

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 25D2078026	<b>(X3) Date Survey Completed</b> 11/23/2020
<b>Name of Provider or Supplier</b> Csl Plasma, Inc	<b>Street Address, City, State</b> 9245 Highway 49, Gulfport, MS	
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>D6033</b>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the personnel records and the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to have a technical consultant who meets the qualification requirements of 493.1411 of this subpart. Findings include: Review of the CMS 209 personnel form revealed no technical consultant listed. Review of the laboratory's personnel records revealed the laboratory director does not meet the qualification requirements of 493.1411 of this subpart. Refer to D6049 (Lack of review of quality control records by a qualified technical consultant). Refer to D6053 (Lack of semiannual evaluation of personnel by a qualified technical consultant). Refer to D6054 (Lack of annual evaluation of personnel by a qualified technical consultant).</p>
<b>D6049</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on review of documentation of monthly review of quality control records, to include calibration verification records, since the last survey on 4-12-18, a qualified</p>

technical consultant failed to document review of these records since 9-4-19. Findings include: Review of documentation of monthly review of quality control records of total protein testing on eight Reichert refractometers, to include calibration verification records, since the last survey on 4-12-18, revealed no documentation of review of these records by a qualified technical consultant since 9-4-19.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

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.

This STANDARD is not met as evidenced by:  
Based on review of the personnel records and the CMS 209 personnel form, a qualified technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year these individuals tested patient specimens. Findings include: Review of the personnel records and the CMS 209 personnel form revealed a qualified technical consultant failed to evaluate and document the performance of the following testing personnel, responsible for moderate complexity testing, at least semiannually during the first year these individuals performed patient total protein testing: Testing Personnel #3, #14, #15, #16, #24, #26, #28, #29.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on review of the personnel records and the CMS 209 personnel form, a qualified technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year these individuals performed patient total protein testing. Findings include: Review of the personnel records and the CMS 209 personnel form revealed a qualified technical consultant failed to evaluate and document the performance of the following testing personnel, responsible for moderate complexity testing, at least annually, after September 2019: Testing Personnel #1, #2, #4, #5, #6, #7, #9, #10, #11, #12, #14, #15, #16, #18, #19, #20, #21, #23, #25.