

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2118112	(X3) Date Survey Completed 09/26/2024
Name of Provider or Supplier Csl Plasma, Inc - Mechanicsburg	Street Address, City, State 4880 Carlisle Pike, Mechanicsburg, 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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview with the assistant manger of quality (AMQ), the laboratory failed to evaluate twice a year the relationship between test results using different instrumentation in chemistry in 2024. Findings include: 1. Review of the laboratory's Six month review of NRI and equipment performance records revealed comparison of test results for total protein testing using 8 of 8 Reicher TS meters was performed in January 2024. 2. On the date of the survey, 09/26/2024 at 12:30 pm, the laboratory failed to provide documentation for the Six month review of NRI and equipment performance performed in July 2024. 3. The AMQ confirmed the findings above on 09/26/2024 at 12:30 PM.</p>
D6050	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency records and interview with the Assistant Manager of</p>

Quality (AMQ), the technical consultant (TC) failed to evaluate direct observation of performance of instrument maintenance and function checks of laboratory testing personnel (TP) who performed total protein examinations in 2023 and 2024. Findings include: 1. On the day of survey, 09/26/2024 at 10:00 AM document review of competency assessments revealed that the technical consultant failed to evaluate direct observation of performance of instrument maintenance and function checks for 1 of 36 TP in 2023 and 1 of 36 TP in 2024: - Annual competency assessment TP #28 (CMS 209 TP #28) 10/18/2023. - Six month competency assessment TP #16 (CMS 209 TP #16) 02/06/2024. 2. The AMQ confirmed the above findings on 09/26/2024 at 10:00 AM.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of competency records and interview with the Assistant Manager of Quality (AMQ), the technical consultant (TC) failed to evaluate assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for laboratory testing personnel (TP) who performed total protein examinations in 2023 and 2024. Findings include: 1. On the day of survey, 09/26/2024 at 10:00 AM document review of competency assessments revealed that the technical consultant failed to evaluate assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for 1 of 36 TP in 2023 and 1 of 36 TP in 2024: - Annual competency assessment TP #28 (CMS 209 TP #28) 10/18/2023. - Six month competency assessment TP #16 (CMS 209 TP #16) 02/06/2024. 2. The AMQ confirmed the above findings on 09/26/2024 at 10:00 AM.

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on review of competency records and interview with the Assistant Manager of Quality (AMQ), the technical consultant (TC) failed to evaluate assessment of problem-solving skills of laboratory testing personnel (TP) who performed total protein examinations in 2023 and 2024. Findings include: 1. On the day of survey, 09/26/2024 at 10:00 AM document review of competency assessments revealed that the technical consultant failed to evaluate assessment of problem-solving skills for 1 of 36 TP in 2023 and 1 of 36 TP in 2024: - Annual competency assessment TP #28 (CMS 209 TP #28) 10/18/2023. - Six month competency assessment TP #16 (CMS 209 TP #16) 02/06/2024. 2. The AMQ confirmed the above findings on 09/26/2024 at 10:00 AM.