Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0699363	09/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Queen's Cancer Center Kuakini	321 N Kuakini St #402, 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
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 review of American Association of Bioanalysts (AAB) proficiency testing records and an interview with the testing personnel on 09/03/2024 at 3:00 PM, it was revealed that the laboratory failed to ensure its hematology proficiency testing evaluation and verification activities were documented. The findings include: 1. 2023 Nonchemistry M1 event: The laboratory reported an Erythrocytes-3 part diff result of 4.07 on Specimen 1. The intended response range was 4.12 to 4.64. 2. 2023 Nonchemistry (Blood cell identification) M2 event: The laboratory reported Bacteria for Specimen 10. The intended response was Yeast. 3. 2023 Nonchemistry (Educational Challenge) M2 Event: The laboratory reported Lymphocyte; atypical, Downey, variant for Specimen 6. The intended response was Blast undifferentiated. The testing personnel stated the laboratory selected the wrong result code as it does not report abnormal hematology slide results. 4. 2024 Nonchemistry (Blood cell identification) M1 event: The laboratory reported Metamyelocyte for Specimen 3. The intended response was Myelocyte. The testing personnel stated the laboratory selected the wrong result code was it does not report abnormal hematology slide results. 5. 2024 Nonchemistry (Blood cell identification) M2 event: The laboratory reported Monocyte, any stage for Specimen 10. The intended response was Lymphocyte, reactive. 6. The testing personnel stated the laboratory's AAB Medical Laboratory Evaluation (MLE) Proficiency Testing Service Proficiency Test Corrective Action Form was not used to document the corrective actions it took for the afore mentioned proficiency testing events and educational challenge.
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 review of 2023 and 2024 AAB Nonchemistry proficiency testing records and an interview with the testing personnel on 09/03/2024 at 3:00 PM, it was revealed that the laboratory director failed to ensure that an approved corrective action plan was followed when the laboratory obtained unsatisfactory testing results. Refer to D tag D5221.