Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1009515	02/20/2018
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 2017: event 2 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and CAP (College of American Pathologists), laboratory proficiency testing documents, and patients test records; and interview with laboratory personnel, the laboratory failed to attain a score of at least 80% for the ANA screening test (Anti-Nuclear Antibody) using the high-complexity TheraTest system. Findings include: a. CMS and CAP reported the score of 60% for ANA testing for the 2nd event of 2017. b. Laboratory proficiency testing records revealed the laboratory obtained 2 unacceptable results out of 5 on 9/12/17, as follows: Sample ID Lab result Acceptable result ---------- ANA-07 Positive Negative ANA-10 Positive Negative c. Laboratory personnel affirmed (2/20/18) the aforementioned unsatisfactory results and score; and thus, unsatisfactory testing for ANA. d. The reliability and quality of patients results reported could not be assured. Based on the stated estimated annual test volume, the laboraotry reported approximately 38 ANA results each month during the timeframe September to November 2017. A few examples are as follows: Date Sample ID ---------- 8/13/17 7063 8/13/17 7084 9/12/17 7146 9/25/17 7192 10/01/17 7294 10/01/17 7332 .
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 2016 - 2017 proficiency testing reports from DEQAS (Vitamin D External Quality Assessment Scheme), laboratory proficiency testing records, and patients test reports; and interview with the Laboratory Director/Technical Consultant, the laboratory failed to verify the accuracy of testing for Vitamin D using the TheraTest ELISA system. Findings include: a. The laboratory chose to participate in DEQAS' proficiency testing program as the means to satisfy the requirement to verify the accuracy of testing using the Euroimmun 25-OH Vitamin D Kit. b. The laboratory reported 5 unacceptable results out of 5 in 2016 and 2017; as follows, and thus, accuracy was not verified: Date Specimen # Reported Target ---------- 11/06/16 501 56.3 96.2 " 502 23.8 40.0 " 503 50.0 80.6 " 504 32.5 57.6 " 505 12.5 21.7 8/12/17 516 31.8 46.5 " 517 44.5 68.3 " 518 77.3 105.0 " 519 22.8 33.2 " 520 78.8 104.1 c. The Laboratory Director /Technical Consultant affirmed (2/20/18) the aforementioned unacceptable results, which were all lower than the Target values. d. The reliability and quality of results reported could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 15 Vitamin D results each month during the timeframes November 2016 - January 2017, and August - September 2017. A few examples are as follows: Date Sample ID ---------- 11/06/16 4989 " 5013 " 5016 12/27/16 6095 " 6102 " 6107 8/12/17 7000 " 7009 " 7123