

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2104714	(X3) Date Survey Completed 04/14/2022
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 5943 South Boulevard, Charlotte, NC	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2019, 2020, 2021, and 2022 AAB(American Association of Bioanalysts) PT(proficiency testing) records and the absence of records, review of PT CA(corrective action) documentation, and staff interview 4/14/22, the laboratory failed to maintain all PT records and failed to ensure the LD(laboratory director) and TP(testing personnel) signed the attestation statements for 7 of 7 testing events in 2020, 2021, and 2022. Findings: Review of the laboratory's Proficiency testing policy revealed, "...5.7 Complete online submission of proficiency testing results. 5.7.1 Review proficiency testing results submission form(s) for completeness. Note: Original proficiency test results submission form(s) will be completed, signed, and retained as original documentation....5.7.5 Log on to report results...5.7.8 Follow instructions to enter: 5.7.8.1: Results for all five(5) test samples. 5.7.8.2 Reagent code. 5.7.8.3 Instrument code. 5.7.9. Print results for donor center records...5.7.10. Analyst reviews documents procedure, signs and dates submission form. 5.7.11 CLIA Director reviews, signs and dates submission form. 5.7.12 Ensure results sheet printout includes the following</p>

information. Add information as necessary: 5.7.12.1. Donor Center name and address. 5.7.12.2. Quadrimester and year. 5.7.12.3. Proficiency testing result(s)...." 1. Review of 2019, 2020, 2021, and 2022 PT records revealed the laboratory failed to maintain all documentation and failed to ensure the LD and TP signed the attestation statements for the following AAB test events. CA documentation(deviation) on file revealed an investigation was completed on April 13, 2022, the day before the survey. a. 2020 Q1 test event: No submission form, no original data sheet(result form), no attestation signed by the LD and TP; b. 2020 Q2 test event: No submission form, and no attestation signed by the LD and TP. CA documentation revealed there was no method code documented and instrument code was incorrect; c. 2020 Q3 test event: No original data sheet(result form), no attestation signed by the LD and TP. CA documentation revealed the center was able to obtain the submission form from the AAB website. d. 2021 Q1 test event: No original data sheet(result form) and no attestation signed by the LD and TP. CA documentation revealed there was no method code documented and instrument code was incorrect; e. 2021 Q2 test event: No attestation signed by the LD and TP. CA documentation revealed there was no method code documented and instrument code was incorrect; f. 2021 Q3 test event: No submission form, no page one of original data sheet(result form), no attestation signed by the LD and TP; g. 2022 Q1 test event: No attestation signed by the LD and TP. At approximately 9:30 a.m., the QA(Quality Assurance) Supervisor stated the previous QA supervisor failed to follow the PT procedure. She confirmed a retrospective review revealed items that were not on file and that the investigation was just completed on 4/13/22.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of personnel competency records and staff interview 4/14/22, the technical consultant(laboratory director) failed to perform the annual competency for 1 of 17 TP(testing personnel # 17) in 2021. Findings: Review of personnel competency records revealed TP #17 had a competency assessment performed in 2019 and 2020, but the annual competency was not completed when due in 2021, and had not been completed at time of survey, a period of approximately 20 months since the last competency assessment was performed in August 2020. At approximately 11: 50 a.m., the assistant manager confirmed there was no moderate annual competency on file for TP #17 in 2021.