

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1090437	<b>(X3) Date Survey Completed</b> 10/15/2024
<b>Name of Provider or Supplier</b> Csl Plasma Abilene	<b>Street Address, City, State</b> 3202-C N, First Street, Abilene, TX	
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>	Based on a recertification survey conducted 10/15/2025, the laboratory was found out of compliance with the CLIA regulations. The following condition not met was: D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; 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 review of the Center for Medicare and Medicaid (CMS) personnel form 209, laboratory personnel records, education records, delegation of duties, laboratory policy, and confirmed in interview, one of two technical consultants (TC) failed to have documentation that met the education qualifications required be delegated TC responsibilities since August 2023. (Refer to D6035)</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</p>

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 Center for Medicare and Medicaid (CMS) personnel form 209, laboratory personnel records, education records, delegation of duties, laboratory policy, and confirmed in interview, the technical consultant failed to have a United States degree equivalency for an education received at a foreign institution, for one of two technical consultants performing duties since August 2023. The findings included: 1. Review of the CMS laboratory personnel form 209, listed the following two technical consultants (TC): TC1 TC2 2. Review of laboratory personnel education records for TC2 included a Bachelor of Science in Medical Technology from a foreign institution. Surveyor asked for records of an evaluation of their credentials to determine the equivalency of their education to an education obtained in the United States, and none was provided. 3. Review of a laboratory delegation of duties signed by the laboratory director on 8/7/2023, listed the following responsibilities delegated to TC2: "Ensure test methodology have the capability of providing quality results. Review test and control data to ensure verification procedures are adequate to determine accuracy, precision and performance including the establishment and review of the center's normal reference interval. Observe laboratory personnel to ensure test methods are performed as required for accurate reliable results. Sign the attestation statements for efficiency testing reporting form; monitor the completion and results of proficiency testing. Ensure adequate analytical performance for the test system by reviewing the quarterly control procedures report. Ensure all necessary corrective actions are taken and documented when significant deviations occur. Ensure an approved procedure manual is available for any aspects of the testing process. Resolve technical problems and ensure corrective action is taken for deviations and the test system is functioning properly prior to reporting test results. Ensure, prior to testing, all personnel have the appropriate education, experience and training and have demonstrated they can perform testing operations reliably. Identify training needs and assure training approach is appropriate for the testing performed.

Evaluate the competency of testing personnel initially, at six months, at 12 months and annually thereafter or when test methodologies or instrumentation changes. Approved testing personnel to perform regulated tests independently." 4. Review of the laboratory document titled "Technical Consultant Qualification and Responsibilities" did not include the evaluation of degrees from foreign institutions to ensure the equivalency to a degree earned in the United States. 5. In an interview on 10/15/2024 at 09:48 hours, in the conference room, the center manager confirmed that TC2 did not have a foreign degree equivalency to verify the educational requirements for the role.