

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2165452	(X3) Date Survey Completed 11/29/2021
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 843e N Parkway, Jackson, TN	
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
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Centers for Medicare and Medicaid Services (CMS) CLIA Application and Survey Summary Report (Casper Report 0096D), communication with the laboratory's proficiency testing (PT) provider and interview with the laboratory's assistant quality manager, the laboratory failed to ensure release of its' proficiency testing result to Health and Human Services (HHS) in 2019, 2020 and 2021. The findings include: 1. Observation of the laboratory on November 29, 2021 at 10 am revealed donor testing for total protein and hematocrit. 2. Review of the Casper Report 0096D revealed no proficiency testing scores. 3. Email communication with the laboratory's PT provider on November 29, 2021 at 12: 13 pm revealed the PT program did not have a CLIA number on file for the laboratory. 4. Interview with the assistant quality manager on November 29, 2021 at 3: 00 pm confirmed the laboratory failed to release the results of its' proficiency testing scores to HHS in 2019, 2020, and 2021.</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>

This CONDITION is not met as evidenced by:
The laboratory director failed to have the required training or experience for performing technical consultant duties. (Refer to D6034)

D6034

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of laboratory personnel records and interview with the assistant quality manager, the laboratory director failed have the required experience to perform technical consultant duties in 2020 and 2021. The findings include: 1. Observation of the laboratory on November 29, 2021 at approximately 10am revealed donor testing for moderately complex total protein. 2. Review of personnel records revealed a job description for the laboratory director for the additional duty of technical consultant. The document was signed on 03/21/20. There was no evidence in the personnel records that the laboratory director had laboratory training or experience in the specialty of chemistry. 3. Interview with the laboratory assistant quality manager on November 29, 2021 at approximately 3:00 pm confirmed there was no documentation the laboratory director had laboratory training or experience in chemistry. The laboratory director began performing technical consultant duties around March 2020 until current survey date.