

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0672105	(X3) Date Survey Completed 12/21/2023
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 1501 Riverside Drive, # 110, Chattanooga, TN	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and the laboratory's Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) evaluation reports, the laboratory failed to maintain satisfactory participation for two out of three proficiency testing events for the Hematocrit % (HCT) non-waived analyte (Refer to D2130) and the Hematology specialty (Refer to D2131) resulting in the initial unsuccessful PT performance.</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of the CMS 155 and the laboratory's 2023 AAB-MLE PT evaluation reports, the laboratory failed to maintain satisfactory performance for two of three test events for the HCT analyte. The findings include: 1. Review of the CMS 155 report revealed the following unsatisfactory HCT scores: -2023 Event one: 20% -2023 Event three: 60% 2. Review of the laboratory's AAB-MLE PT evaluation reports revealed the following unsatisfactory HCT scores: -2023 Event one: 20% -2023 Event three: 60%

D2131

HEMATOLOGY
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of the CMS 155 and the laboratory's 2023 AAB-MLE PT evaluation reports, laboratory failed to achieve satisfactory performance for the overall specialty of Hematology in two of three PT events in 2023. The findings include: 1. Review of the CMS 155 report revealed the following unsatisfactory Hematology PT event scores: -2023 Event one: 20% -2023 Event three: 60% 2. Review of the laboratory's AAB-MLE PT evaluation reports revealed the following unsatisfactory Hematology PT event scores: -2023 Event one: 20% -2023 Event three: 60%