

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

2 **Do I need an AmazonDx.com account to complete the Amazon COVID-19 Test Collection Kit DTC?**

3 Yes. To create an account, go to AmazonDx.com.

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

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

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

7 You must be at least 18 years old.

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

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

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

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

14 **How accurate is the test?**

15 The Amazon COVID-19 Test Collection Kit DTC has received an Emergency Use Authorization from the
16 FDA. Amazon laboratories use a sensitive method called “real-time RT-PCR” to detect the SARS-CoV-2
17 virus that causes COVID-19 disease (<https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html>).

18 While no method is perfect, Polymerase Chain Reaction (PCR) is an accurate way to detect a current
19 infected person or to show a person is not currently infected. For these reasons, it is considered the
20 current gold standard diagnostic approach by the CDC.

21 **Is there an expiration date on the Amazon COVID-19 Test Collection Kit DTC?**

22 Yes. Please refer to the collection kit for use-by or expiration dates.

23 ***Sample Collection***

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

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

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

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

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

33 While holding the handle of the swab, insert the soft tip of the swab 1 inch inside your nostril. Rub the
34 swab in a slow circular motion against the inside walls of your nostril at least 4 times. This should take
35 about 15 seconds. Repeat in your other nostril using the same swab.

36

37 You can watch a video overview of the sample collection process [HERE](#) [link to the video in Amazon Dx].
38 Detailed instructions for use are also included in your collection kit, and are available to download
39 [AmazonDx.com/instructions](https://www.amazon.com/instructions)

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

41 While holding the handle of the swab, insert the soft tip of the swab 1/2 - 3/4 inch (1.3 - 1.9 cm) inside
42 your nostril. As a measurement guide, you can use the end of your pinky finger, which is about 3/4 inch.

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

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

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

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

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

52 Instructions for use are available to download [www.AmazonDx.com/instructions](https://www.amazon.com/instructions)

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

54 If there is an issue with the nasal swab, collection tube with saline, plastic bag with absorbent pad, or
55 return box with shipping label, discard your collection kit components in the regular trash. The lab
56 cannot process your sample if you use your own replacement materials. Please login to your
57 [AmazonDx.com](https://www.amazon.com) account to access Customer Support options to order a replacement collection kit.

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

59 If you spill on a table or other surface, wipe and clean the area with your routine household surface
60 disinfectant. Discard your collection kit components in the regular trash. Please login to your
61 [AmazonDx.com](https://www.amazon.com) account to access Customer Support options to order a replacement collection kit.

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

63 Wipe and clean the surface with your routine household surface disinfectant. Discard your collection kit
64 components in the regular trash. Please login to your [AmazonDx.com](https://www.amazon.com) account to access Customer
65 Support options to order a replacement collection kit.

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

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

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

70 If you are experiencing a medical emergency, seek immediate medical attention. Please login to
71 AmazonDx.com to access Customer Support options to report your experience.

72 **What happens after I finish collecting my sample?**

73 Follow the packaging instructions included with your collection kit. You must use the return box and
74 label that are included with your collection kit. You have 24 hours after you collect your sample to drop
75 off your collection kit at a UPS drop off location. Due to weekend shipping schedules, we recommend
76 collecting and shipping your sample Monday – Friday. Before collecting your sample, confirm the last air
77 drop off time at <http://www.ups.com/dropoff>. Please note only The UPS Store®, UPS Drop Box or UPS
78 Customer Center locations can accept samples.

79
80 If you do not drop off your completed collection kit within 24 hours after sample collection, your test
81 may not be processed. Once Amazon receives your completed collection kit, results will be available
82 within 24 hours.

83 **What do I do if I can't drop off the completed collection kit in time?**

84 If you do not drop off your completed collection kit within 24 hours after sample collection, your test
85 may not be processed. Please login to AmazonDx.com to access Customer Support options.

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

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

89 If your question is not addressed by these FAQs, please login to AmazonDx.com to access Customer
90 Support options.

91 ***Results Notification & Interpretation***

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

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

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

98 Please refer to the Fact Sheet for Individuals included with your collection kit. If you have a positive test
99 result, the virus that causes COVID-19 was found in your sample. You should follow the latest CDC
100 guidance to avoid spreading the virus to others, such as self-isolation, to reduce the potential
101 transmission of disease. There is a small possibility that this test can give a positive result that is wrong

102 (a false positive result). Your healthcare provider will work with you to determine how best to care for
103 you based on the test result along with your medical history and symptoms.

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

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

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

118 **What does sample pooling mean?**

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

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

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

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

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

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

136

137 *This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA*
138 *under an EUA. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2,*
139 *not for any other viruses or pathogens. The emergency use of this product is only authorized for the*

140 *duration of the declaration that circumstances exist justifying the authorization of emergency use of in*
141 *vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food,*
142 *Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization*
143 *is revoked sooner.*