

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0646230	(X3) Date Survey Completed 11/30/2022
Name of Provider or Supplier Clinical Labs Of Hawaii-Kohala Psc	Street Address, City, State 54-383 Hospital Rd, Kapaau, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) proficiency test records and interview with testing personnel on 11/30/2022 at 10:45 a.m., the laboratory failed to review and evaluate its 2021 FH1-A survey ungraded blood cell identification result. The findings included: a. There was non-consensus among participant responses for blood cell identification sample BCP-10. The targeted response was "blast". The laboratory reported "malignant lymphoid cell". Evidence of laboratory review and evaluation of this result was not documented.</p>
D6047	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory technical consultant on 11/30/2022 at 11:45 a.m., the laboratory failed to have procedures for evaluation of the competency of 4 of 4 testing personnel to include direct observations of routine test performance, including patient preparation, specimen handling, processing and testing. The laboratory performed 534 chemistry and 2993 hematology tests annually. The findings included: a. The laboratory failed to include direct observation of iStat</p>

8+ chemistry, microscopic urinalysis and hematology test performance in 2020. b. The laboratory failed to include direct observation of iStat 8+ chemistry, microscopic urinalysis and hematology test performance in 2021.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must 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.

This STANDARD is not met as evidenced by:
Based on review of CAP proficiency test records and interview with testing personnel on 11/30/2022 at 10:45 a.m., the laboratory director failed to ensure all proficiency testing reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. See D211.