Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0213407	09/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Mont Co	2401 Blueridge Avenue Ste 210, Wheaton, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the attestations to the routine integration of PT samples into the patient workload were either missing or inaccurate in three of the five hematology PT events from 2020-2021. Findings: 1. The hematology PT records for three events in 2020 and two events in 2021 were reviewed. 2. The PT attestation form from the hematology 2020 2nd event was missing the signature of the testing person (TP) who performed the testing. 3. The PT attestation form from the hematology 2020 3rd event was missing the signatures of the laboratory director and the TP who performed the testing. 4. The PT attestation forms from the hematology 2021 1st and 2nd events showed three different TP signatures attesting to the routine integration of PT samples into the patient workload, but only one of the three TP actually performed the testing. 5. During the exit interview on 09/23/2021 at 11:30 AM, the TC confirmed that the PT attestations to the routine integration of PT samples into the patient workload were either missing or inaccurate.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on review of the instrument user's manual and maintenance records and interview with the technical consultant (TC), the laboratory failed to consistently document routine monthly maintenance activities for the Medonic M-series hematology analyzer. Findings: 1. The Medonic M-series user's manual stated that cleaning and clot prevention procedures were to be performed monthly. 2. The laboratory documented the performance of the instrument cleaning and clot prevention activities on a monthly log. The log included sections to record the lot number of the kit reagents used to perform each activity, the date the activity was performed, and the initials of the testing person who performed each activity. 3. Monthly maintenance forms from 01/2020 - 08/2021 were reviewed. 4. Lot numbers for the reagents used to perform the cleaning and clot prevention activities were not recorded for 01/2020, 02/2020, 03/2020, and 12/2020. 5. Monthly cleaning and clot prevention performance was not recorded for 04/2020, 06/2020, 09/2020 and 10/2020. 6. During the exit interview on 09/23/2021 at 11:30 AM, the TC confirmed that the monthly maintenance activities and reagent lot numbers used to perform the maintenance activities were not consistently documented in 2020.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure manual and monthly quality control (QC) records and interview with the technical consultant (TC), the laboratory failed to perform parallel testing on new lot numbers of hematology QC to verify performance prior to putting the QC into use for eight out of nine QC lot numbers. Findings: 1. The laboratory's procedure titled "Parallel QC Procedure" stated that "In order to be in compliance with the manufacturer's recommendations, the new lot of hematology controls must be analyzed along with the current lot of controls." The procedure stated that all three levels of QC from the new lot should be tested in parallel with all three levels of the current lot for one to five days. 2. Instrument printouts of monthly QC results from 09/2019-08/2021 were reviewed, which contained results for nine different lot number changes. 3. Based on the start and end date of each lot number, the laboratory did not perform parallel testing on eight of the nine lot numbers found in the QC records (lot numbers 219082, 219113, 220022, 220053, 220082, 220112, 221015, and 221043). 4. During the exit interview on 09/23/2021 at 11:30 AM, the

	TC confirmed that parallel testing to verify the performance of new QC lot numbers was not performed for eight out of the last nine QC lot numbers used for patient testing.
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 quality assurance (QA) and proficiency testing (PT) records, review of the responsibilities of the laboratory director (LD) and clinical consultant (CC), and interview with the technical consultant (TC), the LD failed to document the review of the performed delegated responsibilities to ensure they were performed properly. Findings: 1. The laboratory performed and documented monthly QA reviews of instrument performance (quality control, maintenance, and calibration), temperature logs, proficiency testing results, remedial actions taken, personnel competencies, and complaints using a designated form that was to be signed by the TC and the LD or designee. 2. Review of the QA review forms from 09/2019-08/2021 showed that the forms were signed by the TC and the CC, who is not the LD. 3. The CC, as the LD designee, also signed the PT evaluations distributed by the PT provider with the results of each PT testing event. 4. The document titled "Lab Director Responsibilities" stated that the LD's responsibilities included "Reviewing with the lab supervisor or consulting supervisor all lab procedures and policies and all evaluative material, including proficiency testing results, pertinent to the operation and performance of the lab." 5. The TC stated that the TC and CC were in contact with the LD to discuss operation and performance of the lab, including QA, QC, and PT performance. There was no documentation stating when these meetings occurred and what was discussed or defining how frequently the meetings should occur. 6. During the exit interview on 09/23/2021 at 11:30 AM, the TC confirmed that the LD did not document meetings with the TC and CC regarding laboratory operation and QA, QC and PT performance, to ensure that the delegated LD responsibilities were being performed properly.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures

	each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of quality assurance (QA) and proficiency testing (PT) records, review of the responsibilities of the clinical consultant (CC), and interview with the technical consultant (TC), the laboratory director (LD) failed to define all the responsibilities delegated to the CC. Findings: 1. The laboratory performed and documented monthly QA reviews of instrument performance (quality control, maintenance, and calibration), temperature logs, proficiency testing results, remedial actions taken, personnel competencies, and complaints using a designated form that was to be signed by the TC and the LD or designee. 2. Review of the QA review forms from 09/2019-08/2021 showed that the forms were signed by the TC and the CC, who is not the LD. 3. The CC, as the LD designee, also signed the PT evaluations distributed by the PT provider with the results of each PT testing event. 4. The document titled "Clinical Consultant Duties and Responsibilities" stated that the CC "is involved in the laboratory's Quality Assurance and Quality Control programs." The document did not specifically state which LD responsibilities from the Code of Federal Regulations section 493.1407 were delegated to the CC. 5. During the exit interview on 09/23/2021 at 11:30 AM, the TC confirmed that the LD responsibilities delegated to the CC were not defined.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of personnel competency assessments and proficiency testing (PT) results and interview with the technical consultant (TC), testing of the hematology PT samples was not rotated among all the testing personnel (TP) for evaluation of each individual TP's competency for testing hematology samples. Findings: 1. Personnel competency assessment records showed that five TP were performing hematology testing in 2020 and 2021. 2. Review of five hematology PT events from 2020-2021 showed that only a single TP was testing all the PT samples from all events. 3. During the exit interview on 09/23/2021 at 11:30 AM, the TC confirmed that testing of the hematology PT samples was not rotated among all TP for evaluation of competency.