

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2189774	(X3) Date Survey Completed 01/04/2023
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 1042 Patterson Rd, Dayton, 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 reviews and an interview with the Center Director (CD), the laboratory failed to perform refractometer calibration verification testing procedures with control materials of a different lot number other than those routinely used for daily quality control testing procedures. This deficient practice had the potential to affect 28,000 patients tested in the specialty of Chemistry from 01/04/2022 through 01/04/2023. Findings Include: 1. Review of the laboratory's "Refractometer Semi-</p>

Annual Equipment Comparison" policy and procedure, provided via electronic mail on 01/12/2023 at 12:06 PM by the Quality Assurance Supervisor, found no mention of calibration verification testing procedures with control materials of a different lot number other than those routinely used for daily quality control testing procedures. 2. Review of calibration verification quality control data sheets found a lot number of K304913 used for the calibration control "normal" level solution on the following dates: 06/08/2022 01/07/2022 01/19/2022 12/10/2021 12/09/2021 3. Review of competency assessment sheets for total protein testing found a lot number of K304913 used for the quality control "normal" level solution on the following dates: 06/11/2022 06/13/2022 12/11/2021 12/15/2021 4. The CD confirmed the laboratory conducted calibration verification procedures and daily total protein test quality controls using the same lot number of a "normal" solution level. The interview occurred on 01/04/2023 at 11:33 AM.