

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0699363	(X3) Date Survey Completed 07/29/2026
Name of Provider or Supplier Queen's Cancer Center Kuakini	Street Address, City, State 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: The surveyor's review of the laboratory Cell-Dyn Emerald (Abbott) procedure, Streck establishing quality control instructions, and interview with 1 of 3 testing personnel (TP#1) revealed the laboratory failed to provide a written procedure for the quality control of new lots of Cell Dyn 18 Plus hematology tri-levels control material in 2025 and 2026. The findings include: 1. The laboratory Cell-Dyn Emerald procedure states Section 4 Quality Control: "A2. Controls, 1. Cell Dyn 18 Plus tri-levels controls manufactured by Abbott" "B. Setting Up New Control Lot, 2. Establish New Control Means a. Run the new lot of controls to get at least 15-20 points. Ideally over a two week period". 2. Streck Establishing Quality Control Means and Standard Deviations for Hematology Instrumentation instructions states: "CLSI H26-A2 states new lot of control material should be assayed in parallel with the current lot in use before the expiration of the current lot." "2. Verify the new lot by running each level of control three times in its respective file." "3. Run each level twice a day for 3-5 days to calculate new mean values for each measurand." 3. TP#1 interviewed on 7/29/2026 at 10:45 AM stated the laboratory followed the Streck establishing quality control instructions. TP#1 confirmed these instructions were not included in the Cell-Dyn Emerald procedure and were not approved by the laboratory director. 4. TP#1 interviewed on 7/29/2026 at 10:50 AM stated the laboratory accepted tri-level control material ranges established by the manufacturer for 7 of 7 new lots received in 2025 and 2026: Lot 5034 Received 2/25/2025 Lot 5118 Received 4/30/2025 Lot 5202 Received 7/23/2025 Lot 5286 Received 10/15/2025 Lot 6005 Received 1/7/2026 Lot

	6089 Received 4/1/2026 Lot 6173 Received 6/24/2026 New lot acceptability criteria for Cell Dyn 18 Plus hematology tri-level controls were not provided in the laboratory Cell-Dyn Procedure. 5. The laboratory performed an annual volume of 17,000 hematology tests.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: The surveyor's review of the laboratory Cell-Dyn Emerald procedure, Streck establishing quality control instructions, and interview with 1 of 3 testing personnel (TP#1) revealed the laboratory director failed to ensure that an approved procedure manual was available to all TP for the hematology testing it performed in 2025 and 2026. The findings include: 1. TP#1 interviewed on 7/29/2026 at 10:45 AM stated the laboratory followed Streck Establishing Quality Control Means and Standard Deviations for Hematology Instrumentation instructions for new lots of Cell Dyn 18 Plus tri-levels control material. TP#1 confirmed these instructions were not approved by the laboratory director. 2. TP#1 interviewed on 7/29/2026 at 10:50 AM stated the laboratory accepted manufacturer established Cell Dyn 18 Plus tri-levels control ranges for 7 of 7 new lots received in 2025 and 2026. New lot acceptability criteria were not provided in the laboratory Cell-Dyn Procedure. 3. See D tag D5401.