Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0674128	02/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
David Fitz Patrick Md	1585 Kapiolani Blvd, Suite 1500, Honolulu, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the refrigerator temperature logs and interview with the testing personnel at 1:15pm on 2/21/20, the laboratory failed to document daily temperature readings for the proper storage of reagents and specimens. Findings include: a) The laboratory failed to document the daily temperature reading for the "Clinic Refrigerator in the Laboratory," between October 22, 2019- November 15, 2019. b) Testing personnel confirmed during interview that the refrigerator is used to store quality control material and reagents for the FT4 (Free Thyroxine) and TSH (Thyroid Stimulating Hormone) tests that are performed on the Beckman Coulter Access 2 analyzer, as well as to store patient specimens. c) Based on the Beckman Coulter Access 2 Load Lists, there were 129 FT4 tests and 180 TSH tests performed during October 22, 2019- November 15, 2019.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

	This STANDARD is not met as evidenced by: Based on a review of the refrigerator temperature corrective action log and interview with the testing personnel at 1:15pm on 2/21/20, the laboratory failed to document corrective actions taken when the criteria for proper storage of reagents and specimens were not met. Findings include: a) At the time of the survey on 2/21/20, there was no documentation of corrective action taken after the lab failed to record daily temperature readings for the "Clinic Refrigerator in the Laboratory." See D5413
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of Quality Assessment records on 2/21/20, the laboratory failed to monitor, assess, and when indicated, correct problems identified in the analytic system. Findings include: a) The laboratory's monthly QA Checklist, under Analytic Systems lists that, "Test materials were stored as directed by the manufacturer. (Check that temperature and humidity readings were logged for each day of testing on the Temperature/Humidity Chart)." The laboratory marked this section with a "Y" for Yes. b) The Monthly QA Checklist for both October 2019 and November 2019 failed to monitor and identify the failure to check that temperature readings were logged for each day of testing. See D5413