Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2003025	08/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Physician's Plasma Alliance	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
D0000	Based on a proficiency testing desk review survey performed on 08.16.2023 the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 0155D (CMS 155), the laboratory's 2022 and 2023 American Association of Bioanalysts (AAB) proficiency testing records, and

	staff interview, the laboratory failed to successfully participate in the specialty of Hematology for the Cell ID or automated white blood cell differential (WBC Diff) for three out of three testing events, resulting in non-initial unsuccessful PT participation (Refer to D2130).
D2130	HEMATOLOGY CFR(s): 493.851(f) 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 proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 0155D (CMS 155), the laboratory's 2022 and 2023 American Association of Bioanalysts (AAB) evaluation records, and staff interview, the laboratory failed to maintain satisfactory performance in three out of three PT events for the Cell ID or automated white blood cell differential (WBC Diff) analytes, resulting in non-initial unsuccessful PT participation. The findings include: 1. Review of the CMS 155 report revealed the following unsatisfactory PT scores for Cell ID or WBC Diff analytes: 2022 Event three: Cell ID or WBC Diff: 72% 2023 Event one: Cell ID or WBC Diff: 0% 2023 Event two: Cell ID or WBC Diff: 64% 2. Request and review of the laboratory's AAB PT performance evaluation records revealed the following unsatisfactory scores for Cell ID or WBC Diff analytes: 2022 Event three: Cell ID or WBC Diff: 72% 2023 Event one: Cell ID or WBC Diff: no results available 2023 Event two: Cell ID or WBC Diff: 64% 3. Phone interview with the Quality Assurance (QA) Manager on 08.21.2023 at 3:20 pm confirmed the survey findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 0155D (CMS 155), the laboratory's 2022 and 2023 American Association of Bioanalysts (AAB) evaluation records, and phone interview with the Quality Assurance (QA) Manager, the laboratory director failed to provide overall management and direction to the laboratory for successful participation in proficiency testing (PT). (Refer to D6016)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as

	required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 0155D (CMS 155), the laboratory's 2022 and 2023 American Association of Bioanalysts (AAB) evaluation records, and phone interview with the Quality Assurance (QA) Manager, the laboratory director failed to ensure successful participation in a Department of Health and Human Services (HHS) approved proficiency program. (Refer to D2130)