Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D1022903	05/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Aop Of Hawaii, Pa Dba Hawaii Cancer Care Aiea	98-150 Kaonohi Street, Suite B-219, Aiea, 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 05/22/2019 review of laboratory quality control records and an interview with the laboratory supervisor at 1:30 p.m., it was determined that the laboratory failed to define temperature criteria for the proper storage of its test reagents. The findings include: 1. Manufacturer labeling on Sysmex hematology reagent containers stated storage temperatures as follows: Cell clean 1-30 degrees Celcius Cell Pack DCL 2-35 degrees Celcius Flurocell 2-35 degrees Celcius Lysercell 2-35 degrees Celcius Sulfolyser 2-30 degrees Celcius 2. Manufacturer labeling on each tray of BD Vacutainer blood collection tubes used for hematology and sendout chemistry testing stated a storage temperature range of 4-25 degrees Celcius. 3. The laboratory supervisor stated that ambient temperature in the laboratory was not monitored. 4. The laboratory reported an annual hematology test volume of 40,700.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

	This STANDARD is not met as evidenced by: Based on a 05/22/2019 review of laboratory quality control records and an interview with the laboratory supervisor at 1:30 p.m., it was determined that the laboratory failed to ensure the proper storage of its test reagents. Refer to D tag 5413.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on a 05/22/2019 review of laboratory job descriptions and personnel competency records, and an interview with the laboratory supervisor at 1:30 p.m., it was determined that the laboratory failed to ensure that policies and procedures were established to monitor individuals who conduct Sysmex hematology testing. The findings include: 1. The laboratory supervisor is also the primary testing personnel for the laboratory. The supervisor stated that annual competency assessments were self performed to include direct observation of test performance and instrument maintenance and function checks. 2. Documentation of Laboratory Director participation in and review of laboratory supervisor competency assessment activities was not available for review.