Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0553139	**(X3) Date Survey Completed** 02/26/2018
Name of Provider or Supplier Greater Long Beach Genito Urinary Medical Group	**Street Address, City, State** 3650 South St Ste 408, Lakewood, 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**
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 review of laboratory documents for PSA calibrations and calibration verifications for the Tosoh analyzer, and patients PSA test records; and interview with the Technical Consultant, the laboratory failed to perform calibration verification procedures using the type of materials established by the laboratory and at least once every 6 months. Findings include: a. Laboratory records for PSA calibrations and calibration verifications (Linearity) documented the lot numbers of calibrators used,

	as follows: Date Calibration Calibration verification Lot # Lot # ---------- 2/17/16 ... . 28 -- 2/22/16 ... . 28 -- 4/08/16 ... . -- 28 6/03/16 ... . 33 -- 6/29/16 ... . 38 -- 1/06/17 ... . 38 -- 1/09 /17 ... . 40 -- 4/19/17 ... . 57 -- 8/01/17 ... . 66 -- 8/11/17 ... . -- 66 12/04/17 ... . 75 -- 2/09/18 ... . 79 -- 2/16/18 ... . -- 79 b. The Technical Consultant affirmed (2/26/18) that only two Calibrators were used to calibrate PSA and that the laboratory policy and procedure established for performing calibration verification utilizes a "past lot (number) of Calibrators"; and that the aforementioned records revealed that current lot numbers of calibrators had been used instead. c. The Technical Consultant affirmed (2/26/18) the aforementioned dates that calibration verifications were performed, and that none were performed at least once every 6 months between April 2016 to August 2017. d. The reliability and quality of PSA results reported could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 2,500 PSA results each year. A few examples are as follows: Date number of results reported ---------- 1/20/16 20 10 /19/16 10 11/22/16 53 1/26/17 19 4/24/17 26 6/16/17 30 8/23/17 33 1/10/18 12 2/12 /18 24 .
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 review of patients test records, the lack of laboratory documents, and interview with the Technical Consultant, the laboratory failed to monitor the results of quality control materials over time to assess the accuracy and precision of PSA and Testosterone testing and identify any analytic shifts or trends. Findings include: a. The laboratory was unable to provide for review (Levy-Jennings) documents monitoring QC results over time to identify shifts or trends. b. The Technical Consultant affirmed (2/26/18) the failure to monitor QC results over time to identify shifts or trends. c. The reliability and quality of results reported for PSA and Testosterone could not be assured. Based on the stated estimated annual tests volumes, the laboratory reported approximately 2,500 PSA results and 2,100 Testosterone results each year for 2016 - 2018.