Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0665745	(X3) Date Survey Completed 08/18/2021
Name of Provider or Supplier Pediatric Associates Mont County	**Street Address, City, State** 14955 Shady Grove Road Ste 380, Rockville, 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
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the duties and responsibilities, monthly quality assurance (QA) review worksheets, proficiency testing (PT) records, quality control (QC) records, and interview with the technical consultant (TC), the laboratory director (LD) failed to be actively involved in the operation of the laboratory by assuring that others are performing the delegated duties and responsibilities. Findings: 1. The "Clinical Consultant Duties and Responsibilities" procedure identifies a Clinical Consultant (CC) who acts as the assistant lab director. According to the procedure the CC "is actively involved in monitoring the laboratory's Quality Assurance, Quality Control and Proficiency Testing programs." The CLIA regulations do not recognize the position of an assistant lab director under the moderate or high complexity testing personnel requirements. 2. The monthly QA review records and QC graphs for 2021 and 2020 were reviewed. The review signatures included the TC, CC, and testing personnel but not the LD. 3. During the survey on 08/16/2021 at 12:30 PM, the TC confirmed that the LD does not document review of the QA reviews, PT, and QC records. This is done by the CC who is not qualified as a LD (have at least 20 continuing medical education credit hours in laboratory practice commensurate with

	the director responsibilities defined in 493.1407) and does not provide the LD with a documented summary of the QA reviews. The LD delegated duties and responsibilities and failed to ensure that all duties were properly performed on a routine basis by reviewing the monthly summary provided by the TC.
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 review of the hematology patient log and interview with the technical consultant (TC), the laboratory director failed to ensure that written instructions were provided to the testing personnel for recording proficiency testing (PT) samples on the patient log in the same manner as the patient specimens. Findings: 1. Review of the hematology procedure manual showed that the PT procedures did not instruct the testing personnel to record the PT results on the patient logs in the same manner as the patient specimens. 2. During the survey on 08/18/2021 at 11:30 AM, the TC that the hematology procedure manual did not provide instruction to the testing personnel for recording the PT samples on the hematology patient log in the same manner as the patient specimens.