Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0960104	11/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of Dearborn	2331 Monroe St, Dearborn, MI	

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
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1, the laboratory failed to test two control materials at least each date of its Complete Blood Count patient testing for 1 (12/27/22) of 14 patient testing dates reviewed. Findings include: 1. A review of 14 patient testing dates revealed only one of three control levels was performed on 12/27/22 for Complete Blood Count testing performed on the Beckman Coulter AcT Diff analyzer and four patients received testing on that date. 2. An interview on 11/20/23 at 11:36 am with Testing Personnel #1 confirmed the laboratory did not use at least two control materials of different concentrations on 12 /27/22.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the

	reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1, the laboratory failed to perform corrective action when the laboratory's humidity readings feel outside of operating parameters for 15 (January 2022 to May 2022, October 2022 to June 2023, and October 2023) of 22 months reviewed. Findings include: 1. A review of the laboratory's "Temperature/Humidity Charts" for 2022 and 2023 revealed the humidity range was "30-85%" and the following months humidity was outside the range: a. January 2022, 23 of 23 testing dates had readings below 30%. b. February 2022, 20 of 20 testing dates had readings below 30%. c. March 2022, 25 of 26 testing dates had readings below 30%. d. April 2022, 16 of 23 testing dates had readings below 30%. e. May 2022, 5 of 21 testing dates had readings below 30%. f. October 2022, 9 of 21 testing dates had readings below 30%. g. November 2022, 15 of 23 testing dates had readings below 30%. h. December 2022, 21 of 21 testing dates had readings below 30%. i. January 2023, 21 of 23 testing dates had readings below 30%. j. February 2023, 22 of 22 testing dates had readings below 30%. k. March 2023, 24 of 24 testing dates had readings below 30%. l. April 2023, 15 of 22 testing dates had readings below 30%. m. May 2023, 11 of 21 testing dates had readings below 30%. n. June 2023, 4 of 24 testing dates had readings below 30%. o. October 2023, 4 of 23 testing dates had readings below 30%. 2. The surveyor requested the laboratory's humidity monitoring corrective action on 11/20/23 at 12:20 pm and was not made available. 3. An interview on 11/20/23 at 12:20 pm with Testing Personnel #1 confirmed the laboratory did not perform corrective action when the laboratory's humidity readings were outside of operating parameters.