

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2151373	(X3) Date Survey Completed 03/13/2019
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 140 South Symes Ln, Mustang, OK	
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 initial certification survey was performed 03/13/19. The laboratory was found out of compliance with the following CLIA regulation: 493.801: D2000: Condition: Enrollment and Testing of Samples The findings were reviewed with the assistant manager of quality and the quality specialist at the conclusion of the survey.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records and interview with the assistant manager of quality and the quality specialist, the laboratory failed to enroll in a proficiency testing program in the specialty for which it seeks certification. Findings include: (1) At the beginning of the survey, the assistant manager of quality and the quality specialist stated to the surveyor Total Protein testing was performed using the Reichert TS Meter DSP on fingerstick samples from plasma donors. In addition, the assistant manager of quality stated to the surveyor patient testing began on 08/07/2018; (2) The surveyor asked for proficiency testing records for 2018 and to date in 2019. There was no evidence the laboratory enrolled in a proficiency program for the third event of 2018 for Total Protein; (3) The surveyor reviewed the records with the assistant manager of quality and the quality specialist and asked if the laboratory had enrolled in proficiency testing for 2018. The assistant manager of quality and the quality specialist stated that</p>

the laboratory enrolled in proficiency testing but the first proficiency testing samples they received were for the first event of 2019; (4) The surveyor asked the assistant manager of quality and the quality specialist for the proficiency testing program order invoice. The invoice showed the laboratory ordered the proficiency testing module on 12/07/18, which was too late for the third event in 2018; (5) The surveyor explained to the assistant manager of quality and the quality specialist that enrollment in a proficiency testing program was required prior to the beginning of patient testing.

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the assistant manager of quality and the quality specialist, the technical consultant failed to ensure enrollment in a proficiency testing program commensurate with the testing performed in the laboratory. Findings include: (1) The technical consultant failed to ensure enrollment in a proficiency testing program for Total Protein testing. Refer to D2000.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the assistant manager of quality and the quality specialist, the technical consultant failed to ensure a testing person performing moderate complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) At the beginning of the survey, the surveyor reviewed a random selection of personnel records from 6 of the 14 individuals who performed the moderate complexity Total Protein testing. The test was performed using the Reichert TS Meter DSP on fingerstick samples from plasma donors. For 1 of the 6 testing persons, the surveyor identified the following: (a) Testing Person #12: The testing person transferred to the center and initial training was completed on 05/29 /18, prior to the center opening (08/07/18). There was no evidence a semiannual competency evaluation had been performed (due 11/18). (2) The surveyor reviewed the records with the assistant manager of quality and the quality specialist. The assistant manager of quality stated to the surveyor there was no record available to prove testing person #12 had been evaluated semiannually during the first year of testing.