

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2081927	(X3) Date Survey Completed 02/10/2021
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 401 East 13 Mile Rd, Madison Heights, MI	
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
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by:</p> <ul style="list-style-type: none"> . Based on record review and interview with the Quality Manager, the Technical Supervisor failed to evaluate and document competency at least semiannually in the first year of testing for 1 (Testing Personnel #5) of 16 testing personnel listed on the CMS-209 form. Findings include: 1. A review of personnel records revealed Testing Personnel #5 revealed their initial competency assessment was completed in December 2019 and their annual competency assessment was performed in November 2020. 2. The surveyor requested documentation of the semiannual competency assessment for Testing Personnel #5 on 2/10/21 at and it was not made available. 3. Email correspondence on 2/10/21 with the Quality Manager confirmed the laboratory did not have documentation of the semiannual competency assessment for Testing Personnel #5.