

Nasal Home Collection Kit

Please read these instructions carefully before collecting your sample.
Before you start, make sure you have received the following items:

For Use Under Emergency Use Authorization Only






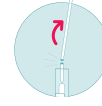





Home Collection Kit Checklist

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

1	Fill up request form for your test online at https://ingenuityd.com/product/home-collection-kit/ or at website of authorized labs.	2	Fill in the vial sticker with the patient ID and sample collection date.
3	Collect your sample following the Instructions. Close the sample transport tube by screwing the lid tightly. Seal the sample transport tube in the biohazard bag.	4	Place the biohazard bag in the Kit box, paste address label and return immediately via FedEx/UPS.
<p>If you have any questions about your test, you can find our contact details on www.ingenuityd.com/</p>			

Home Collection Kit – Nasal Sample: Step-By-Step Instructions

1		<p>Step 1: Before you start</p> <p>Before you start you must read all of the instructions including the warnings in relation to the liquid in the sample transport tube. You must be over the age of 18 to use this sample collection kit.</p>	2		<p>Step 2: Order online</p> <p>For online order, Home collection kit will be dispatched via FedEx. Follow the instructions on the pack insert in your test kit. You should collect your sample on the same day the pickup is scheduled. Do not collect your sample on a Saturday or Sunday as shipping services do not operate on the weekends.</p>
3		<p>Step 3: Wash your hands</p> <p>Wash your hands in warm, soapy water and dry thoroughly.</p>	4		<p>Step 4: Mark the vial</p> <p>Before collecting your sample, write your Name or order ID on vial label. You must also fill in the lab sticker – present in the test box. Follow the video link shared on InguinityD or authorized lab website.</p>
5		<p>Step 5: Remove sample transport tube from kit</p> <p>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 you, refer to the warning section for information on actions to take.</p>	6		<p>Step 6: Remove nasal swab from packaging</p> <p>Partially peel opens 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.</p>

<p>7  Step 7: Insert swab into nostril Gently insert the swab in the vertical position into one nostril until there is gentle resistance.</p>	<p>8  Step 8: Collect 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 your nose at any point. You must collect your sample from both nostrils before placing the swab into the sample transport tube. Please refer to the warning section.</p>
<p>9  Step 9: Repeat in the other nostril Gently insert the swab in the vertical position into the other nostril until there is gentle resistance. 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 your nose at any point.</p>	<p>10  Step 10: 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. Discard the top portion of the swab.</p>
<p>11  Step 11: Screw the lid of 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 your sample from being processed in the lab. Clean the surface of the tube with alcohol wipe or sanitizer.</p>	<p>12  Step 12: Seal the sample transport tube in the biohazard bag Place the sample transport tube in the biohazard bag. To seal the biohazard bag, Zip lock the plastic and fold down.</p>
<p>13  Step 13: Place biohazard bag in test box Place the biohazard bag back into the test kit box. Ensure you have folded the biohazard bag flap to seal it. Ensure you have filled in the lab sticker (located on the inner lid of the test box).</p>	<p>14  Step 14: Wash your hands Wash your hands in warm, soapy water and dry thoroughly.</p>
<p>15  Step 15: Return the sample Paste the address sticker of the lab on the test box. Send the test to the authorized lab immediately via FedEx. Visit www.apps.fedex.com/pickup/schedule or call 1-800-419-4343 to schedule a pickup. Remember, do not collect or return your sample on a Saturday or Sunday as shipping services are not operating. Lab will run the sample using COVID-19 RT-PCR Direct and will update the result on Lab web portal and through text message.</p>	<p>PLEASE READ:</p> <p>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 test, you can arrange a call with a member of our medical team through your online dashboard. They will get in touch with you as soon as possible.</p> <p>CAUTION: You should collect this sample yourself.</p>


WARNING

- You must be over the age of 18 to use this sample collection kit.
- Do not let the liquid in the sample tube touch your skin or eyes.
- If the liquid gets in your eyes, wash it out immediately with lots of water and get medical advice.
- If you still have any symptoms, you should call a physician.
- If the liquid touches your skin wash your skin with soap and water. If you still have any symptoms, you should call a physician.
- If you breathe in the liquid you should get fresh air straight away. If you still have any symptoms, you should call a physician. If you drink the liquid, wash your mouth out with water and drink lots of water afterward. If you still have any symptoms, you should call a Physician.

PURPOSE/INTENDED USE OF DEVICE:

- The Home Collection Kit – Nasal Sample is an in-vitro diagnostic medical device intended for qualitative detection of SARS-CoV-2 in nasal swab specimens, self-collected by individuals at home and returned to a partner accredited laboratory for analysis.
- Eligibility for testing is determined by a healthcare provider based on results of a COVID-19 questionnaire.
- Home Collection Kit – Nasopharyngeal/ Nasal Sample has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- Home Collection Kit- Nasopharyngeal/Nasal sample is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics 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.


Index of Symbols


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

 See outside of kit box for lot number.


 See outside of kit box for expiry date.

 Consult Instructions for use

 In vitro diagnostic medical device.

 Storage temperature: 15°C — 25°C.

 You must be aged 18 or over to use this product.

 Don't re-use

Manufactured by:

BioGenex Lifesciences Pvt. Ltd.

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