Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2126535	06/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma, Inc	2150 Riverside Parkway, Lawrenceville, 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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on June 08, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of reference laboratory test reports, inhouse laboratory test reports, and staff interview, the reference laboratory test reports and inhouse test reports failed to include the required identification information. Findings include: 1. Review of reference laboratory test reports and inhouse test reports for 2018 revealed the facilities failed include the complete address of the laboratory location where the test was performed. 2. An interview with the Center Manager in a conference room on 6/6 /2018 at approximately 2 pm confirmed the inhouse and reference laboratory test reports did not include the complete laboratory address where the test was performed.
D5807	TEST REPORT CFR(s): 493.1291(d)

	Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of inhouse and reference laboratory test reports, the laboratory failed to include reference ranges or normal values on the test report as required.. Findings include: 1. Review of inhouse and reference laboratory test reports for 2018 revealed the laboratory failed to include reference ranges or normal values on the test reports. 2. An interview with the Center Manager in a conference room on 6/8/2018 at approximately 2 p.m. confirmed the inhouse and reference laboratory test reports did not include reference ranges or normal values.