



STATE OF HAWAII  
DEPARTMENT OF HEALTH  
P. O. BOX 3378  
HONOLULU, HI 96801-3378

In reply, please refer to:  
File:

April 22, 2020

The Honorable Kirk Caldwell  
Mayor  
City and County of Honolulu  
530 South King Street  
Honolulu, Hawaii 96813

Dear Mayor Caldwell:

SUBJECT: COVID19 TESTING PROGRAM

Thank you for your efforts in controlling COVID19 in Hawaii. The remarkable flattening of the COVID19 curve is a testament to your prompt measures and leadership. Hawaii now has the lowest incidence of COVID19 infections in the United States.

The Department also applauds your understanding of the importance of testing, contact investigation/tracing as we cautiously begin recovery activities. Your support of our federally qualified health centers, providing telehealth resources and PPE, help ensure that our medically underserved populations have accessible COVID19 screening and testing services.

However, we want to inform you of concerns we have regarding the particular test you chose for your COVID19 testing program.

- The EverlyWell test appears to lack FDA emergency use approval (EUA). **FDA has informed us that tests that do not have EUA cannot be used within the United States.** Additionally, there is no information on the accuracy of this test, presenting significant liability issues for Honolulu and the healthcare providers that collect these specimens. If EverlyWell plans to refer testing to another laboratory, this relationship needs to be disclosed, along with the qualifications and turnaround time for the testing laboratory. In addition, the composition of the transport medium, and its suitability for use in accordance with the instructions provided must be demonstrated.
- This test cannot be used to diagnose or to clear someone of COVID19 infection. Any positive test results would need to be repeated, and the negative results should also be re-evaluated. Using a validated and approved test, such as those available in Hawaii, would avoid the additional confirmatory testing and provide our shared goal of a clearer picture and understanding of COVID infection on Oahu.
- We understand that several community health centers have declined to use the EverlyWell test, explaining that they cannot use a test that is not approved. However, these same clinics have relationships with our Hawaii commercial laboratories which do offer approved tests.

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- It is not clear how EverlyWell would report results to the Department of Health. These reports are mandated by Chapter 11-156, Hawaii Administrative Rules, and are critical for investigation, contact tracing, and other mandated control activities. Further, we have required that all laboratories *must* report both positive and negative results by the Electronic Laboratory Reporting system. Please advise EverlyWell, their laboratory(ies) are expected to confirm they are capable of sending the appropriate electronic messages to us.
- Our local commercial laboratories have ramped up their testing capabilities and can provide turn-around times of 1–2 days. The cost of these tests is also quite competitive, approximately half of the cost of the EverlyWell test.
- As a leader who has supported local businesses, I also encourage you to support our local commercial clinical laboratories.

COVID19 case contact identification, investigation, and surveillance are critical disease control functions and are the purview of the Department of Health. These activities have been occurring since the first reported case and will continue as we strengthen investigative teams. Contact tracing is not the function of our community providers and healthcare centers who lack the mandate, trained staff, and time to conduct these activities. However, the Department does see the community health centers greatly contributing to control efforts through expanded patient education, screening, testing, and participation in our surveillance activities. Your support for clinics, while using a different test, will accomplish these goals.

Thank you for the opportunity to consider our concerns. I would be very happy to further discuss any of these issues with you.

Sincerely,



Bruce S. Anderson, Ph.D.  
Director of Health

c: Governor David Y. Ige  
Lt. Governor Josh Green  
Maj. General Kenneth S. Hara