Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D1022903	02/01/2023
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
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing records and an interview with the general supervisor on 02/01/2023 at 3:00 PM, it was determined that the laboratory failed to participate in the College of American Pathologists (CAP) second hematology testing event of 2021. The laboratory received an unsatisfactory score of 0 for its performance in survey FH9-B. The laboratory performs an annual volume of 45,185 hematology tests. The findings include: 1. The general supervisor stated the laboratory failed to notify CAP of its facility address change. 2. The general supervisor stated the laboratory failed to instruct clerical staff remaining at the former address to contact laboratory personnel when the kit was delivered. 3. The general supervisor stated the laboratory failed to track survey FH9-B's shipment and delivery to the laboratory based on CAP's shipping calendar.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons

	other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing records and an interview with the general supervisor on 02/01/2023 at 3:00 PM, it was determined that the laboratory failed to document the remedial action it undertook for its unsatisfactory performance in the College of American Patholoists (CAP) second hematology testing event of 2021. The laboratory failed to participate in survey FH9-B and received a score of 0. The laboratory performs an annual volume of 45,185 hematology tests.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with the general supervisor on 02/01/2023 between 1:45 PM and 3:00 PM, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in their general laboratory systems. The laboratory performs an annual volume of 45,185 hematology tests. The findings include the following: 1. The laboratory failed to participate in the College of American Pathologists (CAP) second hematology testing event of 2021. See D2123. 2. The laboratory failed to document the remedial action it undertook for its unsatisfactory performance in the College of American Pathologists (CAP) second hematology testing event of 2021. See D2128. 3. The laboratory failed to follow Sysmex calibration verification instructions for its hematology test system model XN850, SN 14154 at least once every 6 months. See D5439.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the

	range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of laboratory maintenance records and an interview with the general supervisor on 02/01/2023 at 1:45 PM, it was determined that the laboratory failed to follow Sysmex calibration verification instructions for its hematology test system model XN850, SN 14154 at least once every 6 months. The laboratory performs an annual volume of 45,185 hematology tests. The findings include the following: 1. Sysmex manufacturer instructions state "Following installation calibration, the operator is requested to verify the instrument calibration every 6 months" to ensure the accuracy of the system. 2. Calibration verification was not performed in 2020. 3. Calibration verification was performed once in 2021 and once in 2022.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing records and an interview with the general supervisor on 02/01/2023 at 3:00 PM, it was determined that the laboratory director failed to ensure an approved corrective action plan was followed for its unsatisfactory performance in the College of American Patholoists (CAP) second hematology testing event of 2021. See D2128.
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 laboratory maintenance records and an interview with the general supervisor on 02/01/2023 at 1:45 PM, it was determined that the laboratory director failed to ensure its quality assessment program was maintained to assure the quality of its System XN850 hematology test system at least once every 6 months. See D5439.