

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1015025	(X3) Date Survey Completed 10/23/2024
Name of Provider or Supplier Stockton Hematology Oncology Medical Group	Street Address, City, State 2316 Orchard Parkway, Ste 110, Tracy, CA	
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
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's proficiency testing (PT) records retrieved from Certification and Survey Provider Enhanced Reporting (CASPER) and interview with the testing personnel (TP), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the specialty of Hematology. The findings include: 1. Based on the records retrieved from CASPER, it was determined that the laboratory obtained an unacceptable score of sixty percent (60%) for Platelet (Plt) analyte for the third event of 2021 (Q3-2021) and a zero percent (0%) score for Hemoglobin (Hgb) analyte for the first event of 2022 (Q1-2022). No records nor corrective action were able to be retrieved at the time of the survey. 2. The TP affirmed by interview on October 23, 2024, at approximately 11:30 a.m. that the laboratory received the scores for statement #1. 3. Based on the laboratory's annual testing declaration submitted on the day of the survey on October 23, 2024, the laboratory analyzed and reported approximately 14,000 Cell Blood Count (CBC) patient test samples for the specialty of Hematology during the time the laboratory had unsatisfactory proficiency testing results for Plt and Hgb. Thus, the accuracy of results during these periods cannot be determined.</p>
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p>

This STANDARD is not met as evidenced by:
 Based on the review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with the testing personnel (TP), it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent, resulting in an unsatisfactory performance for the specialty of Hematology for the first event in 2023 (Q1-2023). The findings include: 1. Based on the survey conducted on October 23, 2024, at approximately 11:30 a.m. and review of the AAB-MLE PT records, it was determined that no corrective action was performed for Cell Blood Count (CBC) panel for Q1-2023 when the laboratory obtained an overall score of 0%. 2. The TP affirmed on October 23, 2024, at approximately 11:30 a.m. that the laboratory obtained the PT scores in statement #1 but missed conducting troubleshooting and developing a corrective action. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 14,000 samples annually for the CBC panel. Thus, the reliability and quality of CBC patient results reported could not be assured at the time when the laboratory failed to attain an overall score of 80 percent.

D5435

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's policies and procedures, preventive maintenance log documentation, five (5) randomly selected patient test results, and interview with the laboratory's testing personnel (TP), it was determined that the laboratory failed to ensure function checks were performed and documented. The findings include: 1. Based on the survey on October 23, 2024, one (1) out of 5 patient records reviewed was found to have an incomplete record for preventive maintenance. Review of the laboratory's temperature checks showed that no documentation was recorded for March 13, 2023, when recording daily temperature, QC, and PM function check logs were implemented prior to patient testing. 2. The TP affirmed by interview on October 23, 2024, at approximately 12:30 p.m. that the lack of documentation cited in statement #1 was missed for the equipment function checks documentation for the randomly chosen patients testing review performed. Patients tests were resulted and reported during this time lacking equipment function checks documentation. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory performed and reported approximately 14,000 patient tests for Hematology.

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 the review of the laboratory's policies and procedures, American Association of Bioanalysts Medical Laboratory Evaluation proficiency testing results for the years 2021, 2022, and 2023, and interview with the testing personnel, the laboratory director is herein cited for failure to 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. The findings include: See D2121 and D2122.