Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D2076582	04/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Queen's Cancer Center Pob1	1380 Lusitana St Suite 608, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a 04/30/2019 review of laboratory personnel competency records and an interview with the testing personnel at 08:30 a.m., it was determined that the laboratory failed to follow its written policy to annually assess employee competency. The findings include: 1. 2017 and 2018 personnel competency assessments were not available for the testing personnel performing Abbott Cell-Dyne 1800 and Cell Dyn Emerald automated hematology testing, manual hematology differential testing, Alfa Wasserman Alera chemistry testing, and Beckman Coulter Access 2 immunology test system verification testing. 2. The testing personnel stated that laboratory operations were negatively impacted by ownership and organizational changes between 2017 and 2018. 3. The laboratory performs 3500 hematology and 5200 chemistry tests annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a 04/30/2019 review of proficiency testing records and an interview with the testing personnel at 08:30 a.m., it was determined that the laboratory failed to document its API proficiency testing evaluation and verification activities. The findings include: 1. The laboratory obtained an unacceptable grade for its sodium

	result on sample CH-03 in the first proficiency testing event of 2017. The laboratory reported a result of 205. The acceptable range was 193-202. The comment, "No corrective action needed" was documented in proficiency testing records. 2. The laboratory obtained an unacceptable grade for its sodium result on sample CH-10 in the second proficiency testing event of 2018. The laboratory reported a result of 151. The acceptable range was 155-163. Documentation of corrective action activities was not available for review.
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 04/30/2019 review of laboratory personnel competency and proficiency testing records and an interview with the testing personnel at 08:30 a.m., it was determined that the laboratory failed to follow its written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems requirements. The findings include: 1. The laboratory failed to follow its written policy to annually assess employee competency. Refer to D tag D5209. 2. The laboratory failed to document its API proficiency testing evaluation and verification activities. Refer to D tag D5221.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a 04/30/2019 review of laboratory procedure manuals and an interview with the testing personnel at 08:30 a.m., it was determined that the laboratory failed to ensure its procedures and changes in procedures were approved, signed and dated by the current laboratory director before use. The findings include: 1. The laboratory Cell Dyn Emerald Procedure Manual and the Cell Dyn Emerald Troubleshooting Manual were not approved, signed and dated by the laboratory director before its use. 2. The testing personnel stated that the laboratory replaced its Cell-Dyne 1800 hematology instrument with the Abbott Cell Dyn Emerald model. The laboratory began testing with the Cell Dyn Emerald instrument in February 2019. 3. The Cell Dyn Emerald Procedure Manual stated "Cell-Dyn Emerald does not require routine daily or weekly maintenance". The testing personnel stated that the procedure manual was not updated to include the recent addition of weekly bleach cleaning activities by the manufacturer. Documentation of the customer notification was not available for review.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

	Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a 04/30/2019 review of laboratory instrument maintenance records and an interview with the testing personnel at 08:30 a.m., it was determined that the laboratory failed to follow manufacturer instructions for equipment maintenance and function checks. Refer to D tag D5429.
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 04/30/2019 review of laboratory maintenance records and an interview with the testing personnel at 08:30 a.m., it was determined that the laboratory failed to perform maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. The findings include: 1. Documentation of monthly Abbott Cell-Dyne 1800 hematology instrument maintenance activities to include "Rinse Lyse Inlet Line and Rinse Reagent Inlet Line" for January through May 2017 and July 2017 through April 2018 was not available for review. 2. Documentation of weekly and monthly Abbott Cell-Dyne 1800 hematology instrument maintenance activities to include "Clean Aspiration Probe" and "Rinse Lyse Inlet Line and Rinse Reagent Inlet Line" respectively for August 2018 through January 2019 were not available for review. 3. The testing personnel stated that the laboratory ceased testing between June 4, 2018 and August 15, 2018 due to the lack of temporary replacement testing personnel. The Abbott Cell-Dyne 1800 hematology instrument and the Alfa Wasserman Alera chemistry instrument were turned off until on leave testing personnel returned to work. The testing personnel stated that the laboratory did not consult the manufacturers about start up procedures for extended periods of non-use. Patient testing resumed after running daily controls. Documentation of Laboratory Director review of startup activities was not available for review. 4. The laboratory performs 3500 hematology and 5200 chemistry tests annually.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by:

	Based on a 04/30/2019 review of proficiency testing records and an interview with the testing personnel at 08:30 a.m., it was determined that the laboratory failed to follow an approved corrective action plan when its API sodium proficiency test results were found to be unacceptable. Refer to D tag D5221.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on a 04/30/2019 review of laboratory maintenance records and an interview with the testing personnel at 08:30 a.m., it was determined that the laboratory failed to follow manufacturer instructions for equipment maintenance and function checks with at least the frequency specified by the manufacturer. Refer to D tags D5411 and D5429.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) 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 04/30/2019 review of laboratory personnel competency records and an interview with the testing personnel at 08:30 a.m., it was determined that the laboratory failed to follow its written policy to annually assess employee competency. Refer to D tag D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on a 04/30/2019 review of laboratory procedure manuals and an interview with the testing personnel at 08:30 a.m., it was determined that the laboratory failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. The laboratory Cell Dyn Emerald Procedure Manual and the Cell Dyn Emerald Troubleshooting Manual were not approved, signed and dated by the laboratory director before its use. Refer to D tag D5407.