

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2064762	<b>(X3) Date Survey Completed</b>  01/21/2021
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  1283 Columbia Drive, Decatur, GA	
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>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 22, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual (SOP) and staff interview, the laboratory failed to follow written policies and procedures as required. Findings include: 1. SOP review revealed the laboratory did not follow the established competency policy and procedure for four (4) of the twelve (12) moderate complexity testing personnel (TP) annual competencies performed in 2019. 2. An interview with the Assistant Quality Manager on 1/21/2021 in a conference room at approximately 11:30 a.m. confirmed the established annual TP competency policy and procedure was not followed for the evaluation of aforementioned TP in 2019..</p>
<b>D6054</b>	<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 annually, after the first year.</p>

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the technical consultant (TC) failed to perform and document annual competencies for moderate complexity TP after the first year as required. Findings include: 1. TP competency document review revealed 2019 annual competency documents were not available at the time of survey for the following TP (CMS 209 - page 1 of 2): TP #9, TP #11, and TP #12; for (CMS 209 - page 2 of 2): TP #9. 2. An interview with the Assistant Quality Manager in a conference room on 1/21/2021 at approximately 11:00 a.m. confirmed the aforementioned lack of TP annual competency documents at the time of survey.