



COVID-19 TESTING

Curative Testing

Summary:

- Based on guidance from the FDA, CDPHE is concerned about the accuracy of the Curative assay and collection methods. As such, we are transitioning away from using Curative.
- As of 1/21/21, CDPHE will no longer use Curative for SARS-CoV-2 (COVID-19) testing in our residential care facilities, correctional facilities, homeless shelters, or other congregate care settings.
- We advise that ONLY symptomatic individuals use Curative community testing sites and that they do an anterior nares or nasopharyngeal swabs and NOT oral.
- If individuals have been tested at a Curative site on or after 1/13/2021 using an oral swab and subsequently tested negative should be retested using an anterior nares swab.
- We do not have additional safety concerns beyond this action nor do we recommend additional testing at this time.
- We will be working with all stakeholders to ensure testing access, availability, and turnaround times.

1. What is Curative?

- a. Curative a commercial lab that provides PCR COVID-19 tests and testing analysis.

2. What entities in Colorado use Curative now?

- a. We use Curative at residential care facilities, correctional facilities, homeless shelters, and other congregate settings .
- b. In total, there are nearly 1,000 congregate facilities across the state using Curative, accounting for an average 70,000 tests per week.
- c. Some local public health agencies use Curative at other sites, as well.

3. What other states use Curative?

- a. We don't have an exhaustive list of other states, but we know Curative is used in Texas, Florida, Delaware, Pennsylvania, California, Illinois, Wyoming, and others.

4. Are we going to continue to use Curative?

- a. To ensure the highest standards for testing, CDPHE will no longer use Curative at congregate settings-- and is moving away from it at community testing sites. If other organizations wish to continue using Curative, we advise that they use it [exactly as authorized by the FDA](#).
- 5. When does the Curative service end?**
- a. As of 1/21/21 CDPHE is no longer using Curative for our residential care facility testing program. We are working with community based sites and local public health agencies to transfer to other labs as well. At community based test sites, we advise collecting anterior nares or nasopharyngeal swabs of **symptomatic** individuals only. If an individual is asymptomatic, we advise that they seek testing at a non-Curative site. If other organizations wish to continue using Curative, we advise that they use it exactly as authorized by the FDA.
- 6. Who is going to take over Curative testing capacity?**
- a. CDPHE, in partnership with local public health agencies and other stakeholders, are executing a transition strategy to move all CDPHE supported testing currently being done by Curative to other labs.
- 7. Will there be a lapse in testing because of this change?**
- a. We are executing a transition strategy to ensure minimal disruption. A priority is to ensure accurate testing is available. We are going to diversify services by engaging existing lab partners.
- 8. Why didn't we stop using Curative when we first heard about the potential problems from the FDA?**
- a. We took swift action immediately after the FDA's initial safety warning, addressing sampling protocol and requiring additional training for testing. Based upon the information we had from other states using Curative, the FDA, and Curative itself we believed that to be the appropriate course of action. When we learned additional information from the FDA in the afternoon of 1/19/21, we adjusted course and began the work to end use of Curative for congregate care settings at CDPHE.
- 9. What was the tipping point for deciding not to use Curative Labs?**
- a. The FDA has become more stringent in its warning. It now says that Curative must only be used under 3 conditions:
 - i. Only for symptomatic individuals within 14 days of onset.
 - ii. Specimen collection must be supervised.
 - iii. Any negative using oral fluid, must be confirmed with a different method.
- 10. When is the soonest we started hearing about problems with Curative?**
- a. On Jan. 4, the [FDA issued a Safety Communication](#) warning that there was a risk of false negatives when the test was not administered in accordance with the labeling instructions. During the time CDPHE was contracted with Curative, CDPHE sought feedback from community partners. When there were concerns identified, CDPHE was unable to validate those concerns through confirmatory testing at the state lab.

11. What are false negatives? And the implications of excess false negatives? How are false negatives different from false positives?

- a. A false negative test result is one where a person has the disease and should test positive but incorrectly receives a negative result. A consequence of a false negative result may be that an infected person continues interacting with other people, possibly putting others at risk of infection.
- b. A false positive test result is one where a person does not have the disease and should test negative but incorrectly receives a positive result. A consequence of a false positive result is that a person may be placed in isolation when it is not needed. In facilities that group infected patients together, this could mean that a person who is not infected is placed with patients who are infected.

12. How much will the decision cost Coloradans?

- a. We are working with our Attorneys General, contracts, and fiscal teams to ensure changes to or termination of the contract with Curative is not a cost borne by Colorado's taxpayers.

13. How many tests did Curative do in Colorado?

- a. 715,619 as of 1/19/21.

14. Does the state think the past tests were accurate?

- a. We have no evidence that Colorado experienced excess inaccurate results from Curative.

15. Does the state believe that inaccurate Curative tests led to outbreaks?

- a. We are not aware of any situations where excess false negatives from Curative led to outbreaks in long term care facilities or other settings. Testing is one tool in the COVID containment toolbox. We use testing in conjunction with other infection prevention strategies like mask wearing, physical distancing, and robust case investigation and contact tracing. Having a holistic approach to COVID prevention is essential and will continue.
- b.

16. Did the state vet Curative before signing a contract with them?

- a. As with every testing vendor, CDPHE engages in a robust vetting process. CDPHE evaluated their FDA Emergency Use Authorization, had reference conversations with other state and municipal customers, evaluated their official documents (Secretary of State filings, Dun & Bradstreet records, and others), and requested samples of all products. Additionally, our clinical and lab teams met with the Curative teams to review data regarding use in community testing sites, corrections and long term care facilities, as well as use for asymptomatic individuals. At the time we began working with Curative, we felt very confident in their assay, logistics, and operations.