

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  12D0667780	<b>(X3) Date Survey Completed</b>  04/22/2021
<b>Name of Provider or Supplier</b>  Hawaii Dept Of Health	<b>Street Address, City, State</b>  191 Kuawa Street, Hilo, HI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	THE LABORATORY IS IN COMPLIANCE WITH THE REQUIREMENTS OF 42 CFR PART 493, REQUIREMENTS FOR CLINICAL LABORATORY.
<b>D3000</b>	<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 September 18, 2020 through April 19, 2021. Findings include: a. According to testing personnel, the laboratory began patient SARS-CoV-2 testing on September 18, 2020. On April 19, 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, September 18, 2020 through April 19, 2021. c. According to testing personnel, 153 patient SARS-CoV-2 test results were performed from September 19, 2020 through April 19, 2021. d. Testing and laboratory personnel confirmed these findings on April 12/20/2021 at 12:35 pm (San Francisco time).</p>