

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2117911	(X3) Date Survey Completed 05/13/2026
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 6014 Lewis Avenue, Toledo, OH	
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
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPLEXITY 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 record review and an interview with the Quality Assurance Manger, the laboratory failed to ensure Technical Consultant (TC) qualification requirements of 493.1411 of this subpart were met. This deficient practice had the potential to affect one out of one TC listed on the CMS-209. Findings Include: 1. The laboratory failed to ensure one out of one individual listed on the CMS-209 Personnel Report and qualified by the Laboratory Director (LD) met the TC minimum education requirements. (Refer to D6035)</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS 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 (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 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for</p>

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)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Quality Assurance Manager, the laboratory failed to ensure the Technical Consultant (TC) met the minimum qualification requirements. This deficient practice had the potential to affect one out of one TC. Findings include: 1. Review of the CMS-209 Personnel Report, approved by the Laboratory Director (LD) by signature and date on 05/11/2026, found one individual qualified by the Laboratory Director to perform the regulatory responsibility of a TC in the speciality of Chemistry. 2. Review of the laboratory's "Technical Consultant Qualification and Responsibilities" delegation form, approval by the LD signature and date on 12/03/2025, found the following: "Technical Consultant Qualification and Responsibilities... ..Bachelor's Degree in a chemical, biological, clinical or medical laboratory science or medical technology..." 3. Review of the listed TC's education documents found a Bachelor's degree in Kinesiology, which does not meet the minimum education requirement for the regulatory role of TC. 4. On 05/13/2026 at 11:05 AM, the Quality Assurance manager confirmed that the laboratory failed to ensure that the TC met the minimum education qualification for the regulatory role.