Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0259028	03/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Piedmont Cancer Institute, Pc	1800 Howell Mill Road, Suite 800, Atlanta, GA	

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	A proficiency testing desk review was completed on March 27,2025. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper 155 report and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (3rd event 0f 2024 and 1st event of 2025), resulting in the first

	unsuccessful occurrence for red blood cell count (RBC). Findings include: Refer to D 2130
D2130	HEMATOLOGY CFR(s): 493.851(f) (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 review of the Centers for Medicare and Medicaid (CMS) Casper 155 report and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive testing events (3rd event of 2024 and 1st event of 2025), resulting in the first unsuccessful occurance for red blood cell (RBC) count. Findings include: 1. A review of Casper Reports 153 and 155 disclosed the laboratory failed RBC on the following: 2024 Event 3 Score 20% 2025 Event 1 Score 60% 2. A review of the laboratory's proficiency testing reports from College of American Pathology (CAP) confirmed the laboratory failed RBC with the aforementioned scores.
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: The laboratory director failed to maintain compliance with successful red blood cell (RBC) proficiency testing (PT) for two consecutive events, resulting in the first unsuccessful performance for RBC. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper 155 report and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two consecutive events (3rd event of 2024 and 1st event of 2025), resulting in the first unsuccessful occurrence for RBC. Findings include: 1. Desk review of Casper Report 155 disclosed the laboratory failed RBC on event 3 of 2024 with a score of 20% and event 1 of 2025 with a score of 60%. 2. Desk review of the laboratory's proficiency testing reports from College of American Pathologist (CAP) confirmed the laboratory failed RBC with the aforementioned scores.