Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2165807	10/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma, Inc	3459 Peach Orchard Road, Augusta, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 7, 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and interview with the Quality Team, the laboratory testing personnel failed to sign the attestation form. The Findings include: 1. Review of PT records(American Associates of Bioanalysts) revealed the laboratory testing personnel failed to sign the attestation form for Chemistry Q1 in 2020. 2. During an interview with the Quality Team on October 7, 2021 at approximately 3:15 PM, in their conference room, confirmed that the testing personnel failed to sign the attestation form.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on laboratory records review and interview with the Quality Team, the laboratory failed to establish a written quality assessment plan (QA) to monitor, assess, and correct problems in the general laboratory. The laboratory did not have a written quality assessment policy that encompasses all of the laboratory's technical and non-technical functions. The Findings include: 1. The laboratory failed to have a QA plan to assess specimen identification and integrity, complaint investigations, personal competency, proficiency testing performance, and corrective action. 2. The laboratory failed to have a QA checklist to assess technical and non-technical functions for the overall laboratory functions. 3. During an interview with the Quality Team on October 7, 2021, at 3:30 PM in their conference room, confirmed that the laboratory did not have a written and established QA policy for the laboratory.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) records and staff interview, the Laboratory Director (LD) failed to acknowledge the the analyst signature was not present on the attestation form. The Findings include: 1. Review of PT(American Association of Bioanalysts) records revealed that the LD failed to acknowledge the analyst signature was not present on the attestation form for Chemistry Q1 2020. 2. During an interview with the Quality Team on October 7, 2021 at approximately 3:05 PM, in their conference room, confirmed that the LD did not acknowledge a signature from the analyst on the attestation form.