Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0557525	(X3) Date Survey Completed 12/09/2025
Name of Provider or Supplier Omid S Shaye Md	**Street Address, City, State** 7320 Woodlake Ave Ste 330, West Hills, 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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 Surveyor review of laboratory's proficiency testing (PT) records, and interview with the laboratory technical consultant on December 9, 2025, at 12:00 p. m., the laboratory failed to attain a score of at least 80% of acceptable responses for chloride, creatinine and bilirubin which is an unsatisfactory analyte performance for the testing event. The findings include: 1. The laboratory participated in the AAB PT program for the years 2024 and 2025. The laboratory scored 60% for creatinine at the M3 event and 40% for chloride at the M1 event in 2025. Furthermore, it also scored 20% for bilirubin at the M3 event and 60% for chloride at the M1 event in 2024. Therefore, the accuracy of the patient test results for the above analytes reported by the laboratory during the failed proficiency testing period cannot be assured and might have harmed patients. 2. The laboratory technical consultant on December 9, 2025, at 12:00 p.m. affirmed that the laboratory received less than 80% score. 3. The laboratory's testing declaration form, signed by the laboratory director on 8/15/2025 stated that the laboratory performs approximately 103,306 tests in routine chemistry, annually.
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 Surveyor review of laboratory's proficiency testing (PT) records, and interview with the laboratory technical consultant on December 9, 2025, at 12:00 p. m., the laboratory failed to attain a score of at least 80% of acceptable responses for platelet which is an unsatisfactory analyte performance for the testing event. The findings include: 1. The laboratory participated in the AAB PT program for the year 2024. The laboratory scored 60% for platelet at the M3 event in 2024. Therefore, the accuracy of the patient test results for platelet reported by the laboratory during the failed proficiency testing period cannot be assured and might have harmed patients. 2. The laboratory technical consultant on December 9, 2025, at 12:00 p.m., affirmed that the laboratory received less than 80% score at the M3 PT event. 3. The laboratory's testing declaration form, signed by the laboratory director on 8/15/2025 stated that the laboratory performs approximately 54,726 tests in hematology, annually.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing and patient test records, and interview with the laboratory technical consultant on December 9, 2025, at 12:00 p.m., the laboratory director failed to assure laboratory's compliance with the applicable regulations and thus had impaired the laboratory test quality and potentially harmed patients. The findings include: See D2087 and D2121
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (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 laboratory's proficiency testing records from AAB, and interview with the laboratory technical consultant on December 9, 2025, at 12:00 p. m., the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance for chloride, creatinine, bilirubin and platelet test. The findings include: See D2087 and D2121.