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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 41D2137808 | (X3) Date Survey Completed 04/27/2022 |
| Name of Provider or Supplier Csl Plasma, Inc | Street Address, City, State 1775 Bald Hill Road, Warwick, RI | |
| 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 |
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| D2007 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to test proficiency testing (PT) samples in the same manner as routine patient samples by testing personnel (TP) who routinely perform the testing in the specialty of Chemistry. Findings include: 1. Record review on 4/27/2022 of the American Association of Bioanalysts (AAB) 2020 and 2021 Chemistry PT records revealed: a. 3 TP did not participate in PT in 2020 and 2021. b. 8 of 11 TP employed in 2021 did not participate in PT. 2. Staff interview with the Associate Director of Operations and Quality (ADOQ) on 4/27/2022 at 10:15 AM confirmed the above findings. The ADOQ stated, a. "It was easier to have a senior TP do the PT testing because they were familiar with PT." b. "I was not aware that PT events can be split amongst several TP." 3. The laboratory performs 30,000 Chemistry tests annually.</p> |