Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0863604	01/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pediatrics East, Inc-Germantown	7465 Poplar Ave Suite 201, Germantown, 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	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 review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and the laboratory's American Proficiency Institute (API) proficiency testing (PT) evaluation reports, the laboratory failed to maintain satisfactory participation for two out of three PT events for the automated white blood cell (WBC) differential (DIFF) resulting in the first unsuccessful PT occurrence for the WBC DIFF analyte. (See 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 desk review of the CMS 155 and the laboratory's 2023 API PT evaluation reports, the laboratory failed to maintain satisfactory performance for two out of three test events for the automated WBC DIFF analyte. The findings include: 1. Review of the CMS 155 report revealed the following unsatisfactory WBC DIFF scores: 2023 Event one 60% 2023 Event three 73% 2. Review of the API PT evaluation report for 2023 Event one revealed an overall score of 60% for the WBC DIFF analyte. 3. Review of the API PT evaluation report for 2023 Event three revealed an overall score of 73% for the WBC DIFF analyte.