

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2238325	(X3) Date Survey Completed 11/07/2023
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 4441 Pennell Road Suite B, Unit 152a, Aston, 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 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 02/01/2022 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 16:00 and Monday to Friday 07:00 to 19:00). 3. On the day of the survey, 11/07/2023 at 10:46 AM, during an interview, the OM stated that the laboratory did not have a qualified supervisor onsite for every hour of patient testing.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessment records and interview</p>

with the office manager(OM), the laboratory failed to establish a competency assessment procedure to assess the competency of 1 of 1 technical consultant (TC) for their supervisory responsibilities performed in 2022 and 2023. Findings include: 1. On the day of the survey, 11/07/2023 at 10:51 am, a review of laboratory's competency records revealed that the laboratory director (LD) failed to perform a competency assesment for the TC for their supervisory responsibilities performed in 2022 and 2023. 2. The OM confirmed the findings above on 11/07/2023 at 01:05 pm.