Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2097028	03/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Octapharma Plasma, Inc	83-B Great Southern Blvd, Columbus, 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 Supervisor (QAS), and the Assistant Center Manager (ACM), 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. This deficiency could affect 54,773 patients. 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 two out of two of the laboratory's 2018 calibration verification and QC documentation records revealed the same QC lot numbers used for daily QC procedures were utilized for the calibration verification procedures as listed below: QC level Lot number Expiration Date Calibration Dates Calibration Verification Date Normal K302383 07/2020 03/28 /2018 - 04/07/2018 04/15/2018 Normal K303248 04/2021 11/05/2018 - 11/15/2018 11 /13/2018 4. The QAS, and the ACM confirmed the laboratory conducted equipment performance calibration verification procedures as well as the daily routine QC procedures with the same lot numbers of QC material that were also utilized for daily QC testing procedures and WERE AWARE that a QC lot number different from the lot number routinely utilized for daily QC testing was required. The interviews occurred on 03/04/2019 at 9:30 AM.