

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2120214	(X3) Date Survey Completed 01/08/2020
Name of Provider or Supplier Octapharma Plasma Inc	Street Address, City, State 16845 Torrence Ave, Lansing, IL	
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor review of CASPER Report 155 Proficiency Testing (PT) records, and communications with the Proficiency Testing American Association of Bioanalysts (AAB) program personnel; this laboratory failed to successfully participate in the testing of PT samples for Routine Chemistry and Total Protein during events 2 and 3 of 2019. Findings include: Review of CASPER Report 155 and communication with the (AAB) PT provider on 01/08/19 at 10:08 AM, confirmed the initial unsuccessful PT performance under the specialty of Chemistry for PT events 2 and 3 of 2019. See D-2096.

D2096**ROUTINE CHEMISTRY**

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on surveyor review of CASPER Report 155 Proficiency Testing (PT) records, and communications with the Proficiency Testing American Association of Bioanalysts (AAB) program personnel; this laboratory failed to successfully participate in the testing of PT samples for Routine Chemistry and Total Protein during events 2 and 3 of 2019. Findings include: 1. Review of the CASPER Report 155 on 01/06/2019 at 8:15 AM, revealed that the initial unsuccessful PT performance was under the specialty of Chemistry as listed below. CHEMISTRY Routine Chemistry - EVENT-2, 2019 = 0% Unsat Routine Chemistry - EVENT-3, 2019 = 0% Unsat Total Protein - EVENT-2, 2019 = 0% Unsat Total Protein - EVENT-2, 2019 = 0% Unsat 2. During a phone communication with the (AAB) PT vendor on 01/08/19 at 10:08 AM, confirmed the failing scores under the specialty of Chemistry for PT events 1 and 2 of 2019.