Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0707127	03/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Providence Medical Foundation	27799 Medical Center Rd, Ste 460, Mission Viejo, 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) 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 surveyor review of the API proficiency testing evaluation report for the third event of 2022 and interview with the laboratory staff on 03/22/2024 at 11:30 AM, the laboratory failed to attain a score of at least 80 percent for MCH, MCV, Platelet count, RWD, Red Cell Count for the 3rd event of 2022. The finding include: 1) The laboratory performed Complete Blood Cell Counts (CBC) using HORIBA ABX Micros 60 Analyzer. The laboratory participated in the American Proficiency Institute (API) proficiency testing program in 2022 and 2023. The laboratory attained a score of 60 percent for MCH, MCV, Platelet Count, RWD, Red Cell Count for the 3rd event of 2022, which was unsatisfactory for the testing event. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. 2) On 12/30/2022, the laboratory director confirmed that the laboratory attained a score of 60 percent by signing the proficiency testing performance evaluation form. 3) The laboratory's testing declaration form, signed by the laboratory director on 03/22/2024 stated that the laboratory performed approximately 53646 tests in hematology, annually.
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 surveyor review of the API proficiency testing evaluation report for the second event of 2022 and interview with the laboratory staff on 03/22/2024 at 11:30 AM, the laboratory failed to take remedial action for the unacceptable results of Hematocrit, MCHC, MCV, Platelet Count and RWD in the 2022 second event. The finding include: 1) The laboratory performed Complete Blood Cell Counts (CBC) using HORIBA ABX Micros 60 Analyzer. The laboratory participated in the American Proficiency Institute (API) proficiency testing program in 2022 and 2023. The laboratory attained a score of 80% for Hematocrit, MCHC, MCV, Platelet Count and RWD in the 2022 second event. The laboratory failed to take remedial action for the unacceptable results. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. 2) On 08/23/2022, the laboratory director reviewed and signed the proficiency testing performance evaluation form, stated that corrective action is not necessary. 3) The laboratory's testing declaration form, signed by the laboratory director on 03/22/2024 stated that the laboratory performed approximately 53646 tests in hematology, annually.
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 surveyor review of the API proficiency testing evaluation report and interview with the laboratory staff on 03/22/2024 at 11:30AM, the laboratory director failed to provide effective direction to identify the problems that requires corrective action for the unacceptable results in the second event of 2022. The finding include: See 2128
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

	This STANDARD is not met as evidenced by: Based on surveyor review of the API proficiency testing evaluation report and interview with the laboratory staff on 03/22/2024 at 11:30AM, the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance. The finding include: 1) The laboratory performed Complete Blood Cell Counts (CBC) using HORIBA ABX Micros 60 Analyzer. The laboratory participated in the American Proficiency Institute (API) proficiency testing program in 2022 and 2023. The laboratory attained a score of 60 percent for MCH, MCV, Platelet Count, RWD, Red Cell Count for the 3rd event of 2022, which was unsatisfactory for the testing event. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. 2) On 12/30/2022, the laboratory director signed the proficiency testing corrective action form and stated that there was possible issue with sample 14 and 15 without providing any effective direction for the maintenance of acceptable levels of analytical performance. 3) The laboratory's testing declaration form, signed by the laboratory director on 03/22/2024 stated that the laboratory performed approximately 53646 tests in hematology, annually.