

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D2192339	<b>(X3) Date Survey Completed</b>  11/16/2022
<b>Name of Provider or Supplier</b>  Csl Plasma Inc	<b>Street Address, City, State</b>  3309 Caldwell Boulevard, Nampa, ID	
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>D6004</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory personnel educational documents and an interview with the center manager on 11/16/2022, the laboratory director failed to ensure that the laboratory employed a qualified technical consultant (TC). The findings included: 1. A review of the CMS 209 and laboratory personnel educational documents identified that the individual listed on the CMS 209 as the TC failed to have documentation of a qualifying diploma in chemical, physical, biological or medical laboratory science. 2. An interview with the center manager on 11/16/2022 at 9:15 am confirmed that the TC failed to have a qualifying diploma and has been performing TC responsibilities since March 2022. 3. The laboratory reports performing 31,373 total protein tests annually.</p>
<b>D6033</b>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPLEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification</p>

requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory personnel educational documents and an interview with the center manager on 11/16/2022 the laboratory failed to have a technical consultant who meets the educational qualification requirements of 493.1411 of this subpart. See D6035

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1411

(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 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 review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory personnel educational documents and an interview with the center manager on 11/16/2022, the individual identified as the technical consultant (TC) failed to meet the educational requirements as defined at 42 C.F.R.493.1411. The findings included: 1. A review of the CMS 209 identified a new TC since the

previous inspection on 5/25/2021. 2. A review of educational documents identified the individual listed on the CMS 209 as the TC failed to have documentation of a qualifying diploma in a chemical, physical, biological or medical laboratory science. 3. The individual identified as the TC has been performing in this capacity since March 2022. 4. An interview with the center manager on 11/16/2022 at 9:15 am confirmed the above findings. 5. The laboratory reports performing 31,373 total protein tests annually.