

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0670194	(X3) Date Survey Completed 06/23/2021
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 5500 Central Avenue, Charlotte, NC	
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
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 review of personnel records 6/23/21 and the deficiency cited at D6065, the laboratory failed to verify that 1 of 38 testing personnel (TP # 18) met the minimum education requirements for performing moderate complexity testing.</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <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</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records, absence of documentation, and interview with</p>

the TC (Technical consultant) and Center Manager 6/23/21, the laboratory failed to verify that 1 of 38 testing personnel (TP # 18) met the minimum education requirements for performing moderate complexity testing. Findings: Review of personnel records revealed TP#18 had an Associates degree in Occupational Studies. There was no additional evidence to show the TP had earned an Associates degree in a chemical, physical or biological science or medical lab technology from an accredited institution. There was no other education documentation on file. At approximately 12pm, the TC and Center manager confirmed there was no other education documentation on file for TP#18.