

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2160081	<b>(X3) Date Survey Completed</b>  04/01/2024
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  1341 S Main Ave, Suite 210, Taylor, 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's plan of correction (POC) received on 05/17/2023 for PA SA deficiencies cited and the letter received from CMS Plasma, Inc to the PA Resource email account on 03/18/2024, the laboratory failed to ensure that the PA regulation of having a supervisor on site during all normal scheduled working hours in which tests were performed was met from 03/21/2023 through 04/01/2024. Findings include: 1. The PA regulation (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 Sunday-Saturday from 09:00 am to 05:00 pm according to the information in the state system. 3. Review of the application for Exception to Section 5.22 (f) form signed by the Laboratory Director (LD) on 03/09 /2022 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." 4. Interview with the assistant manager of quality on 03/21/2023 at 10: 23 am, revealed that there was not a supervisor on site during all normal scheduled working hours in which chemistry testing was performed from 03/31/2021 to 03/21 /2023. 5. The POC received on 05/17/2023 stated, "CSL will begin the recruitment process to comply with the PA state requirements for supervisor and will hire, train and put in place these individuals as soon as possible. Efforts will be focused to place the role on or before the completion date (12/31/2023). 6. The laboratory requested an extension on December 14, 2023, which was granted till 03/21/2024. 7. A letter was received by the PA SA from the laboratory on 03/18/2024, stating, "We have posted</p>

for this position and are actively recruiting, though we have discovered individuals meeting the position requirements are rare. Until we secure the General Supervisor positions necessary to bring centers into compliance with PA requirements, CSL continues to manage our locations adhering to federal CLIA standards." 8. An email received on 03/28/2024 from CSL Plasma, Inc. confirmed the laboratory is not in compliance with the PA SA regulation pertaining to having a qualified general supervisor during all normal working hours in which tests are being performed. \* PA SA: Pennsylvania State Agency