

## ***About this Amazon COVID-19 Test Collection Kit DTC***

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### **Is an Amazon account needed to complete the Amazon COVID-19 Test Collection Kit DTC?**

Yes. An Amazon account is required to use the Amazon COVID-19 Test Collection Kit DTC. If you have an Amazon account for your household, you can create unique profiles for each family member on AmazonDx.com

### **If I am experiencing symptoms of COVID-19, can I use the Amazon COVID-19 Test Collection Kit DTC?**

Yes, you may use this Collection Kit whether or not you have symptoms.

### **How old do I need to be to use the Amazon COVID-19 Test Collection Kit DTC?**

The Amazon COVID-19 Test Collection Kit DTC is available for use by individuals 18 years and older when self-collected, individuals 14 years and older when self-collected under adult supervision, and individuals 2 years and older when collected with adult assistance.

### **Can I use the Amazon COVID-19 Test Collection Kit DTC if I am pregnant?**

We recommend that you consult your physician or healthcare provider. You may also follow the guidance from the [CDC](#) and [WHO](#) with regards to COVID-19 testing while pregnant.

### **How long will it take to receive results?**

Your Collection Kit comes with pre-paid next-day delivery to the lab via UPS, and test results will be shared within 24 hours from arriving at the lab.

### **How accurate is the test?**

The Amazon COVID-19 Test Collection Kit DTC has received an Emergency Use Authorization from the FDA. Amazon laboratories use a sensitive method called “real-time RT-PCR” to detect the SARS-CoV-2 virus that causes COVID-19 disease (<https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html>). While no method is perfect, Polymerase Chain Reaction (PCR) is an accurate way to detect a current infected person or to show a person is not currently infected. For these reasons, it is considered the current gold standard diagnostic approach by the CDC.

### **Does the Amazon COVID-19 Test Collection Kit DTC expire?**

Yes. The expiration date is printed on the side of the collection kit box and will be at least 90 days from the date of purchase. Kits cannot be registered after the expiration date.

### **I previously purchased a kit when it was approved for individuals aged 18+ years but haven't used it yet. Can I use this for a child 2+ years old now?**

Yes, you can use the 18+ kit for individuals aged 2 years and older. Please follow the updated instructions for use on how to collect the sample as the instructions differ for individuals aged 2 years and older and individuals aged 14 years and older. Updated instructions for use for all ages can be found [here](#).

Individuals aged 14 years and older may collect their own sample under adult supervision. For individuals aged 2 years and older, collect the sample with adult assistance. If you are collecting the

sample for a child, explain the process step-by-step in advance so they know what to expect. Be careful not to insert the swab too far into the child's nostril. If you feel resistance, stop.

For individuals 14 years and older, hold the handle of the swab and insert the soft tip of the swab  $\frac{1}{2}$  -  $\frac{3}{4}$  inch (1.3 – 1.9 cm) inside your nostril. For children 2–13 years old, insert the swab no more than  $\frac{1}{2}$  inch (1.3 cm). Rub the swab in a slow circular motion against the inside walls of the nostril at least 4 times. This should take about 15 seconds. Repeat in the other nostril using the same swab.

## **Sample Collection**

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### **How long does it take to complete the sample collection process?**

The process takes 15-20 minutes overall. First time users will need another 5 minutes to create their profile on AmazonDx.com. Registering your collection kit on AmazonDx.com takes less than 5 minutes. The sample collection process typically takes 5-10 minutes. Please refer to the instructions provided with your collection kit for more information.

### **How quickly should I collect my sample after I register my collection kit?**

You should collect your sample immediately after registering your collection kit. Sample collection takes less than 10 minutes.

### **When should I collect my sample?**

Collect your sample Monday – Friday, excluding holidays. Before collecting your sample, make sure you will be able to drop it off at an eligible UPS location the same day. You must drop it off before the UPS location's last air drop off time, which you can check at <http://www.ups.com/dropoff>. Eligible location types include The UPS Store®, UPS Drop Box and UPS Customer Center locations. UPS Access Point locations, such as CVS and other retailers do not guarantee next day delivery, which may result in your test being cancelled.

### **How do I collect the sample?**

Individuals aged 14 years and older may collect their own sample under adult supervision. For individuals aged 2 years and older, collect the sample with adult assistance. If you are collecting the sample for a child, explain the process step-by-step in advance so they know what to expect. Be careful not to insert the swab too far into the child's nostril. If you feel resistance, stop.

For individuals 14 years and older, hold the handle of the swab and insert the soft tip of the swab  $\frac{1}{2}$  -  $\frac{3}{4}$  inch (1.3 – 1.9 cm) inside your nostril. For children 2–13 years old, insert the swab no more than  $\frac{1}{2}$  inch (1.3 cm). Rub the swab in a slow circular motion against the inside walls of the nostril at least 4 times. This should take about 15 seconds. Repeat in the other nostril using the same swab.

You can watch a video overview of the sample collection process [HERE](#) [link to the video in Amazon Dx]. Detailed instructions for use are also included in your collection kit, and are available to download [here](#).

71 **How far do I insert the nasal swab?**

72 For individuals 14 years and older, hold the handle of the swab and insert the soft tip of the swab  $\frac{1}{2}$  -  $\frac{3}{4}$   
73 inch (1.3 – 1.9 cm) inside your nostril.

74 For children 2–13 years old, insert the swab no more than  $\frac{1}{2}$  inch (1.3 cm). If collecting a sample from a  
75 child, be careful not to insert the swab too far into the child's nostril. If you feel resistance, stop.

76 **How do I open the swab without touching the soft tip?**

77 Locate the handle end of the swab package. Peel apart the swab package where indicated, using the  
78 tabs. Hold the swab by the handle and do not set it down on any surface.

79 **How do I safely put the swab inside the collection tube?**

80 While holding the swab by the handle, put the swab soft tip down in the tube so that the soft tip reaches  
81 the bottom, but do not spill the fluid. To break off the swab handle, hold the tube firmly. Bend the swab  
82 handle at the indicator line back and forth against the collection tube until it breaks. Discard the swab  
83 handle. Recap the tube. Make sure the cap is on tight, so that no fluid can spill out.

84 **What if my instructions for use are damaged or missing?**

85 Instructions for use are available to download [here](#).

86 **What if my collection kit or one of the components is missing or damaged?**

87 If there is an issue with the nasal swab, collection tube with saline, plastic bag with absorbent pad, or  
88 return box with shipping label, discard your collection kit components in the regular trash. The lab  
89 cannot process your sample if you use your own replacement materials. Please log in to AmazonDx.com  
90 to access Customer Support options or call [877-485-0385](tel:877-485-0385) to order a replacement collection kit.

91 **What if I spilled the fluid from the collection tube?**

92 If you spill on a table or other surface, wipe and clean the area with your routine household surface  
93 disinfectant. Discard your collection kit components in the regular trash. Please log in to AmazonDx.com  
94 to access Customer Support options or call [877-485-0385](tel:877-485-0385) to order a replacement collection kit.

95 **What if I touch my swab on a surface other than the inside of my nostrils?**

96 Wipe and clean the surface with your routine household surface disinfectant. Discard your collection kit  
97 components in the regular trash. Please log in to AmazonDx.com to access Customer Support options or  
98 call [877-485-0385](tel:877-485-0385) to order a replacement collection kit.

99 **What if I get the fluid from the collection tube on my skin or in my eyes?**

100 If the fluid touches your skin or eyes, rinse cautiously with water for several minutes. If you are wearing  
101 contacts, remove them and rinse again.

102 **I'm experiencing side effects from sample collection (e.g., bloody nose). What do I do?**

103 If you are experiencing a medical emergency, seek immediate medical attention. Please log in to  
104 AmazonDx.com to access Customer Support options or call [877-485-0385](tel:877-485-0385) to report your experience.

**How do I send my sample to the lab?**

If the test taker is under 18 years old, an adult should assist with packaging and UPS drop off.

Follow the packaging instructions included with your collection kit. Complete the sample collection and drop off Monday – Friday, excluding holidays, due to UPS shipping schedules. You must use the return box and label that are included with your collection kit. Drop off your sample at an eligible UPS location on the same day you collect it. Eligible location types include The UPS Store®, UPS Drop Box or UPS Customer Center locations. UPS Access Point locations, such as CVS and other retailers do not guarantee next day delivery, which may result in your test being cancelled. Before collecting your sample, confirm the last air drop off time at <http://www.ups.com/dropoff>.

If you do not drop off your sample the same day you collect it, it may not be processed. Once Amazon receives your sample, results will be available within 24 hours.

**What do I do if I can't drop off the sample in time?**

If you do not drop off your sample the same day as your sample collection, your test may not be processed. Please log in to AmazonDx.com to access Customer Support options or call [877-485-0385](tel:877-485-0385).

**I have additional questions about the sample collection process. What do I do?**

Carefully read all of the instructions provided with your collection kit. You can also watch a video overview of the sample collection process [HERE](#) [link to the video in Amazon Dx].

If your question is not addressed by these FAQs, please log in to AmazonDx.com to access Customer Support options or call [877-485-0385](tel:877-485-0385).

***Results Notification & Interpretation***

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**How will I know when my test result is available?**

You will be alerted via email and SMS text message when your result is available. It is vital that you provide an accurate email and US mobile phone number that can receive SMS text messages during the registration process. Once available, your result can be viewed through AmazonDx.com on your personal computer or smartphone.

**I received a positive result, what does that mean?**

Please refer to the Fact Sheet for Individuals included with your collection kit. If you have a positive test result, the virus that causes COVID-19 was found in your sample. You should follow the latest CDC guidance to avoid spreading the virus to others, such as self-isolation, to reduce the potential transmission of disease. There is a small possibility that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test result along with your medical history and symptoms.

**I received a negative result, what does that mean?**

Please refer to the Fact Sheet for Individuals included with your collection kit. A negative test result means that the virus that causes COVID-19 was not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19.

You might test negative if the sample was collected early during your infection. You could also be exposed to COVID-19 after your sample was collected and then have become infected. In particular, people infected with COVID-19 but who have no symptoms may not shed enough virus to trigger a positive test. This means that you could possibly still have COVID-19 even though the test result is negative. If your test is negative, but you either develop symptoms or continue to have symptoms and/or they get worse, you should reach out to your healthcare provider who will work with you to determine the next steps you should take. If you have no symptoms but have been tested because your doctor thought you may have been exposed to COVID-19, you should continue to monitor your health and let your healthcare provider know if you develop any symptoms of COVID-19. If you develop symptoms you may need another test to determine if you have contracted the virus causing COVID-19.

#### **What does sample pooling mean?**

If your result report does not say that pooling was used in the testing of your sample, your sample was tested individually and not pooled.

If your result report does say that sample pooling was used, this means that the laboratory combined your sample with other individuals' samples prior to testing. In sample pooling, if a pool tests positive, the samples in the pool are re-tested individually to identify which sample in the pool is positive. Sample pooling is a common laboratory practice for populations with low positivity rates.

If your sample was pooled and you have a negative test result, the result is most likely a true negative. Those who have extremely low levels of virus may have a small chance of a false negative result from pooled testing. This is because patient samples with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

If you are concerned, you should talk with your healthcare provider.

#### **I received a result that was not positive or negative, what does that mean?**

This means that the lab could not process your sample and the result could not be interpreted. Tests are unable to be processed for a variety of reasons. This occasionally occurs when there are sample collection issues or collection kit defect issues due to transit. Re-collection and re-testing is recommended. Please log in to access direct Customer Support options to order a replacement collection kit.

*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 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.*