

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2173678	<b>(X3) Date Survey Completed</b>  10/26/2023
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc - State College	<b>Street Address, City, State</b>  265 Northland Center, State College, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3009</b>	<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 record review and interview with the Office Manager (OM), 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 11/09/2021 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 07:00 to 15:00 and Monday to Friday 07:00 to 19:00). 3. A review of the CMS-209 form on 10/26/2023 revealed that a qualified general supervisor was not on-site during all hours of patient testing from 11/09/2021 to the day of the survey. 4. On the day of the survey, 10/26/2023 at 11:33 AM, during an interview, the OM stated that the laboratory did not have a qualified supervisor onsite for every hour of patient testing.</p>