

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0699363	(X3) Date Survey Completed 03/11/2021
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
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory procedures and an interview with the General Supervisor and testing personnel on 03/11/2021 at 3:00 p.m., it was determined that the Laboratory Director failed to specify in writing, the responsibilities and duties of each consultant and supervisor, as well as each person engaged in the pre-analytic, analytic, and post analytic phases of hematology testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. The findings include: 1. The testing personnel stated her responsibilities and duties were described in the Laboratory Manager Job Description to include Administrative Duties, Efficient Workflow Environment, Quality Control, Maintenance and Education. The Laboratory Manager Job Description stated that the testing personnel was responsible to "establish quality standards, supervise QC, inspect staff's work and adjusts laboratory policies and procedures as needed when standards are not met". For high complexity testing, the Laboratory Director may delegate the establishment and maintenance of quality assessment and quality control programs to the Technical Supervisor. The Laboratory Director was designated as the Technical Supervisor on the Laboratory Personnel Report Form CMS 209. 2. The</p>

responsibilities and duties delegated by the Laboratory Director to the General Supervisor were not available for review.