

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2259734	(X3) Date Survey Completed 01/13/2023
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 118 W Bay Area Boulevard, Webster, TX	
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
D0000	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's records from September 2022 to December 2022, patient results from September 2022 to December 2022, and confirmed in an interview found the laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for six of six Reichert digital refractometers for the test of total protein for four of four months. The findings were: 1. Review of the laboratory's records revealed the laboratory started performing total protein date was 9/9/2022. 2. Further review of the laboratory's records from</p>

September 2022 to December 2022 revealed the laboratory did not have a method in place to monitor quality control values over time to detect shifts and trends for six of six Reichert digital refractometers for the test of total protein for four of four months. September 2022 October 2022 November 2022 December 2022 3. Review of patient results from September 2022 to December 2022 revealed the following: September 2022 Total Donor Volume: 671. Random review the patient results in September 2022 revealed 10 patients had total protein performed. 9/12/2022 Donor #: 12548896 Total Protein: 8.1 g/dL 9/12/2022 Donor #: 12548908 Total Protein: 8.1 g/dL 9/13/2022 Donor #: 12546794 Total Protein: 7.9 g/dL 9/13/2022 Donor #: 12551990 Total Protein: 7.7 g/dL 9/14/2022 Donor #: 12556449 Total Protein: 7.5 g/dL 9/14/2022 Donor #: 12556248 Total Protein: 8.9 g/dL 9/15/2022 Donor #: 12559309 Total Protein: 7.3 g/dL 9/15/2022 Donor #: 12559391 Total Protein: 7.9 g/dL 9/16/2022 Donor #: 12561776 Total Protein: 6.7 g/dL 9/16/2022 Donor #: 12561647 Total Protein: 8.7 g/dL October 2022 Total Donor Volume: 1349. Random review the patient results in October 2022 revealed 10 patients had total protein performed. 10/17/22 Donor #: 12639631 Total Protein: 8.0 g/dL 10/17/22 Donor #: 12639544 Total Protein: 8.4 g/dL 10/18/22 Donor #: 12136070 Total Protein: 8.3 g/dL 10/18/22 Donor #: 12643389 Total Protein: 8.5 g/dL 10/19/22 Donor #: 12625201 Total Protein: 8.5 g/dL 10/19/22 Donor #: 12645736 Total Protein: 8.1 g/dL 10/20/22 Donor #: 12650273 Total Protein: 7.9 g/dL 10/20/22 Donor #: 12650432 Total Protein: 8.1 g/dL 10/21/22 Donor #: 10530764 Total Protein: 7.8 g/dL 10/21/22 Donor #: 00G4XJX Total Protein: 8.1 g/dL November 2022 Total Donor Volume: 1367. Random review the patient results in November 2022 revealed 10 patients had total protein performed. 11/14/22 Donor #: 10665605 Total Protein: 7.7 g/dL 11/14/22 Donor #: 12709592 Total Protein: 6.8 g/dL 11/15/22 Donor #: 12712955 Total Protein: 8.0 g/dL 11/15/22 Donor #: 12712840 Total Protein: 8.3 g/dL 11/16/22 Donor #: 12715531 Total Protein: 8.4 g/dL 11/16/22 Donor #: 12715422 Total Protein: 8.4 g/dL 11/17/22 Donor #: 12694738 Total Protein: 8.4 g/dL 11/17/22 Donor #: 10922759 Total Protein: 8.3 g/dL 11/18/22 Donor #: 11009329 Total Protein: 7.7 g/dL 11/18/22 Donor #: 12720720 Total Protein: 8.2 g/dL December 2022 Total Donor Volume: 1377. Random review the patient results in December 2022 revealed 10 patients had total protein performed. 12/20/22 Donor #: 10303973 Total Protein: 7.7 g/dL 12/20/22 Donor #: 12788745 Total Protein: 7.7 g/dL 12/21/22 Donor #: 12792246 Total Protein: 8.4 g/dL 12/21/22 Donor #: 12792334 Total Protein: 9.0 g/dL 12/22/22 Donor #: 12794020 Total Protein: 7.9 g/dL 12/22/22 Donor #: 12794064 Total Protein: 8.9 g/dL 12/23/22 Donor #: 12760231 Total Protein: 6.3 g/dL 12/23/22 Donor #: 12736887 Total Protein: 6.3 g/dL 12/24/22 Donor #: 12161074 Total Protein: 8.0 g/dL 12/24/22 Donor #: 12543680 Total Protein: 6.8 g/dL 4. An interview with the center manager and assistant manager of quality on 1/12/2023 at 1:00 pm in a conference room confirmed the above findings. Key: QC=Quality Control CBC=Complete Blood Count

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on the review of the laboratory's submitted CMS 209, testing personnel records, and confirmed in an interview found the laboratory failed to have educational

equivalent documentation to qualify one of 13 testing personnel (TP) who performed moderate complexity testing on six of six Reichert digital refractometers for the test of total protein. (Refer to D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on the review of the laboratory's submitted CMS 209, testing personnel records, and confirmed in an interview found the laboratory failed to have educational equivalent documentation to qualify one of 13 testing personnel (TP) who performed moderate complexity testing on six of six Reichert digital refractometers for the test of total protein. The findings were: 1. Review of the laboratory's submitted CMS 209 signed by the LD on 1/9/2023 identified 13 TP who performed moderate complexity testing on six of six Reichert digital refractometers for the test of total protein. DMS number: 5480002 SN: 16005-0222 DMS number: 5480003 SN: 16042-0322 DMS number: 5480004 SN: 16043-0322 DMS number: 5480005 SN: 16048-0322 DMS number: 5480006 SN: 16009-0222 DMS number: 5480007 SN: 16047-0322 2. Review of the laboratory's TP educational records revealed the laboratory failed to have documentation of educational equivalency to qualify one of 13 TP who obtained the educational degree from outside of United States. TP#5 Hired Date 02/28/2022 3. An interview with the center manager and assistant manager of quality on 1/12/2023 at 10:00 am in a conference room confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services LD=Laboratory Director