

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0619547	(X3) Date Survey Completed 04/26/2023
Name of Provider or Supplier Clinical Labs Of Hawaii Wailuku -Mmg	Street Address, City, State 2180 Main Street 2nd Floor, Wailuku, 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
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on a review of CAP hematology proficiency testing records and an interview with the on-site testing personnel on April 26, 2023 at 11:30 AM, it was determined that the laboratory failed to participate in the second FH1-B testing event of 2022 resulting in a score of 0%. The laboratory performed an annual volume of 5757 tests in 2022. The findings include: 1. The on-site testing personnel confirmed cell ID or WBC diff, RBC, HCT, HGB, WBC and platelet testing were not performed on 5 of 5 event samples (FH1-06, FH1-07, FH1-08, FH1-09, FH1-10). 2. The on-site testing personnel confirmed the laboratory failed to notify the CLIA state agency and the CAP proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with the failure to perform proficiency testing. 3. The on-site testing personnel confirmed the laboratory failed to follow its External Proficiency Testing Procedure, Responsibilities to CMS. An initial letter of explanation and a notification letter "when testing was resumed and PT has been performed satisfactorily, either on-schedule or off-schedule" was not sent to the CIA state agency.</p>

D5293

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of general laboratory systems quality assessment records and an interview with the on-site testing personnel on April 26, 2023 at 12:00 PM, it was determined that the laboratory failed to include a review of the effectiveness the corrective actions it took to resolve its unsatisfactory CAP FH1-B proficiency testing performance. The laboratory received a 0% score for failing to participate in the second testing event of 2022. The findings include: 1. The on-site testing personnel stated that the laboratory's failure to participate in the CAP proficiency testing event was not detected until the FH1-B Hematology Participant Summary of results was reviewed. 2. The on-site testing personnel confirmed taking a leave of absence during the scheduled proficiency testing survey delivery date and due date. 3. The laboratory External Proficiency Testing Procedure, Responsibilities states the "Laboratory Manager, general supervisor, or lead tech will assign the testing on a rotating basis to an appropriate staff member, review the results prior to submission by the due date, and obtain the Laboratory Director and testing personnel signatures on the Attestation Form". Documentation of these activities by this designated personnel was not available for review. The on-site testing personnel stated that laboratory policies and procedures were not revised to prevent the recurrence of non-participation.

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 CAP Hematology testing records, general laboratory systems quality assessment records and an interview with the on-site testing personnel on April 26, 2023 between 11:00 AM and 12:30 PM, it was determined that the laboratory director failed to ensure that an approved corrective action plan was followed when proficiency testing results are found to be unsatisfactory. The findings include: 1. The laboratory failed to participate in the second FH1-B testing event of 2022 resulting in an unsatisfactory a score of 0%. See D tag D2123. 2. The laboratory failed to include a review of the effectiveness the corrective actions it took to resolve its unsatisfactory proficiency testing performance in the second testing event of 2022. See D tag D5293.