Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0901953	08/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Levine Laboratory	2001 Santa Monica Blvd, Ste 390 W, Santa Monica, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on the review of American Association of Bioanalysts (AAB) 2019 proficiency testing reports, request for 2019 laboratory proficiency testing records, and an interview (August 6, 2019, 9:00 A.M.) with a laboratory's testing person, the laboratory failed to perform/document corrective action for unsatisfactory cortisol proficiency performance. Findings include: a. Review of AAB proficiency testing reports, the laboratory had unsatisfactory proficiency performance for 2019 Q1 cortisol test (scored 60%). b. A testing person confirmed that the corrective action documentation for the above unsatisfactory cortisol proficiency testing was unavailable. c. The laboratory usually performs 2 to 3 patient cortisol tests per proficiency testing event.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory's quality control material(s) testing records and interview with a testing person (August 6, 2019, 9:15 A.M.), the laboratory failed to document control level 3 for the Free Triiodothyronine test (FT3) test. Findings inclulde: a. For the FT3 test, the laboratory daily runs three levels of control material. b. One of four patient sampled had the FT3 test performed (January 3, 2019). The FT3 quality control records for patient #1 showed quality control results for levels 1 and 2. There were no record of quality control level 3. c. A testing person asserted that all three quality control levels were run for with the above patient, but level 3 was not recorded.