

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0619602	(X3) Date Survey Completed 12/02/2022
Name of Provider or Supplier Clinical Labs Of Hawaii-Lanai Community Hospital	Street Address, City, State 628 7th St, Lanai City, 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 American Proficiency Institute (API) proficiency test records and interview with the laboratory general supervisor on 12/02/2022 at 9:45 a.m., the laboratory failed to review and evaluate its unacceptable 2021 iSTAT Protime (PT) result. The laboratory performed 100 PT tests annually. The findings included: a. The laboratory reported a PT result of 31.1 seconds for sample PT1-06 in the 2nd Event of its Hematology/Coagulation survey. The expected result range was 22.1-30.0 seconds. Evidence of laboratory review and evaluation of this result was not documented.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director on 12/02/2022 at 10:30 a.m., the laboratory failed to twice annually verify the accuracy of the Potassium Hydroxide (KOH) testing it performed in 2021 and 2022.</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p>

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 API proficiency test records and interview with the laboratory general supervisor on 12/02/2022 at 9:45 a.m., the laboratory director failed to ensure that an approved corrective action plan was followed for its unacceptable 2021 iSTAT Prottime result. See D5211.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on record review and interview with the laboratory director on 12/02/2022 at 10:30 a.m., the laboratory director failed to twice annually verify the accuracy of the KOH testing services it provided. See D5217.