

Dr. Frank Ong
Chief Scientific and Medical Officer
Everlywell

Thursday, April 23, 2020

Re: COVID-19 Testing Program

Dear Dr. Anderson:

Thank you for all of the work you and the State of Hawaii, Department of Health have been doing to serve the people of Hawaii during these uncertain times. Everlywell is proud to be part of the City of Honolulu's efforts to prevent the spread of COVID-19 on the island of O'ahu and are confident that our work will benefit the community and the state's larger response to containing this virus.

We are aware of the letter you sent to Mayor Caldwell on April 22, with the subject "COVID19 TESTING PROGRAM". We regret to inform you that some of the information included in your letter is inaccurate. We hope that this letter will provide clarification regarding the COVID-19 tests that Everlywell is making available to the City of Honolulu.

The tests that Everlywell has made available to the City of Honolulu are accurate, reliable, clinically validated, and authorized for use in the diagnosis of COVID-19 in the United States pursuant to the FDA's *Policy for Diagnostic Tests for the Coronavirus Disease-2019 during the Public Health Emergency*, issued on March 16, 2020. The COVID-19 tests are processed by Everlywell's CLIA-certified laboratory partners. **Our laboratory partners have submitted their validation data and reports to the FDA and are operating under the FDA's Emergency Use Authorizations for these tests.**

We wanted to offer the following additional points:

1. There are no "FDA approved" tests for COVID-19 at this time. Rather, the FDA is authorizing tests for COVID-19 through the FDA's Emergency Use Authorization (EUA) framework. We are happy to provide links to the test EUAs in use at our partner laboratories.
2. The accuracy for the tests meet or exceed the performance criteria set forth by the FDA for COVID-19 testing. We are happy to share data about the accuracy, sensitivity, and specificity of these tests with you or any members of your team.
3. These laboratories are running the gold standard molecular tests (rt-PCR) for the presence or absence of the virus that causes COVID-19. These are diagnostic tests for COVID-19 authorized under the FDA EUA framework.
4. The tests will be administered by physicians licensed to practice medicine in the state of Hawaii. Physicians licensed to practice medicine in Hawaii also oversee each test requisition, each test result, and each diagnosis associated with this testing. Results are generally available within 48 hours of the samples arriving at the lab.

5. All positive and negative test results are reported to all mandated local and federal reporting agencies.

We are disappointed that Everlywell was not contacted prior to the letter's release so that we could answer your questions or address your concerns. We look forward to a productive dialogue with you and your team. The residents of O'ahu deserve access to accurate, reliable COVID-19 testing, which we are ready and able to provide. We look forward to supporting Mayor Caldwell, the City of Honolulu, and the Hawaii Department of Health during the course of this pandemic. We are at your disposal if you have any further questions.

Signed,
Dr. Frank Ong
Chief Medical and Scientific Officer
Everlywell