

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 32D2183243	<b>(X3) Date Survey Completed</b> 03/02/2021
<b>Name of Provider or Supplier</b> Csl Plasma, Inc	<b>Street Address, City, State</b> 320 Wyatt Dr Suite B, Las Cruces, NM	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	During an initial survey completed on 03/02/2021 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following condition: 42 CFR Part 493.1411 Technical Consultant
<b>D6033</b>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the review of personnel records, CMS (Centers for Medicare &amp; Medicaid Services) Personnel Report Form 209, and email, the laboratory failed to have a qualified Technical Consultant. Findings are: The laboratory failed to have documentation of laboratory training/experience for the laboratory's Technical Consultants. See D 6035</p>
<b>D6035</b>	<p><b>TECHNICAL CONSULTANT QUALIFICATIONS</b> CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant 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</p>

in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on the review of personnel records, CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, and email, the laboratory failed to have documentation of laboratory training/experience for the laboratory's Technical Consultants (TC). Findings are: A. Review of the CMS Personnel Report Form 209 signed on 03/02/2021 by the Laboratory Director indicated the following: 1. The Laboratory Director also served as one of the laboratory's Technical Consultants. 2. A second person, TC#2, was also designated as a Technical Consultant. B. Review of the education, training and resume for the Laboratory Director failed to show any documentation of laboratory training for the specialty of Chemistry to meet the minimum qualification of one year. The laboratory's Assistant Manager for Quality provided a transcript for an internal Technical Consultant training called "Technical Consultant Learning Path" signed by the corporate office's quality team on 11/12/2020. The Assistant Manager for Quality also provided a copy of the curriculum (plan of study) for both the Laboratory Director and Technical Consultant responsibilities but no hands-on training or experience using the refractometer (a device used for measuring protein in a blood sample). C. Review of the personnel records for TC#2 indicated no specific documentation such as letters from previous employers, co-workers, or other records indicating her 2 year direct laboratory experience in Chemistry. D. Review of an email dated 03/03/2021 at 6:59 pm from the Assistant Manager of Quality indicated: "I wanted to follow up with you in regard to our Technical Consultants [TC#2] and [Laboratory Director] and their supporting documentation for the TC role. As of end of business day 3/3/21 we were unable to obtain the requested supporting documentation from previous employers, for both [TC#2] and [Laboratory Director]; however the process has been initiated for both individuals."