

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2166795	(X3) Date Survey Completed 08/21/2023
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 5370 Allentown Pike, Temple, PA	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review and interview with the office manager, the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which Total Protein testing was performed from 07/28/2021 to the date of the survey. Findings include: 1. The PA regulations (5.23 (b)(1)) states: "A general supervisor who meets all the requirements of subsection (a) (1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. The laboratory performs patient testing Monday through Sunday according to the information in the CMS-116 form (Saturday and Sunday 08:00 to 15:00 and Monday to Friday 07:00 to 19:00). 3. A review of the CMS-209 form on 08/21/2023 showed that the laboratory director acts as the only Clinical Consultant and Technical Consultant for the laboratory. The director directs 3 other laboratories and has an exception to the 5.22 form signed. 4. On the day of the survey, 08/21/2023 at 11:33 am, during an interview, the office manager stated that the laboratory did not have a qualified supervisor onsite for every hour of patient testing.</p>