

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2096292	(X3) Date Survey Completed 05/16/2019
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 11430 E Freeway Suite 350, 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	<p>The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 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.</p>
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 Personnel Report, personnel records and staff interview, it was revealed that the 1 of 24 testing personnel did not have the appropriate education credentials and training required 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 review of personnel records and interview of laboratory personnel, it was revealed that the facility failed to ensure that prior to testing patients' specimens, all personnel had the appropriate education required to perform moderate complexity testing. Findings were: 1. A review of personnel records available at the time of the survey revealed that 1 of 22 testing personnel 7 (TP #7) had no documentation of education as proof of qualification as a moderate complexity testing person. 2. An interview of the quality manager in the office on 5/16/19 at 1000 hours, and following the facility representative's own review of the records, the above findings were confirmed. She acknowledged that the diploma was not from an accredited school and the testing person was unaware it was a fraud diploma.