Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2159325	03/10/2026
Name of Provider or Supplier	**Street Address, City, State**	
Rma Of Northern California	150 Spear St Ste 500, San Francisco, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory Endocrinology proficiency testing records for 2023 - 2025 and patients specimen test records, and interview with Testing Persons-1 and 6 (CMS209 Laboratory Personnel, 3/07/26), it was determined that the laboratory failed to include proficiency samples into the regular workflow to be tested by personnel routinely testing patients specimen. Findings included: 1. Laboratory proficiency testing records documented all Endocrinology Proficiency samples for 5 out of 5 consecutive events in 2023 - 2025 were tested by Testing Person-1. . 2. Patients test records for 6 out of 6 days during the timeframe July - December 2025 revealed other Testing Personnel, including "AL" and Testing Persons -2 and -3, performed routine testing, as follows: Date Testing Person Specimen tested ---------- 7/06/25 AL 61 out of 61 8/10/25 TP-2 51 out of 51 9/14/25 TP-2 66 out of 66 10/19/25 TP-3 59 out of 59 11/09/25 TP-2 63 out of 63 12/07/25 TP-3 43 out of 43 3. Testing Person-1 affirmed (March 10 at 3:30 PM) the aforementioned findings: that other Testing Persons routinely tested patient specimen but proficiency samples weren't included in their workload. .
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 Roche Cobas e411 chemistry analyzer (serial number 90F0-10) for Estradiol, FSH (Follicle Stimulating Hormone), serum HCG (Human chorionic gonadotropin, preganancy test), LH (Luteininzing Hormone) and Progesterone; review of calibration verification records for 2023 - 2026, the lack of 3 out of 6 records, and interview with Testing Person-1, it was determined that the laboratory failed to verify calibrations at least once every six months. Findings included: 1. The Roche Cobas e411 utilized 2-points calibrations. Thus, the calibrations needed verifying at least once every six months. 2. A laboratory record documented calibration verification was performed in August 2023. For the timeframe August 2023 to March 2026, the laboratory failed to have 3 out of 6 records for verifying calibrations, as follows: None within 6 months after February 2024 None within 6 months after February 2025 None anytime after February 2025 3. Testing Person-1 affirmed (3/10/26 at 1:44 PM) the aforementioned findings, that calibration verifications were not performed at least once every six months. . .
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the findings and deficiency cited at D2007, the Laboratory Director is herein cited for not ensuring that proficiency samples were incorporated into the routine workload of Testing Personnel. See D2007.