Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2084641	08/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma, Inc	5398 Northfield Road, Maple Heights, OH	

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: REPEAT Based on record review and interviews with the Quality Assurance Manager (QAM), and the Field Quality Manager (FQM), the laboratory failed to perform refractometer calibration verification testing procedures with control materials of a different lot number than those routinely used for daily quality control testing procedures. Findings Include: 1. Review of the laboratory's "Calibration Verification" policy and procedure, provided on the date of the inspection, found calibration

	verification instructions to utilize "Refractrol Abnormal, Normal and High Serum Protein Reference Control...a low value, a mid-point value, and a maximum value near the upper limit of the range...for new equipment and equipment returned from repair." 2. Review of the laboratory's 2018 calibration verification and QC documentation revealed the same QC lot numbers that were performed for daily QC procedures were utilized for the calibration verification procedures as listed below: QC level Lot number Expiration Date Normal K301818 07/31/2019 Abnormal K301008 08/31/2018 4. The QAM and the FQM confirmed the laboratory conducted calibration verification procedures with the same lot numbers of two levels of QC material utilized for daily QC testing procedures and were aware a QC lot number different from the lot number routinely utilized for daily QC testing was required. The interviews occurred on 08/28/2018 at 11:33 AM.