

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2003025	(X3) Date Survey Completed 08/21/2023
Name of Provider or Supplier Physician's Plasma Alliance	Street Address, City, State 124 Old Gray Station Rd, Johnson City, 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: Hematology: The laboratory failed to maintain satisfactory participation in two consecutive events for the Cell I.D. or automated white blood cell differential (WBC Diff) analyte and the white blood cell (WBC) analyte, resulting in the initial unsuccessful proficiency testing (PT) occurrence for Cell I.D. or WBC Diff and WBC (Refer to D2130 and D2131).</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 CASPER Report 0155D and the laboratory's 2022-2023 Proficiency Testing (PT) performance summary records from the American Association of Bioanalysts (AAB) Proficiency Testing program and staff interview, the laboratory failed to maintain satisfactory performance for the Cell I.D. or automated white blood cell differential (WBC Diff) analyte in the 3rd event of 2022 and 1st event of 2023 and the white blood cell (WBC) analyte in the 1st and 2nd events of 2023, resulting in the initial unsuccessful PT occurrence. The findings include: 1. A review of the CMS 0155D report revealed unsatisfactory Cell I.D. or WBC Diff analyte scores of 72% for the 3rd event of 2022 and 0% for the 1st event of 2023 and WBC analyte scores of 0% for the 1st and 2nd events of 2023. 2. A request and review of the laboratory's AAB PT records revealed unsatisfactory Cell I.D. or WBC Diff analyte score of 72% for the 3rd event of 2022, WBC analyte score of 0% for the 2nd event of 2023, and no scores available for the 1st event of 2023, resulting in the initial unsuccessful PT occurrence. 3. Phone interview with Quality Assurance (QA) Manager on 08.21.2023 at 3:20 pm confirmed the above findings.

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 CASPER Report 0155D and the laboratory's 2022-2023 Proficiency Testing (PT) performance summary records from the American Association of Bioanalysts (AAB) Proficiency Testing program and staff interview, the laboratory failed to achieve satisfactory performance for the overall specialty of Hematology in two consecutive PT events in 2023 (event 1 and 2). The findings include: 1. Review of CASPER CMS 155 report, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for specialty of Hematology in two consecutive events: 2023 Event 1: 0% 2023 Event 2: 64% 2. Request and review of the AAB performance evaluation records revealed the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for specialty of Hematology in two consecutive events: 2023 Event 1: no results available 2023 Event 2: 64% 3. Phone interview with Quality Assurance (QA) Manager on 08.21.2023 at 3:20 pm confirmed the above findings.