

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2176184	(X3) Date Survey Completed 12/22/2020
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 5225 Bay Road, Saginaw, 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: . Based on record review and interview with the center manager, the Technical Consultant (TC) failed to evaluate the performance of testing personnel at least semiannually during the first year for 1 (Testing Personnel (TP) #1) of 19 testing personnel. Findings include: 1. An interview on 12/22/2020 at approximately 9:30 am the center manager revealed the laboratory initially started testing January 28, 2020. 2. A review of testing personnel competency assessments revealed for 1 (TP1) of 19 TP, lack of documentation for a semi-annual performance evaluation during the first year of transferring from another plasma center location. 3. Review of the "CLIA Personnel Reference Guide" policy revealed on page 7-8 "Specific training for Testing Personnel" states, "If an employee transfers from one center location to another approval from the technical consultant at the new location must be obtained by completing a new Technical Consultant Observation Worksheet prior to the employee performing regulated testing, at six and twelve months following the transfer and annually thereafter." 4. During the exit interview on 12/22/2020 at 11:35 am, the center manager confirmed the testing personnel above did not have a semiannual performance evaluation.</p>