Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0954568	**(X3) Date Survey Completed** 05/09/2025
Name of Provider or Supplier Endocrine And Metabolic Research Lab	**Street Address, City, State** 1124 W Carson St, Room 231, Torrance, 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**
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(g) (d)(9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control material, calibrator, and interview with the laboratory technical supervisor on May 9, 2025, at 12:30 p.m., the laboratory failed to use different lot's control material from the calibrator. The findings include: 1. The laboratory used an LC-MS/MS method to detect hormones in the patient sample. It used a calibrator to calibrate the system by a standard curve and ran quality control each time of testing. However, it used the calibrator material from the same lot of quality control material. Therefore, the validity of the test method cannot be assured and might have had harmed patient. 2. The laboratory technical supervisor on May 9, 2025, at 12:30 p.m., affirmed that the laboratory used the calibrator material from the same lot of quality control material. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/16/2025, stated that the laboratory performs approximately 5,200 LC-MS tests, annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities

	to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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 policy & procedure, quality control and patient test records, and interview with the laboratory technical supervisor on May 9, 2025, at 12:30 p.m., the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D5467 and D6093.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control material, calibrator, and interview with the laboratory technical supervisor on May 9, 2025, at 12:30 p.m., the laboratory director failed to ensure that the laboratory established and maintained the quality control programs to assess the quality of laboratory services provided. The findings include: See D5467.