Collect your sample at home using the contents inside this pack. It's good to know.™ consult your pharmacist or visit LetsGetChecked.com/activate

Get checked in four simple steps:

1. Activate your kit online, using the unique ID provided.
   Before you start you must read all of the instructions provided with the kit.
   This sample collection kit is suitable for the following individuals:
   ✓ Adults aged 18+: Self-collect
   ✓ Teenagers aged 12-17: Self-collect with adult (18+) supervision
   ✓ Children aged 2-11: Adult (18+) to collect

2. Collect your sample at home using the contents inside this pack.

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

4. Your sample is analyzed at the LetsGetChecked lab and results are available online typically within 24-72 hours.
   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.

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. 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.

If the contents of the sample transport tube are spilled or make contact with the skin or eyes, refer to the warning section for information on actions to take and use a new collection kit.

Kit contents include:
1 x Nasal Swab
1 x Sample Transport Tube
1 x Biohazard Bag
1 x Test Box
1 x Return Label

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
### Conditions or Risk Factors for Increased Risk of Severe COVID-19 Illness

- 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
- Sickle cell disease
- Type 2 diabetes mellitus
- Asthma (moderate-to-severe)
- Cerebrovascular disease (affects blood vessels and blood supply to the brain)
- 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
- Liver disease
- Pregnancy

### Emergency Warning Signs for COVID-19

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:

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake up or stay awake
- Bluish lips or face