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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 37D0470270 | (X3) Date Survey Completed 01/18/2022 |
| Name of Provider or Supplier Csl Plasma, Inc | Street Address, City, State 716 Nw 23rd, Oklahoma City, OK | |
| 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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| D0000 | The recertification survey was performed on 01/18/2022. The findings were reviewed with the associate of operations and quality, assistant manager of quality, and assistant center manager during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with a standard-level deficiency cited. |
| D5211 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the assistant center manager and the assistant manager of quality, the laboratory failed to review and evaluate proficiency testing results for one of six events. Findings include: (1) On 01/18/2022, the surveyor reviewed 2020 and 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2021 Chemistry Q2 Event (i) Total Protein - five of five results exhibited a positive bias (aa) Sample 6 - SDI of 2.4 (bb) Sample 7 - SDI of 3.1 (cc) Sample 8 - SDI of 4.6 (dd) Sample 9 - SDI of 3.4 (ee) Sample 10 - SDI of 2.5 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the assistant center manager and the assistant manager of quality. The assistant manager of quality stated on 01/18/2022 at 12:20 pm the biases had not been addressed.</p> |