

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2110204	(X3) Date Survey Completed 09/24/2019
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 1600 S Water Street, Kent, OH	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Center Manager (CM) and the Quality Assurance Assistant Manager (QAAM), the Laboratory Director failed to attest to the routine integration of total protein proficiency testing (PT) samples into the patient workload using the laboratory's routine methods for three out of three PT events in 2018 and two out of two PT events in 2019. All patient total protein testing had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Lab Director/Technical Consultant Shared Task Performance Guide", provided on the date of the inspection, found the following statement: "Attestation statement at initial testing signed by LD/TC and results received from testing agency reviewed and signed by LD/TC." LD; Laboratory Director TC; Technical Consultant 2. Review of the laboratory's "Technical Consultant Qualification and Responsibilities" acknowledgement page, signed and dated by the Laboratory Director and the TC on 07/30/2018, did not find any mention of the delegation of Laboratory Director PT attestation to the TC. 3. Review of the laboratory's 2018 and 2019 American Association of Bioanalysts (AAB) PT event attestation forms did not find the Laboratory Director's attestation via signature and date, however revealed TC signatures as indicated below: 2018 Chemistry Q1 TC no longer employed Chemistry Q2 TC no longer employed Chemistry Q3 TC no longer employed 2019 Chemistry Q1 TC/TP#1 Chemistry Q2 TC/TP#1 TP; testing personnel 4. The Inspector requested the Laboratory Director's letter delegating the PT attestation as the Laboratory Director to a qualified TC from the CM and the QAAM. The CM and the QAAM mentioned they believed the bullet point statement</p>

"Monitor the completion and results of Proficiency Testing." that is on the "Technical Consultant Qualification and Responsibilities" acknowledgement page covered the Laboratory Director PT attestation delegation to the TC and confirmed the Laboratory Director did not specifically delegate this responsibility to the TC in any other written document and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 09/24/2019 at 10:35 AM.