Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D2002618	(X3) Date Survey Completed 03/21/2018
Name of Provider or Supplier Hawaii Cancer Care Liliha Clinic	**Street Address, City, State** 2226 Liliha St, Ste B204, 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
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a review of test records and interview of the general supervisor on 3/21/18, the laboratory failed to maintain a record system including the identity of the personnel who performed the laboratory's hematology tests. Findings included: a. The laboratory reported white blood cell count, red blood cell count, hemoglobin, hematocrit, platelet, and white blood cell differential test results on patients using their hematology analyzer. At the time of the survey, the laboratory had no records of the identity of personnel who performed these hematology tests on 5 patients tested between 7/7/17 and 12/26/17. b. The laboratory tested and reported 22,000 hematology test results on patients each year.
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 patient test records, the laboratory's "Quality Assurance Checklist" and interview of the general supervisor on 3/21/18, the laboratory failed to 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. Findings included: a. The laboratory did not establish written policies and procedures to monitor and correct their failure to maintain a record system including the identity of the personnel who performed the laboratory's hematology tests. See D5787. b. The laboratory failed to follow their policies and procedures that monitored, assessed, and detected potential problems with their hematology testing. 1. The laboratory's quality assurance procedure included a "Quality Assurance Checklist" that indicated calibration of their hematology analyzer should be done "every six months." According to the laboratory's calibration records, their Cell Dyn instrument was calibrated on 1/20/16 and 10/14/16, which was an interval of longer than 6 months. 2. The laboratory's "Quality Assurance Checklist" listed the frequency of their inter lab correlation study as "every six months." According to their correlation study records, a study was done on October 2014, July 2015, February 2016, and February 2017. Intervals of more than 6 months occurred in 2015 and 2016. c. The laboratory tested and reported 22,000 patient hematology results in one year.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of patient test reports and interview of the general supervisor on 3 /21/18, the laboratory's test reports did not indicate the name and address of the laboratory location where the test was performed. Findings included: Test reports of 5 patients tested between 7/7/17 and 12/26/17 were printed and reviewed. One test report, dated 12/26/17, reported a CEA test result that had been performed at another laboratory. There was no name or address of that laboratory on the final test report.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of patient test reports and interview of the general supervisor on 3 /21/18, the laboratory failed to establish and follow written policies and procedures

	for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. Findings included: The laboratory did not establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct their failure to indicate the name and address of the laboratory location where the test was performed. See D5805.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of test reports and quality assurance records and interview of the general supervisor on 3/21/18, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. Findings included: a. The laboratory failed to 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. See D5791. b. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. See D5891.