

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2136874	(X3) Date Survey Completed 05/01/2018
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 1543 S Hawkins Avenue, Akron, 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	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Quality Assurance Supervisor (QAS), the Center Manager (CM) 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. Findings Include: 1. Review of the laboratory's "Calibration Verification" policy and procedure, provided on the date of the inspection, found</p>

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	K302383	07/31/2020
Abnormal	K301822	11/30/2019

3. Further review of the laboratory's 2018 calibration verification and QC documentation found two out of three QC levels (Normal and Abnormal) were used from 02/09/2018 to 04/04/2018 on seven out of seven of the laboratory's refractometers for new equipment performance calibration verification procedures dated 02/09/18, 02/28/18 and 03/14/18 as well as for the daily routine QC procedures. 4. The QAS, CM and the ACM confirmed the laboratory conducted new equipment performance calibration verification procedures dated 02/09/18, 02/28/18 and 03/14/18 as well as the daily routine QC procedures with the same lot numbers of two levels of QC material that were also utilized for daily QC testing procedures and were unaware that a QC lot number different from the lot number routinely utilized for daily QC testing was required. The interviews occurred on 05/01/2018 at 3:10 PM.