

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D2176572	(X3) Date Survey Completed 02/24/2023
Name of Provider or Supplier Hilo Benioff Medical Center Nonwaived	Street Address, City, State 1190 Waiuanuenue Ave, Hilo, 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
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 proficiency testing records and an interview with the technical consultant on 02/24/2023 at 10:30 AM, it was determined that the laboratory failed to participate in the College of American Pathologists (CAP) second AQI sodium testing event of 2022. The laboratory received an unsatisfactory score of 0 for its performance in survey AQI-B. The laboratory performs an annual volume of 150 sodium tests. The findings include: 1. The laboratory failed to submit results on samples AQI-06, AQI-07, AQI-08, AQI-09, AQI-10 and was assigned Code 42 [No credit assigned due to absence of response].</p>
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score,</p>

remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:
Based on a review of proficiency testing records and an interview with the technical consultant on 02/24/2023 at 10:30 AM, it was determined that the laboratory failed to undertake and document the remedial action it took for its unacceptable PO2 blood gas result on specimen AQI-15 in the CAP third AQI testing event of 2021. The laboratory performs an annual volume of 150 PO2 blood gas tests.

D2121

HEMATOLOGY
CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:
Based on a review of proficiency testing records and an interview with the technical consultant on 02/24/2023 at 10:30 AM, it was determined that the laboratory failed to document the remedial action it undertook for its unsatisfactory hemoglobin test performance in the CAP third testing event of 2021. The laboratory performs an annual volume of 150 hemoglobin tests. The findings include: 1. The laboratory received an AQI-C survey hemoglobin analyte score of 40%. Sample AQI 11, AQI-13, and AQI-15 results were outside of the limits of acceptability.

D2128

HEMATOLOGY
CFR(s): 493.851(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:
Based on a review of proficiency testing records and an interview with the technical consultant on 02/24/2023 at 10:30 AM, it was determined that the laboratory failed to take and document the remedial action it took for its unacceptable hemoglobin result on specimen AQI-07 in the CAP second AQI testing event of 2022. The laboratory performs an annual volume of 150 hemoglobin tests. The findings include: 1. The laboratory received an AQI-B survey hemoglobin analyte score of 80%. Sample AQI-07 reported result was outside of the limits of acceptability.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that 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 a review of proficiency testing reports and an interview with the technical consultant on 02/24/2023 at 10:30 AM, it was determined that the laboratory director failed to ensure that all of its CAP proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings include: 1. The laboratory failed to document the corrective action it took for its unsatisfactory sodium test score of 0 in the second AQI testing event of 2022. See D2089. 2. The laboratory failed to undertake and document the remedial action it took for its unacceptable PO2 blood gas result on specimen AQI-15 in the third AQI testing event of 2021. See D2094. 3. The laboratory failed to document the remedial action it undertook for its unsatisfactory hemoglobin test performance in the third AQI testing event of 2021. See D2121. 4. The laboratory failed to undertake and document the remedial action it took for its unacceptable hemoglobin result on specimen AQI-07 in the second AQI testing event of 2022. See D2128.