

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2140718	(X3) Date Survey Completed 10/17/2019
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 16950 Ella Blvd Suite 320, Houston, 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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: 493.1421 D6063 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were 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.
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's personnel records and staff interview it was revealed the laboratory failed to ensure testing personnel were qualified. Findings include: 1. The laboratory failed to have documentation of education for 2 of 33 testing personnel to qualify them to perform moderate complexity testing (refer to D6065).</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p>

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of education for 2 of 33 testing personnel to qualify them to perform moderate complexity testing. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 10/18/19) revealed 33 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for 2 of 33 testing personnel. The testing personnel missing the documentation of education: Testing Person #1 Testing Person #2 3. Further review of the laboratory's personnel records revealed that testing person #1 had documentation of a high school diploma from an organization called Adison High School. Adison High School as a fraudulent online high school whose accreditation was not recognized by the United States Department of Education. 4. The laboratory was asked to provide the documentation of education. No documentation was provided. 5. An interview with the Assistant Manager of Quality on 10/17/19 at 11:20 a.m. in the conference room, revealed the laboratory did not have the documentation of education for testing person #1 or testing person #2. This confirmed the above findings.