

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2173681	<b>(X3) Date Survey Completed</b>  11/13/2023
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  3470 William Penn Hwy, Pittsburgh, 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 review of the laboratory personnel report (PA state) record, application for Approval To Direct More Than Two Laboratories (Exception to Section 5.22(f)) form and interview with the Center Manager (CM), 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 tests were performed from 10/21/2021 to the day of 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. Review of the application for Exception to Section 5.22 (f) form signed by the Laboratory Director (LD) on 11/09/2021 states: " the laboratory director will appoint a qualified general supervisor for each laboratory who will be on-site to oversee laboratory operations during all hours in which testing is being performed and who will review quality control records on a weekly basis". 3. On the day of the survey, 11/13/2023 at 12:30 pm, review of the laboratory personnel report (PA State) and personnel credentials revealed the LD was the only qualified personnel listed as Technical Consultant (TC) for the laboratory. 4. The hours of Laboratory testing are Monday - Friday 7:00am-7:00pm, Saturday and Sunday 8:00am-4:00pm (CMS 116). 5. The LD serves as director for CSL Plasma-Homestead (CLIA #39D2173684) and CSL Plasma- McKeesport (CLIA #39D2132144). (CMS-116) 6. The CM confirmed the findings above on 11/13/2023 at 2:18 pm.</p>