Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0675138	07/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pacific Hematology Oncology Associates	2100 Webster St Ste 225, San Francisco, 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 Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interviews with three technical consultants and the laboratory manager on July 8, 2026, the laboratory failed to attain at least 80 percent acceptable responses, resulting in unsatisfactory performance for White Blood Cell (WBC), Red Blood Cell (RBC), Hemoglobin (Hgb), Hematocrit (Hct), and WBC differential analytes/tests across multiple 2024 Hematology specialty events. The findings include: 1. Review of the AAB-MLE PT documentation for 2024 revealed that the laboratory received an unsatisfactory scores of multiple analytes/tests in different event periods. The results are as followed: a. RBC 60% - 2024 first testing event; b. Hct 40% - 2024 first testing event; c. Hgb 60 % - 2024 first testing event; d. WBC 60% - 2024 first testing event; e. WBC differential 60% - 2024 second testing event; f. WBC 0% - 2024 third testing event. 2. The technical consultants and laboratory manager confirmed in an interview on July 8, 2026 at approximately 10:40 a.m. that the laboratory received the unsatisfactory scores in 2024. 3. According to the testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 3,800 patient samples annually for Hematology specialty that included the WBC, RBC, Hgb, Hct, and WBC differential analytes/tests including the period when the unsatisfactory scores were obtained. .
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 surveyor's review of the laboratory's policy and procedure, eight randomly chosen patient records from January 19, 2024 to June 25, 2026, lack of personnel competency documentation, and interviews with the three technical consultants and laboratory manager on July 8, 2026, as specified in the personnel requirements in subpart M, the laboratory failed to perform the personnel competency assessment prior to patient testing. The findings include: 1. The laboratory's policy was to conduct competency assessments for all testing personnel at least annually. The template presented at the time of the survey included an option for initial for any new personnel. 2. The surveyor reviewed eight patient records from January 19, 2024 to June 25, 2026 wherein the tests were performed by the multiple testing personnel (TP). The laboratory lacked competency assessment records for the years 2024, 2025 and 2026, and that no corrective action documentation was available at the time of the survey. 3. The technical consultants and laboratory manager confirmed in an interview on July 8, 2026, at approximately 11:10 a.m. that the competency assessments for all TP were not performed for the years 2024, 2025 and 2026. 4. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory reported and performed approximately 3,800 patient samples annually, including the time when the competency assessment policy was not followed and performed. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the lack of reference intervals documentation for the Sysmex XN430, review of laboratory's policy and procedure and interviews with the three technical consultants and laboratory manager on July 8, 2026, the laboratory failed to complete and verify the performance specifications required prior to patient testing. The findings include: 1. The surveyor reviewed the laboratory's policy, procedure, and performance specifications for the Sysmex XN430 and found that the laboratory did not verify the manufacturer's reference intervals during the instrument's installation period 2. The technical consultants and the laboratory manager confirmed during interviews on July 8, 2026, at approximately 9:45 a.m., that the laboratory did not verify the reference intervals, which resulted in missing documentation in the performance specifications binder. 3. According to the testing declaration submitted

	during the survey, the laboratory performed and reported approximately 3,800 hematology tests annually using the Sysmex XN430 during the period when reference interval verification was not documented. .
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 record review, lack of preventive maintenance record and interviews with the three technical consultants and the laboratory manager on July 8, 2026, the laboratory failed to document and retain preventive maintenance performed on July 24, 2025 prior to patient testing. The findings include: 1. The laboratory performed preventive maintenance at different frequencies depending on the specific maintenance required prior to patient testing. However, the preventive maintenance documentation for July 24, 2025 was missing, and no corrective action documentation was available for review at the time of the survey. 2. The technical consultant and the laboratory manager confirmed during interviews on July 8, 2026, at approximately 11: 40 a.m., that the preventive maintenance performed on July 24, 2025 could not be retrieved and that no corrective action documentation was available for review. 3. According to the testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 3,800 tests annually, which included the period when preventive maintenance was missed as described in this deficiency. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of the laboratory's verification of performance specifications documentation, and interviews with the three technical consultants and laboratory manager, the laboratory director failed to ensure that the verification procedures was complete prior to patient testing. See D5421 .
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by:

	Based on review of the laboratory's proficiency testing documentation for the first, second and third events of 2024, and interviews with the three technical consultants and laboratory manager on July 8, 2026, the laboratory director is herein cited due to failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. See D2121 .
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, lack of preventive maintenance record and interviews with the three technical consultants and laboratory manager on July 8, 2026, the laboratory director is herein cited for failure to ensure that the quality assessment policy was followed to ensure compliance and identify failures as they occur. See D5435 .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on the lack of competency assessment records for all testing personnel and interviews with the three technical consultants and the laboratory manager on July 8, 2026, the laboratory director failed to ensure that, prior to patient testing, all testing personnel had the appropriate training and demonstrated the ability to perform testing operations reliably. See D5209 .