

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0667781	(X3) Date Survey Completed 04/22/2021
Name of Provider or Supplier Hawaii Dept Of Health	Street Address, City, State 3040 Umi St, Lihue, HI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	THE LABORATORY IS IN COMPLIANCE WITH THE REQUIREMENTS OF 42 CFR PART 493, REQUIREMENTS FOR CLINICAL LABORATORY.
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on laboratory personnel remote questioning and the responses provided, the laboratory failed to report patient SARS-CoV-2 test results as required since the laboratory began patient SARS-CoV-2 testing on April 30, 2020 through April 16, 2021. Findings include: a. According to testing personnel, the laboratory began patient SARS-CoV-2 testing on April 30, 2020. On April 16, 2021, the laboratory was granted access to the State's SARS-CoV-2 test reporting portal. b. According to laboratory personnel, patient SARS-CoV-2 test results were not reported to the State's SARS-CoV-2 test reporting portal as required during this period of patient testing, April 30, 2020 through April 16, 2021. c. According to testing personnel, 1,262 patient SARS-CoV-2 test results were performed from April 30, 2020 through April 16, 2021. d. Testing and laboratory personnel confirmed these findings on April 12/20 /2021 at 12:35 pm (San Francisco time).</p>