Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0702479	03/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Unilab Corporation	6985 Arlington Ave, Ste A, Riverside, 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 observation of the Siemens ADVIA Centaur and Siemens Dimension analyzers, review of laboratory records for verifying instrument calibrations, the lack of laboratory records, and interview with the Technical Consultant (Testing Person-1), it was determined that the laboratory failed to verify calibrations at least once every 6 months. Findings included: a. Laboratory records revealed calibrations were verified as follows: ADVIA Centaur: 4/26/17 * 11/14/17 * 6/04/18 12/05/18

	---------- Dimension: 12/16/16 * 7/18/17 1/09/18 7/16/18 1/08 /19 b. The laboratory was unable to provide for review records verifying calibrations within 6 months of April 2017, November 2017, and December 2016 (*). c. The Technical Consultant/ Testing Person-1 affirmed (2/26/19 at 3pm) the aforementioned lack of records; and thus the failure to verify calibrations at least once every 6 months. d. The reliability and quality of results reported could not be assured for Comprehensive Metabolic Panel (chemistry) during October 2017 and May 2018, and quatitative B-hCG (pregnancy) during June 2017. Based on the stated estimated annual tests volumes (2/12/19), for each month the laboratory reported approximately 3,500 chemistry results and approimately 100 pregnancy results.