



# Frequently Asked Questions

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## ABOUT OUR LAB

Curative Inc. is a rapid diagnostics firm based in Southern California (San Dimas, CA). It is led by a team of world-class biologists and scientists with the mission of scaling up COVID-19 testing capacity in the U.S. as fast as possible.

Our lab operates 24 hours a day, seven days a week in order to process results quickly. We work closely with UCLA and the FDA to conduct clinical research studies in order to better understand the COVID-19 virus and help make testing better and more widely available across the United States. Our software team develops lab software and open source technology that anyone can use to set up testing sites.

## FAQs - Test Kits

### ➤ **What kind of test does Curative offer?**

Curative kits test for the presence of COVID-19 RNA in an oral-fluid sample. This is not a serology or immunity test.

### ➤ **Is Curative's test a home-testing kit?**

No. Curative's test is an observed self-collected test. It is not defined as an 'at-home test' or 'home-testing kit' and should not be utilized as such.

### ➤ **How quickly are results released?**

From the time we receive a sample at our lab, we release results within 48 hours depending upon lab capacity.

### ➤ **Is this test authorized by the FDA?**

Yes, Curative's test is authorized under the FDA's Emergency Use Authorization (EUA). As of 3/23/2020 we have notified the FDA of our operation and received approval to operate commercial testing. The test is NOT authorized for at home sample collection.

<https://www.fda.gov/media/137089/download>

### ➤ **What is the accuracy, especially compared to nasopharyngeal tests?**

Our test is ~90% accurate. That means if 10 patients have coronavirus, our test would accurately diagnose 9 of those patients as covid-positive. The nasopharyngeal test is



~80% accurate. Our test is just as accurate if not more than the NP test, especially during the two week window when patients are most infectious.

➤ **What is the sensitivity of the test?**

Our test detects 200 copies of the virus per mL.

➤ **What studies have been done on this type of test?**

Here is a preprint of a research study we did with UCLA:

<https://www.medrxiv.org/content/10.1101/2020.04.11.20062372v1>

➤ **What is inside a test kit?**

Each EUA-approved collection kit includes a barcoded biohazard bag with an oral fluid swab, a test tube (with stabilizing liquid), an absorbent cotton round, and paper instructions.

➤ **What do I do with the liquid inside the test tube?**

It is best to use caution when handling the test-tube. The tube contains a hazardous liquid used to stabilize your sample. Be careful not to spill or drink the liquid. If the liquid touches someone's skin or they ingest it, please follow the instructions in the [Safety Data Sheet](#).

➤ **What if a test kit is damaged?**

You must provide a new test kit and scan the new barcode to the existing appointment. Write "Re-issued" on the new test kit and dispose of the old one as biohazard.

➤ **How long does a test kit last for if used? If unused?**

- An unused kit is good for 6 months.
- Our tests will produce accurate results even when the test kit (plus human sample) has been heated to 104°F for 4 days.

## **FAQs - Sample Collection**

➤ **Can patients eat or drink before taking the test?**

Patients cannot eat, drink, chew gum, or smoke in the 20 minutes leading up to their test. If they have, please ask them to wait 20 minutes before collecting a sample.



➤ **Who needs to be present as the observer? Can I observe myself?**

The observer may be any personnel who is trained on proper testing protocol. You **CANNOT** be an observer for your own test.

➤ **What does the observer do?**

The observer watches to make sure the patient performs a thorough test. They should be ready to intervene if any of the following steps are missed or performed inadequately:

- Cough deeply 3-5 times
- Swab for 20 seconds:
  - Inside of each cheek
  - Upper and lower gums
  - Underneath and top of tongue
  - Roof of mouth
- The swab has not been touched, dropped, or contaminated in any way
- The cap on the tube is secure and the swab tip is facing downward in the liquid
- The return bag is securely sealed so the tube doesn't fall out

➤ **Barcode scanners:** We provide one barcode scanner per testing site. Barcode scanners are used to scan test kit barcodes and match them to patient information. After scanning in the kit barcode, write the appointment number in sharpie on the outside of the test kit bag. This serves as a second validation point to connect the kit to the patient.

➤ **What if a test was scanned, but not used?**

Since we do not currently have a way of deleting a scanned barcode, the unused test-kit must be disposed of as biohazard.

➤ **What if someone needs to use another test kit?**

If you encounter a patient returning for a repeat test or a kit becomes unusable after scanning it, do not reuse the previous appointment. Create a new appointment for each test kit.

➤ **What if someone swallows the liquid ?** Please refer to the Safety Data Sheet [here](#).

➤ **How do patients make appointments?**

We offer a customizable online platform ([app.curativeinc.com](http://app.curativeinc.com)) for you to manage your testing operation. You can create appointments for your staff in advance as well as in person.



➤ **Staff training and support:** Our training material can be found: If you still have questions, you can always call your Customer Support to troubleshoot any issues that come up.

➤ **Are there any age limits for testing?**

No minimum or maximum age limit.

## **FAQ - Results**

➤ **Where are the samples processed?**

We test all samples in our CLIA-certified labs in San Dimas, CA and Washington DC.

➤ **How are the results delivered?**

Depending on preference, we can email each patient their result (whether negative, positive, or indeterminate), give you access to our results portal, and/or provide a spreadsheet of all results. We also report all positive results to the local department of public health.

➤ **What if a patient has not received test results within the expected time-frame?**

If a patient has not received test results after five days, we ask that they contact our support team at [support@curativeinc.com](mailto:support@curativeinc.com).

➤ **How to interpret my results ?**

- **QNS = Quantity Not Sufficient** - There was not enough liquid inside the test tube and a test was unable to be performed. The test tube cap was likely not screwed on tightly enough and the liquid inside the tube spilled out.
- **SNR = Sample Not Received** - The physical test kit was not received at the lab. It may have been lost in transit.
- **TNP = Test Not Performed** The sample was not able to be tested due to either patient information issues, missing sample tube, or sample contamination. This can happen if a sample wasn't scanned in at appointment check-in.
- **Repeat** - If a test was inconclusive the first time around, a second test is performed.
- **Indeterminate** - Between 1-3% of test results are indeterminate. A test was performed two times, but there wasn't enough human material to generate a conclusive result. This is most often caused by patients not coughing before swabbing their mouth or by not swabbing their mouth long enough. If the swab



dropped on the floor or scrapped another surface, that could contaminate results as well.