Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0211974	02/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Mont County	3416 Olanwood Court, Suite 108, Olney, MD	

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
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the written procedure manual, interview with the technical consultant, and the testing person, the laboratory did not establish corrective action procedures for all areas of the laboratory when testing did not meet the laboratory's criteria of acceptability. Findings: Refer to D5781 1. The laboratory did not have written step by step corrective procedures to follow for hematology testing when problems occurred. 2. The technical consultant confirmed that written corrective procedures were not available when hematology testing did not meet the laboratory's criteria of acceptability.
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 review of the written procedure manual, interview with the technical consultant, and the testing person, the laboratory did not document corrective action procedures when the hematology analyzer did not meet the laboratory's criteria of acceptability. Findings: 1. The laboratory had analyzer problems in April of 2017 and December of 2016. On December 29, 2016 the testing person documented on the daily quality control printouts that the analyzer was leaking. The manufacturer came onsite for repairs on December 30, 2016. 2. On April 25, 2017 the manufacturer was on site to repair the analyzer lamp. 3. The testing person stated that the analyzer start up was failing and new controls were opened. 4. Corrective action procedures were not documented stating the problem for the repairs by the laboratory. 5. The technical consultant confirmed that corrective action procedures were not documented when the analyzer did not meet the laboratory's criteria of acceptability.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the technical consultant written notes, interview with the technical consultant (TC), and the testing person, the TC failed to provide the technical and scientific oversight for all areas of the hematology laboratory when errors and problems occurred during patient testing. Findings: 1. The TC did not document in the TC notes the problems that occurred with the hematology analyzer in April 2017 and December 2016. In the TC notes the remedial action box was circled for no problems during the month of April and December. Refer to D5781. 2. On April 26, 2017 quality controls were performed on the hematology analyzer and June 3, 2016 calibration verification procedures were performed on the hematology analyzer. The name nor initials of the testing person who performed the test was not documented anywhere in the laboratory. The TC reviewed the analyzer printouts but did not confirm the testing person responsible for performing the quality controls and the calibration verification. 3. The TC confirmed that the technical and scientific oversight for all areas of the hematology laboratory when errors and problems occurred during patient testing was not performed.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of the written procedure manual, interview with the technical consultant (TC), and the testing person, the TC did not establish and ensure that corrective action procedures for all areas of the laboratory were followed when testing

	did not meet the laboratory's criteria of acceptability. Findings: Refer to D5779 and D5781 The TC did not ensure that step by step corrective procedures were followed for hematology testing when problems occurred.