Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1009515	04/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
J Lee Md Medical Corporation	1010 W Laveta Ave, Ste 360, Orange, 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
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(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 review of the laboratory's records, the proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed RF (Rheumatoid Factor) qual and enrolled with CAP (College of American Pathologist) proficiency testing (PT) program to verify the accuracy of the testing system. b. The laboratory attained a score of 60 % for RF in the Q1 2020 CAP Diagnostic Immunology PT program which was unsatisfactory analyte performance for the testing event. c. The laboratory performed in approximately 35 patient samples monthly. d. The laboratory staff affirmed (4/27/22 @11:10 am) that the laboratory attained a score of 60 % for RF qual in the Q1 2020 CAP Diagnostic Immunology PT program which was unsatisfactory analyte performance for the testing event.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 review of the laboratory's records, the proficiency testing (PT) result reports,

	and interview with the laboratory staff, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed routine chemistry using ACE Wasserman system and enrolled with AAB (American Association of Bioanalysts) proficiency testing (PT) program to verify the accuracy of the testing system. b. The laboratory attained a score of 60 % for GGT (gamma glutamyl transferase) in the Q2 2021 AAB PT program which was unsatisfactory analyte performance for the testing event. c. The laboratory performed GGT in approximately 42 patient samples monthly. d. The laboratory staff affirmed (4/27/22 @10:10 am) that the laboratory attained a score of 60 % for GGT (gamma glutamyl transferase) in the Q2 2021 PT program which was unsatisfactory analyte performance for the testing event.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, the proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory failed to verify the accuracy of any test or procedure it performs that is not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed hs CRP is not listed in the subpart I of 42 CFR part 493, by ACE Wasserman system. b. The laboratory elected to enroll with AAB (American Association of Bioanalysts) PT program to verify, at least twice annually, the accuracy of the testing system. b. The laboratory attained scores of 0 % for hs CRP in both of Q1 and Q2 2021 AAB PT events, which were unsatisfactory analyte performance for the testing events. c. The laboratory performed hs CRP in approximately 154 patient samples monthly. d. The laboratory staff affirmed (4/27/22 @10:10 am) that the laboratory attained scores of 0 % for hs CRP in both of Q1 and Q2 2021 AAB PT events were unsatisfactory analyte performance.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, the instrument verification documents, and interview with the laboratory staff, it was determined that the laboratory failed to have the current laboratory director approved, signed, and dated for procedures or changes in procedures before use. The findings included: a. The laboratory was moved to a new location. b. The laboratory had performed verifications for the existing instruments for ACE Wasserman and Celldym 1800 systems. c. There were no evidence that the current laboratory director had approved, signed, and dated the verification documents.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that 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 records, the proficiency testing (PT) resault reports and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of this part. The findings included: a. The laboratory performed routine chemistry, hematology, and general immunology. b. The laboratory elected and enrolled its PT with 1) AAB (American Association of Bioanalysts), 2) CAP (Colleage of American pathologists) to verify the accuracy of the test systems and proccedures it performed to verify and ensure the accuracy of the patient test results reports. c. The laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of this part, see D-2075, D-2087 and D-5217.