

About this Amazon COVID-19 Test Collection Kit DTC

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

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

38 For individuals 14 years and older, hold the handle of the swab and insert the soft tip of the swab $\frac{1}{2}$ - $\frac{3}{4}$
39 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
40 (1.3 cm). Rub the swab in a slow circular motion against the inside walls of the nostril at least 4 times.
41 This should take about 15 seconds. Repeat in the other nostril using the same swab.

42

43 **Sample Collection**

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

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

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

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

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

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

59

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

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

65 For individuals 14 years and older, hold the handle of the swab and insert the soft tip of the swab $\frac{1}{2}$ - $\frac{3}{4}$
66 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
67 (1.3 cm). Rub the swab in a slow circular motion against the inside walls of the nostril at least 4 times.
68 This should take about 15 seconds. Repeat in the other nostril using the same swab.

69 You can watch a video overview of the sample collection process [HERE](#) [link to the video in Amazon Dx].
70 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.

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

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

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

114
115 If you do not drop off your sample the same day you collect it, it may not be processed. Once Amazon
116 receives your sample, results will be available within 24 hours.

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

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

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

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

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

125 ***Results Notification & Interpretation***

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

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

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

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

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

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

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

152 **What does sample pooling mean?**

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

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

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

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

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

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

170

171 *This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA*
172 *under an EUA for use by authorized laboratories. This product has been authorized only for the detection*
173 *of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this*
174 *product is only authorized for the duration of the declaration that circumstances exist justifying the*
175 *authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under*
176 *Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the*
177 *declaration is terminated or authorization is revoked sooner.*