

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2132947	(X3) Date Survey Completed 05/23/2018
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 2930 Sw 59th St, Oklahoma City, OK	
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
D0000	The findings were reviewed with the QA Supervisor by phone after the conclusion of the survey.
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, interview with the quality assurance supervisor, and consultation with the proficiency testing program customer support, the laboratory failed to ensure the proficiency testing program released all data to CMS and to the State Agency for 2017 and 2018. Findings include: (1) Prior to the survey, the surveyor printed the facility's proficiency testing scores for review from the Federal database on 05/21/2018. The scores for 2017 and 2018 did not print. Therefore, it appeared that the laboratory did not participate in proficiency testing; (2) At the survey, the surveyor asked the quality assurance supervisor when the laboratory began patient total protein testing using the Reichert TS Meter DSP. The quality assurance supervisor stated to the surveyor that patient testing began on 09/20/17; (3) The surveyor then asked the quality assurance supervisor about the proficiency testing. The quality assurance supervisor explained that for 2017, the laboratory performed an off-cycle testing event. The surveyor reviewed the proficiency testing records, which verified the laboratory participated in proficiency testing for the off-cycle event on 10/17/17 and for the first 2018 event on 01/31/18; (4) The surveyor asked the quality assurance supervisor if the laboratory had authorized the proficiency testing program to release its scores to CMS and to the State Agency. The quality assurance supervisor contacted the facility's corporate office via email. The corporate office emailed a copy</p>

of the "2018 Order Confirmation" form. Although the proficiency testing order form included the note, "Results to be sent to CLIA/State," the laboratory's CLIA number was not included on the order confirmation form; (5) After the survey, the surveyor contacted the proficiency testing program customer support, who verified the proficiency testing confirmation form would include the laboratory's CLIA number if it had been provided to the proficiency testing program and the scores would only be released to CMS and to the State Agency if the laboratory's CLIA number had been provided; (6) The surveyor contacted the quality assurance supervisor for the laboratory and explained in order for the proficiency testing program to provide testing scores to CMS and to the State Agency, the laboratory's CLIA number must be provided to the proficiency testing program.