Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1009515	10/29/2025
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
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 observation of the Alfa Wassermann ACE Alera (serial number 10020237) chemistry analyzer, review of 2022 -2024 proficiency testing reports from AAB (American Association of Bioanalysts) and CMS (report 155D, Individual Laboratory Profile), and laboratory proficiency testing records; and interview with laboratory personnel, it was revealed that the laboratory failed to attain minimum satisfactory scores of 80% for Calcium. Findings included: a. AAB and CMS reported unsatisfactory scores for Calcium based on the laboratory's unacceptable results, as follows:. Event/Year Score Unacceptable Results ---------- 3 / 2022 0% 5 out of 5 1 / 2024 60% 2 out of 5 b. Laboratory personnel affirmed (10/29/25 at 2:30 PM) the aforementioned proficiency testing records indicative of unsatisfactory testing. c. The laboratory reported 800 test results annually for Calcium (LAB144A, Laboratory Testing Declaration, 9/14/25). The reliability and quality of results reported for Calcium during the timeframes September -December 2022 and January - April 2024, could not be assured duting this Survey. Laboratory personnel affirmed (10/29/25 at 2:30 PM) the monthly test volumes. Several results randomly selected for review are, as follows. Month Total test Date Sample ID volume ---------- 2022 Sept 200 9/08/22 103282 2022 Dec 290 12/08/22 104425 2024 Jan 400 1/05/24 109025 2024 Feb 320 2/01/24 109361 .
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 observation of the Cell Dyn 1800 (serial number 19406AY) hematology analyzer, review of 2024 proficiency testing reports from AAB (American Association of Bioanalysts) and CMS (report 155D, Individual Laboratory Profile), and laboratory proficiency testing records; and interview with laboratory personnel, it was revealed that the laboratory failed to attain minimum satisfactory scores of 80% for Red Blood Cell Count (RBC). Findings included: a. AAB and CMS reported the unsatisfactory score of 60% for the 1st Event of 2024 based on the laboratory's 2 unacceptable results out of 5 for RBC. b. Laboratory personnel affirmed (10/29/25 at 2:30 PM) the aforementioned proficiency testing records indicative of unsatisfactory testing. c. The reliability and quality of results reported for RBC during the timeframe January - April 2024, could not be assured during this Survey. The laboratory reported 600 test resulats annually (LAB144A, Laboratory Testing Declaration, 9/14/25). Several randomly selected for review are, as follows: Date Sample ID ---------- 1/05/24 109025 2/01/24 109361 " 109368 " 109374 .
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 observation of the TheraTest Laboratories Inc test system (serial number 2801) utilizing ELISA methodology, review of proficiency testing reports from CAP (College of American Pathologists), API (American Proficiency Institute), and AAB (American Association of Bioanalysts) for 2022 - 2024, laboratory proficiency testing records and records for alternate methods for verifying accuracy of testing, and interview with laboratory personnel, it was revealed that the laboratory failed to verify the accuracy of testing for Vitamin D in 2022, 2023, and 2025; CRP-HS (C-Reactive Protein, High Sensitivity) in 2024, and the following ANA (Anti-Nuclear Antibodies) analytes in 2022, 2023, and 2024: ssDNA RNP/Sm Chromatin dsDNA SSA (Ro) Scl-70 Sm SSB (La) Centromere a. VITAMIN D 1. In 2022, the laboratory participated in CAP's proficiency testing program as their chosen means to verify the accuracy of testing for Vitamin D. In 2023 - 2025, the labortory switched to participating in API's program. The laboratory reported unacceptable results indicating unsatisfactory testing and failed to verify accuracy of testing, as follows: Program Event Unacceptable Results Score ---------- CAP A/ 2022 2 out of 3 = 33% CAP B/ 2022 3 out of 3 = 0% API 1 / 2023 1 out of 2 = 50% API 2 / 2025 0 out of 2 = 0% 2. Laboratory personnel affirmed (10/29/25 at 1:30PM) the aforementioned unacceptable results and unsatisfactory scores. 3. The laboratory failed to provide for review any additional records utilizing alternate means to verify the accuracy of testing for Vitamin D during 2022, 2023, and 2025. 4. And thus, the laboratory failed to prove that testing for Vitamin D was accurate during all of 2022, the first half of 2023 and the second half of 2025. 5. The reliability and quality of

	results reported for Vitamin D in 2022, 2023, and 2025 could not be assured during this Survey. The laboratory reported 300 results annually (LAB116 Laboratory Testing Declaration, 9/14/25). A few results randomly selected for review are, as follows: Date Sample IDs ---------- 3/06/22 273635; 273637; 273642 4/03/22 2737440 5/21/22 2737514; 2737642 1/14/23 2738832 3/05 /23 2739216 5/21/23 2739438; 2739632 8/02/25 81644 9/06/25 81647 10/18/25 81926 b. CRP-HS 1. In 2024, the laboratory participated in AAB's proficiency testing program for CRP-HS as their chosen means to comply with this regulation to verify the accuracy of non-regulated analytes. 2. For the 3rd Event of 2024, the laboratory received two unknowns for testing and reported 1 unacceptable result out of 2 for an unsatisfactory score of 50%. 3. Laboratory personnel affirmed (10/29/25 at 1:30PM) the aforementioned findings. 4. The laboratory failed to provide for review any additional records utilizing alternate means to verify the accuracy of testing for CRP-HS during 2024. 5. And thus, the laboratory failed to prove that testing for CRP-HS was accurate during the timeframe September - December 2024. 6. The reliability and quality of results reported for CRP-HS could not be assured during this Survey. The laboratory reported 600 results annually (LAB116 Laboratory Testing Declaration, 9 /14/25). c. ANA/9 1. In 2022: the laboratory participated in CAP's program, "S2 - Special Immunology", as the chosen means to comply with this regulation. The S2 program didn't include testing for ssDNA, Chromatin, SCL-70, and Centromere. i. The laboratory failed to provide for review any records for alternate means of verifying the accuracy of testing for ssDNA, Chromatin, SCL-70, and Centromere in 2022; and thus, the laboratory failed to verify accuracy of testing during 2022. 2. In 2023: the laboratory participated in TheraTest Laboratories, Inc's proficiency testing program for ssDNA, Chromatin, Centromere, and Scl-70 as the chosen means to verify the accuracy of testing. i. The laboratory failed to have records from TheraTest evaluating/scoring results for dsDNA, Sm, RNP/Sm, SSA (Ro), and SSB (La); and thus, the laboratory failed to verify accuracy of testing for these five analytes in 2023. 3. In 2024: the laboratory failed to have records verifying the accuracy of testing for all nine analytes: ssDNA, dsDNA, Sm, RNP/Sm, SSA (Ro), SSB (La), Chromatin, Scl-70, and Centromere; and thus, it was revealed the laboratory failed to verify the accuracy of testing during 2024. 4. The reliability and quality of results reported in 2022 - 2024 could not be assured. The laboratory reported a combined total of 4,500 results annually (LAB116 Laboratory Testing Declaration, 9/14/25). A few randomly selected from the afrementioned timeframes are, as follows: Date Sample ID ---------- 2/05/22 273479 3/20/22 2737268 4/16/22 2737495 7/10/22 2738005; 2738008 11/20/22 2738581; 2738585 3/25/23 2739319 7/15/23 2739917 12 /26/23 2740417 3/17/24 2741062 9/02/24 27420574 10/26/24 80181 12/14/24 80485 .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical

	parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation of the Alpha Wassermann ACE Alera chemistry analyzer, review of the GEMCAL Calibrator Reference Serum (Lot # F4770, Exp Date 11/30 /25), the lack of records, and interview with the Testing Person, it was determined that the laboratory failed to verify assay calibrations at least once every six months. Findings included: a. Following the manufacturer's instructions, the analyzer was calibrated using Alpha Wasserman's GEMCAL Calibrator consisting of a single reference concentration. b. Records documented the calibrations were verified, as follows: Dates of Calibration Verification ---------- 6 /23/23 7/11/24 7/11/25 c. The laboratory failed to have additional records verifying calibrations. Laboratory personnel affirmed (10/29/25 at 5 PM) the aforementioned dates and that calibrations were verified once per year. d. And thus, the laboratory failed to comply with this requirement to perform calibration verifications at least once every 6 months. e. The reliability and quality of results obtained using the Alpha Wasserman test system could not be assured in 2022 - June 2025. The laboratory reported a combined total of 9,450 chemistry results annually (LAB116 Laboratory Testing Declaration, 9/14/25). A few randomly selected from this timeframe for review are, as follows: Date Sample ID ---------- 8/25 /22 103140 9/08/22 103282 12/08/22 104425 12/05/23 108689 1/05/24 109025 2/01 /24 109374 .
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 the serious and cumulative nature of deficiencies cited, the Laboratory Director is herein cited for not ensuring acceptable test performances in 2022 - 2025. Findings included: a. Under the Laboratory Director's management, the laboratory failed to maintain satisfactory testing for Calcium. See D2087. b. Under the Laboratory Director's management, the laboratory failed to maintain satisfactory testing for RBC. See D2121. c. Under the Laboratory Director's management, the laboratory failed to verify that testing was accurate. See D5217. d. Under the Laboratory Director's management, the laboratory failed to verify calibrations at least once every six months. See D5439.