Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2134446	01/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Csl Plasma, Inc	3800 E State St, Rockford, IL	

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
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel records and laboratory records, the laboratory did not have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. Findings: 1. Review of personnel records revealed that there was no documentation to show that the laboratory director is qualified to director moderate complexity tests and testing personnel. See D tag 6003. 2. Review of laboratory records revealed that the laboratory director did not ensure verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. See D tag 6013 3. The laboratory director did not specify in writing the responsibilities and duties of the technical consultant. See D tag 6032
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American

	Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: Based on review of personnel records and interview, there was no documentation to show that the laboratory director is qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests. Findings: 1. Review of personnel records for the laboratory director revealed that a document titled, "Laboratory Director Qualification and Responsibilities" was used when qualifying the laboratory director. The document indicates that the laboratory director is a MD, DO, DPM with a license to practice medicine in the state in which the laboratory is located and, beginning September 1, 1993, has at least 20 continuing medical education (CME) credit hours in laboratory practice or laboratory training equivalent to 20 CMEs. 2. The laboratory submitted a letter from COLA as evidence of the 20 CMEs. The last paragraph of the letter reads, "Enclosed are your Certificates of Completion for the Lab Director Program from LabUniversity. However, when the surveyor asked for the actual Certificates of Completion, none was submitted to her. 3. During survey date 01/10/18 at 12:00 PM, the Assitant Manager of Quality confirmed the surveyor's findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on review of procedures manuals; laboratory records; and interview, the laboratory director failed to be responsible for ensuring that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. Findings: 1. Review of the laboratory's validation procedures for their digital refractometer revealed that there was a procedure titled, "New Center Normal Reference Interval (NRI) Establishment. It states, "As part of the completion of the initial validation the Lab Director or Technical Consultant will utilize a published Total Protein NRI such as Stedman Laboratory Reference Range Values to review the Refractrol Assay Sheets and determine if the manufactures control ranges includes the entire NRI range. 2. Review of laboratory records revealed that the following statement is at the bottom of the validation record: "I have reviewed the Refractrol Assay Sheets and verified the manufacturer's ranges against the published NRI and have determined the controls used for validation are suitable." After this statement, there is a space for the lab director's and/or technical consultant signature. Neither the laboratory director nor the technical consultant has signed and approved the validation of the laboratory's test method. 3. During survey date 01/10/18 at 12:00 PM, the Assistant Manager of Quality confirmed the surveyor' findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview, the laboratory director failed to spedify, in writing, the responsibilities and duties of the technical consultant. Findings: 1. Review of personnel records revealed that the responsibilities and duties of the Technical Consultant are delegated by the laboratory director. However, review of a document titled, "Technical Consultant Qualifications and Responsibilities," the current laboratory director did not sign and date the document. Someone other than the laboratory director for this laboratory location signed and dated on the line designated for the laboratory director. 2. During survey date 01/10/18 at 12:00 PM, the Assistant Manager of Quality confirmed the surveyor's findings.