

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2097597	(X3) Date Survey Completed 09/21/2023
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 107 Franklin Mills Blvd, Philadelphia, 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 record review and interviews with the assistant manager of quality #1 (AMQ), assistant manager of quality #2 (AMQ), assistant center manager (ACM) and 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 total protein testing was performed from 08/12/2021 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 Friday from 06:00 am to 08:00 pm and Saturday through Sunday from 07:00 am to 05:00 pm according to the information in the CMS-116 form. 3. Review of the laboratory personnel report (Pennsylvania State) form on 09/21/2023 showed that the laboratory director (LD) acts as the only general supervisor for the laboratory. The LD directs two other laboratories and has an exception to the 5.22 form signed. 4. On the day of the survey, 09/21/2023 at 12:50 pm, during an interview, the AQM #1, AQM #2, ACM and CM stated that the laboratory did not have a qualified supervisor onsite for every hour of patient testing according to chapter 5 section 5.23 of the Pennsylvania State regulations for clinical laboratories.</p>