

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0862927	(X3) Date Survey Completed 02/05/2019
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 4977 Ayers Street Suite A, Corpus Christi, TX	
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
D0000	<p>Complaint investigation TX00301619 was substantiated. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY 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 laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of education to qualify the technical consultant to perform his duties. (refer to D6035) Key: CMS - Centers for Medicare and Medicaid Services</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</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 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 laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 1 technical consultants. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (approved and signed by the laboratory director on 02/05/2019) revealed the laboratory identified 33 testing personnel. 2. Between May 2018 and October 2018, testing personnel number 15 (as listed on the Form CMS 209) was performing testing personnel competency assessments. He performed the competency assessments on the following randomly reviewed testing persons: Testing Personnel 3 (as listed on Form CMS 209) Testing Personnel 6 (as listed on Form CMS 209) Testing Personnel 13 (as listed on Form CMS 209) Testing Personnel 14 (as listed on Form CMS 209) Testing Personnel 16 (as listed on Form CMS 209) Testing Personnel 27 (as listed on Form CMS 209) Testing Personnel 31 (as listed on Form CMS 209) 3. Based on review of the laboratory's "Technical Consultant Qualification and Responsibilities" it stated, "Bachelors in a chemical, physical, biological, clinical laboratory science, or medical technology and 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." The statement had a box to the right that was check-marked. 4. A review of the laboratory's personnel files for testing personnel 15

(as listed on Form CMS 209) revealed the technical consultant had a Bachelor of Science degree in Mathematics. 5. An interview with the Assistant Director of Quality on February 5, 2019 at 17:50 hours in the conference room confirmed the findings.
Key: CMS - Centers for Medicare and Medicaid Services