Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0600646	(X3) Date Survey Completed 03/12/2025
Name of Provider or Supplier Sierra Hematology And Oncology	**Street Address, City, State** 1580 Creekside Dr Ste 230, Folsom, 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	HEMATOLOGY CFR(s): 493.851(a) (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 the surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) records, interviews with the laboratory supervisor (LS) and testing personnel (TP), it was determined that the laboratory failed to attain at least 80 percent of the acceptable response resulting to an unsatisfactory performance for the Hematology second event in 2022 (Q2-2022) for the White Blood Cell (WBC) differential test. The findings include: 1. Based on the surveyor's review of the laboratory's PT records, API reported a 67% score for the WBC automated differential test for Q2-2022. Further review of the quality assessment documentation showed that this score was negatively impacted by the 0% score for Monocytes. 2. The LS and TP affirmed on March 12, 2025 at approximately 9:50 a.m. that the laboratory obtained the PT scores mentioned in statement #1. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 16,412 samples annually for Hematology that included the WBC automated differential test in the Cell Blood Count panel. Thus, the reliability and quality of Hematology patient results reported could not be assured at the time when the laboratory failed to attain an unacceptable score of at least 80 percent.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on the review of the laboratory's quality assessment policies and procedures, personnel competency documentation, seven (7) patient records, and an interview with the laboratory supervisor (LS) on March 12, 2025, at approximately 9:20 a. m., as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform competency assessment for several laboratory personnel for the years 2022, 2023, and 2024. Findings include: 1. Based on the review of the laboratory's quality assessment policies and procedures, competency evaluation records, and 7 patient records, the laboratory is herein cited for the deficient practice for failure to perform competency assessment for several testing personnel (TP) for the years 2022, 2023, and 2024. a. KC was missing competency for 2021. b. OR was missing competencies for 2022, 2023, and 2024. c. HW was missing competency for 2024. 2. The LS affirmed by interview on March 12, 2025, at approximately 9:20 a. m. that the laboratory had no records of any competency assessment specified in statement #1 for the years 2022, 2023, and 2024 for the Folsom, CA location. 3. According to the laboratory's annual testing declaration submitted at the time of the survey, the laboratory reported and performed approximately 16,412 tests for Hematology for which competency assessments of several testing personnel were not performed.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(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. (b)(2)(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 the surveyor's review of the laboratory's preventive maintenance (PM) documentation, observations during the tour, and an interview with the laboratory supervisor (LS), it was determined that the laboratory failed to ensure performed tests and function checks were documented properly prior to patient testing. The findings include: 1. Based on the review of the laboratory's PM documentation, no annual calibration records were found for the thermometer for the years 2022 and 2023. 2. The LS affirmed by interview at approximately 10:40 a.m. on March 12, 2025, that the laboratory missed to perform an annual calibration for the thermometer as mentioned in statement #1. 3. Based on the annual testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 16,412 patient tests for Hematology, including the time the missing annual PM for the thermometer occurred.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory

	services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the deficiencies cited, the Laboratory Director is herein cited for deficient practice in ensuring that systems for the preanalytic, analytic, and postanalytic phases of the laboratory were monitored and followed. Findings include: 1. The laboratory received unsatisfactory performance results for Hematology. See D2121. 2. Competency assessments were missed to be performed. See D5209. 3. Missing maintenance and function check documentation. See D5435.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, American Proficiency Institute (API) proficiency testing (PT) results for the years 2022, 2023, and 2024, and interview with the laboratory supervisor, 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: 1. Based on the review of the API PT results, the laboratory received an 80% score for Platelet analyte for three consecutive events: second event of 2023 to first event of 2024. 2. Based on the surveyor's review of corrective action reports (CAR), incomplete or missing documentation were found for the following events: a. Second event of 2023: Incomplete CAR found. b. Third event of 2023: None found. c. First event of 2024: Incomplete CAR found. 3. The LS affirmed by interview on March 12, 2025, at approximately 9:50 a.m. that there were no completed CAR for any of the three events mentioned in statement #2. 4. Based on the testing volume declaration submitted at the time of survey, the laboratory performed and reported approximately 16,412 tests for Hematology during the time that CAR were missed or not completed.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures and interview with the laboratory supervisor on March 12, 2025 at approximaately 9:05 a. m., the laboratory director is herein cited for the deficient practice of lacking a written

	delegation of responsibilities to qualified personnel involved in preanalytic, analytic, and postanalytic phases of testing process.