Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0662980	(X3) Date Survey Completed 03/16/2022
Name of Provider or Supplier Aop Of Hawaii, Pa Dba Hawaii Cancer Care Honolulu	**Street Address, City, State** 500 Ala Moana Blvd, Suite 6-230, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter Access 2 procedure manual and maintenance logs and confirmation by the general supervisor on 03/16/2022 at 3:00 PM, it was determined that the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. The findings include: 1. Beckman Coulter Access 2 Instructions for Use, Chapter 6. Maintenance, Section Weekly Maintenance states "In order to keep the Access 2 system running properly, perform weekly maintenance once every seven days. NOTE: If the system is not used to run assays every day, it is still important to perform weekly maintenance on schedule to ensure that the system is ready when needed." Weekly maintenance tasks on the maintenance log includes clean instrument exterior, inspect liquid waste bottle, check waste filter bottle, inspect /clean primary probes, replace/clean aspirate probes, run daily maintenance, and run system check. 2. Beckman Coulter Access 2 weekly maintenance and system checks were not performed for 1 of 4 weeks in January 2020, 2 of 4 weeks in February 2020, 2 of 4 weeks in March 2020 and 2 of 4 weeks in April 2020. 3. The laboratory performed 1745 CEA, 1778 ferritin, 709 Free T4, 672 PSA, and 1324 TSH tests on the Beckman Coulter Access 2 in 2021.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter Access 2 procedure manual and maintenance logs and confirmation by the general supervisor on 03/16/2022 at 3:00 PM, it was determined that the laboratory director failed to ensure that its quality assessment program was maintained to assure the quality of the Beckman Coulter Access 2 testing services it provided to include the identification of failures in quality as they occurred. See CFR 493.1254 (a)(1), D tag D5429.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of laboratory procedures and confirmation by the general supervisor on 03/16/2022 at 3:30 PM, it was determined that the laboratory director failed to specify in writing, the responsibilities and duties of the general supervisor and testing personnel engaged in the performance of all phases of general immunology, routine chemistry, endocrinology, and hematology testing to include the following: 1. Which examinations and procedures each individual is authorized to perform 2. Whether supervision is required for specimen processing, test performance or result reporting 3. Whether supervisory or director review is required prior to reporting patient test results The laboratory performed 4195 general immunology tests, 205753 routine chemistry and endocrinology tests, and 74217 hematology tests in 2021.