Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D2040245	04/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Qmc Punchbowl Nuclear Medicine Department	1301 Punchbowl St, 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
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 04/17/2019 review of laboratory manuals and quality control records, direct observation and an interview with testing personnel at 2:00 p.m., it was determined that the laboratory failed to define temperature criteria for the proper storage of reagents and for accurate and reliable test system operation. The findings include: 1. Three separate timed samples are collected from each patient for BVA 100 Daxor blood volume testing. These samples are collected into 6 mL K3E K3 EDTA tubes. Manufacturer labeling on each tray of these tubes, lot# B18113DU, expiration date 05/14/2020, stated store at 4-25 degrees Centigrade or 40-77 degrees Fahrenheit. 2. The Queen's Medical Center Blood Volume Manual, Exhibit 1. Flowchart of actions to address QC test failures, stated the operating temperature range for the BVA 100 Daxor blood volume test system was 65-85 degrees Fahrenheit. If the temperature is not within range, testing personnel are to "correct temperature variance" and "wait 2 hours". 3. Testing personnel stated that the temperature of the room where the EDTA tubes are stored and where BVA 100 Daxor blood volume testing is also performed is not monitored. 4. The laboratory performs an estimated annual volume of 500 blood volume tests.
D6010	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(2) 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)(2) 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 04/17/2019 review of laboratory manuals and quality control records, direct observation and an interview with testing personnel at 2:00 p.m., it was determined that the laboratory failed to ensure that the environmental conditions of the laboratory are appropriate for the blood volume testing it performs. Refer to D tag 5413.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a 04/17/2019 review of laboratory manuals and proficiency testing records, and an interview with testing personnel at 2:00 p.m., it was determined that the laboratory failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings include: 1. The laboratory submits a patient sample twice a year to Daxor for parallel blood volume testing. 2. Documentation of laboratory director or technical consultant review of 6 of 6 Daxor proficiency testing reports, 04/01/2016, 10/27/2016, 04/06/2017, 09/06/2017, 02/20 /2018 and 12/06/2018 was not available for review.