

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2136878	<b>(X3) Date Survey Completed</b>  05/09/2019
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  2093 Elm Road Ne, Warren, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6053</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> 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 interviews with the Center Manager (CM), Associate Director of Operations and Quality (ADOQ), Quality Specialist (QS) #1, QS#2 and testing personnel (TP) #4, the Technical Consultant (TC) failed to evaluate and document the competency of TP#10 and TP#13 who were responsible for moderate complexity total protein testing procedures at least semiannually during the first year the individuals tested patient specimens. All patients tested by TP#10 and TP#13 in 2018 and 2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 05/09/2019, revealed seven out of 17 individuals listed and credentialed as TP who had performed patient total protein testing procedures since the facility opened on 10/25/2017. 2. Review of the laboratory's "CLIA Oversight" policy and procedure, provided on the date of the inspection, approved, signed and dated by the Laboratory Director, revealed the following "Direct Observation and Assessment of Testing Personnel" competency assessment instruction: "Testing personnel have completed initial training with designated trainer or are due for 6 month or annual approval." 3. Review of two out of seven of the laboratory's 2018 and 2019 semiannual competency assessment records, provided on the date of the inspection, did not find any record that a 12 month (the second semiannual) competency assessment was conducted on TP#10 and TP#13 during their first year of testing patient specimens. 4. The Inspector requested the laboratory's 2018 and 2019 12 month (the second semiannual) competency assessment records for TP#10 and TP#13 from the CM, ADOQ, QS#1, QS#2 and</p>

TP#4. The CM, ADOQ, QS#1, QS#2 and TP#4 confirmed that the laboratory did not follow their written policy and procedure, misunderstood the "semiannual" regulation interpretation, did not assess the second semiannual competency of new TP during the first year of testing patient specimens, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 05/09/2019 at 4:15 PM.