

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2123107	(X3) Date Survey Completed 09/08/2022
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 1655 S College St Suite C, Auburn, AL	
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
D2093	<p>ROUTINE CHEMISTRY CFR(s): 493.841(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and an interview with the Assistant Manager of Quality, the laboratory failed to submit results within the timeframe specified by the proficiency testing provider. This was noted for one out of ten 2019 to 2022 AAB PT events. The findings include: 1. A review of the AAB PT records revealed the testing personnel performed the Total Protein testing for the AAB 2020-Q1 survey on 2/18/2020, however the laboratory received a score of zero percent due to "Failure to Participate". 2. During an interview on 9/8/2022, at 10:00 AM, the Assistant Manager of Quality confirmed the laboratory failed to submit results to AAB by the due date, and stated the Quality personnel did not fully understand the electronic submission procedure, and needed retraining. .</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and an interview with the Assistant Manager of Quality, the laboratory failed to perform an internal self-evaluation of Total Protein results after</p>

the laboratory missed the submission deadline specified by the proficiency testing provider. This was noted for one out of ten 2019 to 2022 AAB PT events. The findings include: 1. A review of the AAB PT records revealed the laboratory received a score of zero percent due to "Failure to Participate" on Total Protein testing on the AAB 2020-Q1 survey. 2. During an interview on 9/8/2022, at 10:00 AM, the surveyor confirmed the laboratory's failure to submit results to AAB by the due date, and then asked if the laboratory had performed an internal self-evaluation of Total Protein results after AAB had released the scores and acceptable ranges. The Assistant Manager of Quality reviewed the Quality Assurance (Trackwise) report, and stated, "It's not mentioned in the Trackwise record, No". SURVEYOR ID #32558 Licensure and Certification Surveyor